

PD-ABF-047
20287

FINAL EVALUATION

OF

PROJECT SUPPORT

SUPPLY, PRODUCTION, AND PROMOTION OF ORAL REHYDRATION SALTS

Cooperative Agreement No. DPE-0009-A-00-5050-00

Prepared for the

Agency for International Development

S&T/Office of Health

Office of International Health
Public Health Service
Department of Health and Human Services
Rockville, MD 20857

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March 31, 1989

Evaluation conducted under the Resources Support Services Agreement (RSSA), between the S&T/Office of Health and the PHS/Office of International Health. Report prepared by Devres, Inc. and submitted to the Office of International Health, under Contract No. 282-88-0009.

PREFACE

This report provides findings and recommendations related to a final evaluation review of Project SUPPORT (Supply, Production, and Promotion of Oral Rehydration Salts) conducted in the U.S., Guatemala, and Ghana during September and October 1988. The report is based on field visits to Guatemala during the period of October 16 to 22, 1988, and to Ghana during the period of October 23 to 28, 1988. The evaluation team conducted interviews in Washington D.C. during the week of September 25 to 30, 1988, and in Seattle during October 10 to 12, 1988.

Project SUPPORT was funded for an initial three years in August 1985 by the Agency for International Development (A.I.D.) under a cooperative agreement with the Program for Appropriate Technology in Health (PATH) in Seattle, Washington. The Project Director is John B. Tomaro, Ph.D. The project is managed in AID/W by Robert M. Clay, Deputy Chief, Division of Health Services, Office of Health, Bureau for Science and Technology. Shortly after this evaluation, Lloyd Feinberg became project manager of this project.

ACKNOWLEDGEMENTS

The final evaluation of SUPPORT was carried out under Resources Support Services Agreement (RSSA) No. BAS-0249-R-HI-4208 between the Office of Health, Bureau of Science and Technology, Agency for International Development and the Office of International Health, U.S. Public Health Service (PHS), Department of Health and Human Services. Support services were provided by Devres, Inc., under Contract No. 282-88-0009 with the Public Health Service.

The evaluation team wishes to express its deep appreciation to the many individuals who assisted and participated in the field evaluation activity in Guatemala and Ghana.

In Guatemala, officials of the Ministry of Health, and staff members of ADAMED, HEALTHCOM, INCAP, and UNICEF were willing to provide the team with extensive briefings and opportunities to observe project activities. The team wishes to thank the following individuals and their staffs: Dr. Elmer Nunez, Director of Maternal and Child Health, Guatemala Ministry of Health; Mr. Jose Maria Gonzalez y Gonzalez, Managing Director of ADAMED; Dr. Jose Romero, Resident Advisor of the HEALTHCOM Project in Guatemala; Dr. Hernan Delgado, Director of the Program for Control of Diarrheal Diseases, INCAP, and Mr. Solomon Cohen, Chief of the Planning and Development Unit, INCAP; and Dr. William Vargas, UNICEF.

Special thanks are extended to Dr. John A. Massey, Health and Population Officer, and Mr. Andres Kreffft, Child Survival Coordinator, USAID/Guatemala, for their guidance and assistance.

In Ghana, officials of the Ministry of Health, the firm of DANAFCO, Ltd., and UNICEF were willing to provide the team with extensive briefings and opportunities to observe project activities. The team wishes to thank the following individuals and their staffs: Dr. Moses E. K. Adibo, Director of Medical Services, and Dr. Nii Ayikuma Adamafio, Deputy Director of Medical Services, Ghana Ministry of Health; Mr. Yaw Berko, Managing Director of DANAFCO, Ltd., and Ms. Patience Kuruneru, Program Officer at UNICEF in Ghana.

Special thanks are extended to Dr. James R. Kirkland, Population Development Officer, USAID/Ghana, for his guidance and assistance.

At PATH in Seattle, the team's briefings by the project SUPPORT staff members were thorough and beneficial to our gaining an understanding of the Guatemala and Ghana project activities. The team wishes to thank Dr. Gordon W. Perkin, Dr. John B. Tomaro, and the other project participants for their kind assistance to the team during its stay in Seattle.

The Cognizant Technical Officer for the project, Mr. Robert M. Clay, AID/W, provided extensive background information and was avail-

able to assist the team throughout the process of the evaluation. His assistance was very helpful and greatly appreciated.

Finally, the team wishes to express its thanks to the Office of International Health, U.S. Public Health Service, in Rockville, Maryland, and to DEVRES, Inc., of Bethesda, Maryland, for their support and assistance in arranging logistics and word processing for the travel and report preparation aspects of the evaluation.

LIST OF ACRONYMS AND ABBREVIATIONS

A.I.D.	Agency for International Development (USAID denotes A.I.D. overseas missions)
AID/W	A.I.D./Washington
ADAMED	Name of private drug manufacturing firm in Guatemala selected by PATH for Project SUPPORT
ADDR	Applied Diarrheal Disease Research. An A.I.D. centrally funded health project that conducts applied research on priority diarrheal disease problems; managed by Harvard Institute for International Development.
AED	Academy for Educational Development
ALIMENTOS S.A.	Name of the first pharmaceutical firm in Guatemala that was approached by PATH for possible manufacture of ORS.
APHA	American Public Health Association
BP	British Pharmacopeia
CBD	Community Based Distribution
Cedi	Ghanaian unit of currency (294 Cedis = U.S. \$1.00 at time of report)
CDD	Control of Diarrheal Diseases
CIF	Cost, Insurance, and Freight
CPS	Central Procurement System
CRS	Contraceptive Retail Sales
CSM	Contraceptive Social Marketing
CTO	Cognizant Technical Officer; A.I.D. terminology for the project officer responsible for a project
DANAFCO	Name of private drug manufacturing firm in Ghana selected by PATH for Project SUPPORT
FDA	Food and Drug Administration
GIMPA	Ghana Institute of Management and Public Administration
GMPs	Good Manufacturing Practices. The procedures and methods followed in the course of manufacturing pharmaceutical. These are accompanied with thorough documentation.
GSMP	Ghana Social Marketing Program, managed by the Ghanaian firm, DANAFCO
HAF	Home Available Fluids; preparations such as broths or rice water that are traditionally administered to those experiencing diarrhea
HEALTHCOM	Communication for Child Survival; an A.I.D. centrally-funded health project, managed by the Academy for Educational Development (AED)
HPN	Health, Population, and Nutrition

HSM	Health Social Marketing
IEC	Information, Education, Communication
INCAP	Institute of Nutrition for Central America and Panama
IGSS	Institutuo de Guatemaltaco de Seguridad Social (the social security institute of Guatemala)
IP	International Pharmacopeia
I PROFASA	Private sector social marketing firm in Guatemala, under USAID/Guatemala contract
KAP	Knowledge, Attitudes, Practices
LAPROMED	Name of University of San Carlos' pharmaceutical training and testing laboratory in Guatemala, which is setting-up for ORS production
LINTAS	Advertising and marketing research agency in Accra, Ghana
L.O.C.	Letter of Credit
L.O.P.	Life of Project, A.I.D. term for the duration of a project, usually noting its beginning and end dates.
LUCAM	Name of the pharmaceutical laboratory
MCH	Maternal and Child Health
MFEP	Ministry of Finance and Economic Planning
MIS	Management Information System
MOH	Ministry of Health
MOH/HED	Health Education Division of the Ministry of Health in Ghana
MSH	Management Sciences for Health, the A.I.D. PRITECH Project contractor
NCIH	National Council of International Health
NF	National Formulary
ORS	Oral Rehydration Salts or Solution
ORT	Oral Rehydration Therapy
OTC	Over the Counter, meaning non-prescription drugs
PACD	Project Activity Completion Date
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technologies in Health
Pharmahealth	Subcontractor for training to Danafcc
PHENCO	Name of pharmaceutical manufacturer in Ghana that PATH had considered to produce ORS.
PIB	Ghanaian Prices and Income Board; responsible for regulating and approving any price increases of domestically produced products
PMA	Project Monitoring Assistance; a newly developed monitoring tool of A.I.D.'s Health Office used to

monitor the implementation and financial status of its centrally-funded projects.

POP Point of Purchase

POS Point of Sale

PPC, (A.I.D./PPC) A.I.D.'s Office of Program and Policy Coordination

PRE, (A.I.D./PRE) A.I.D.'s Office of Private Enterprise

PRICOR II Primary Health Care Operations Research; an A.I.D. centrally funded project managed by the Center for Human Services.

PRITECH Technologies for Primary Health Care; a centrally funded project of A.I.D.'s Office of Health, managed by Management Sciences for Health (MSH)

QA/QC Quality Assurance/Quality Control

Quetzal Guatemalan currency (2.70 Quetzales = U.S. \$1.00 at time of report).

SAPRM Semi-Annual Project Review Meeting; meeting convened between the A.I.D. project officer (CTO) and SUPPORT project staff.

S&T/H Bureau for Science and Technology, Office of Health, A.I.D.

SOMARC Social Marketing for Change; an A.I.D./Population centrally-funded project of A.I.D.'s Office of Population, managed by the Futures Group

SOP Standard Operating Procedure

SOW Scope of Work

SRO ORS as it is written and known in Spanish

SSS Sugar and Salt Solution--a preparation of sugar and salt that some educational campaigns recommend to be mixed at home.

SuperSuero SUPPORT ORS product of Guatemala's public sector manufacturer Supply, Production, and Promotion of Oral Rehydration Salts; a centrally-funded project of A.I.D. Office of Health, and the focus of this evaluation.

TA Technical Assistance

TRO ORT as it is written and known in Spanish

UNICEF United Nations Children's Fund

USP United States Pharmacopeia

WHO World Health Organization

GLOSSARY OF TERMS

- Burn rate** A.I.D. terminology for the rate at which a project spends or "burns" money. This is usually given as a per month amount.
- Buy-in** Term used by A.I.D. to describe the administrative mechanism by which missions or regional bureaus can contract for the services of centrally-funded projects. The interested group "buys-in" for the specified services for an agreed upon amount.
- Demixing** Synonymous with segregation. See segregation.
- Segregation** Separation of ingredients in a dry blended powder product during the manufacturing process that is usually the result of these ingredients' varying specific gravity or particle size. Segregation can result in products' final composition varying from one sample to another. Synonymous with "demixing".
- Social Marketing** Adaptation and application of commercial marketing methods to develop programs that address public health needs via the marketing of products such as contraceptives.
- Stratification** Separation of ingredients of any dry blended powder product in a unique vertical fashion.

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EXECUTIVE SUMMARY

A. Objectives and Methodology

The goals of Project SUPPORT (Supply, Production, and Promotion of Oral Rehydration Salts) were: (1) to increase access to oral rehydration salts (ORS) through assistance to local producers and (2) to test the feasibility of health sector programs joining private and public organizations in partnership. The project was funded by A.I.D. under a cooperative agreement signed in August 1985 for an initial three-year period. An additional 14 months were added later, making the new closing date: October 31, 1989.

The project was first co-managed by the A.I.D. Bureau for Private Enterprise and the Office of Health of the Bureau for Science and Technology; and later was transferred to be managed by the Office of Health. The project was implemented by the Program for Appropriate Technology in Health (PATH), located in Seattle, Washington.

This report presents findings and recommendations from a final project evaluation requested by A.I.D. Field studies were conducted for the evaluation during September and October 1988. The evaluation team consisted of: Professor Hridaya N. Bhargava, Ph.D.; Craig W. Carlson; Robert C. Emrey, team leader; and James R. Messick.

Objectives for the evaluation were: (a) to document project experience for possible follow-on projects; (b) to assess the potential for further public-private cooperation; (c) to recommend activities for the 14-month project time extension; and (d) to assess the project design and implementation. The evaluation methodology consisted of observations and discussions as well as reviews of project documents. The team visited A.I.D. offices in Washington, D.C., the PATH offices in Seattle, Washington, and two overseas sites: Guatemala and Ghana. Two previous evaluations, conducted in 1987, were available for review.

B. Background to Oral Rehydration Therapy

Oral Rehydration Therapy (ORT) produces dramatic results in controlling the often lethal effects of diarrhea on young and malnourished children. Dehydration and consequent body electrolyte imbalances accompany most bouts of diarrhea in children throughout the developing world. The effects of rainfall and other environmental patterns in each country produce a diarrhea season or seasons, when incidence increases. It is expected that ORS usage will increase during such high seasons. Control of Diarrheal Disease (CDD) programs are increasingly common elements in developing countries' health systems (112 countries as of 1987, according to the World Health Organization).

Oral rehydration salts (ORS) are packages containing scientifically determined amounts of four ingredients: sodium

chloride, potassium, glucose, and bicarbonate or citrate. The ORS material is mixed in a container of water by a health worker or family member. A critical step in the use of ORS is the dilution and mixing of the proper amount of water. Over-concentrations of the salts can be dangerous. Most international and bilateral health donor agencies have joined together in their encouragement of ORT programs and distribution of ORS packets. The internationally accepted ORS formula is unsweetened on the premise that infants are not able to detect that the mixture is somewhat bitter. Public health authorities are concerned that older users might over consume a sweetened ORS mixture and receive overconcentrations of the ingredients.

C. Status of ORS Production

ORS packets are more complex to produce than one might expect. Several physical and chemical properties of the materials require special attention and procedures in the mixing and packing processes. Production of ORS packets must adhere to the high quality control standards of a pharmaceutical product. These standards are known in the industry as Good Manufacturing Practices (or GMP).

Current annual output of ORS worldwide is over 300 million packets. While ten years ago the packets were produced mostly in Europe, now more than half the output comes from developing country producers. Most of the ORS packets used in public health programs contain the WHO formula, which is an unsweetened mixture. Pharmaceutical firms in some countries also produce some amounts of sweetened and colored ORS mixtures, where permitted by local laws. These producers claim they can expand markets and sales with the sweetened formula. Local production in developing countries has advantages, such as tailoring packet designs to local customs. Disadvantages of local production included: potentially higher costs compared to imports and possible non-compliance with GMP.

D. Project Concept, Design, Strategy, and Products

Project SUPPORT was planned to harness private initiative to replace what was a continuing financial burden in paying for public distribution of ORS packets. The project provided financing and technical assistance for production and marketing of ORS packets. Initially, A.I.D. did not explicitly direct the implementing organization, PATH, to employ experienced marketing personnel nor to develop marketing strategies and marketing plans in country programs. A.I.D. believed that sufficient marketing expertise would already exist in the local private firms selected by PATH. Commercial risks to local producers were to be reduced through application of expert knowledge by PATH. Financial resources were provided to purchase equipment, instruments, raw materials, or promotional activities. The combination of risk reduction and financial resources was intended to induce candidate local producers to join the project.

By the end of the project, PATH was to have assisted producers in four countries and for at least two of them to be in production. The project also required the Recipient (PATH) to: (a) advise A.I.D. on how best to make its own ORS purchases; (b) provide technical advice and expertise to ORS manufacturers; and (c) study other products that might be encouraged for local production in developing countries.

The SUPPORT Project was an amendment to an existing project, called HEALTH-LINK, dealing with local production of other health-related products. Therefore, there was not a separate project paper which outlined specific rationale for local production of ORS. Rather, the rationale was contained in a cooperative agreement and accompanying documents. Project SUPPORT could work potentially in a country having either: considerable, little, or even no oral rehydration therapy acceptance. Several vastly different project strategies would be required depending on whether a SUPPORT activity is replacing overseas ORS purchases with a local supply alternative or servng as catalyst for a new or slowly developing national ORT program. The evaluation team interpreted the project cooperative agreement as a partnership effort between A.I.D. and PATH--as is envisioned for cooperative agreements under Federal Government procurement regulations.

E. Country Assessment and Company Selection

Assessment of countries for the project was made against four key guidelines which were prepared by PATH: (a) existence of sufficient demand and need for ORS; (b) degree of government support for ORS; (c) level of technical feasibility and know-how available in the country; and (d) designation as an A.I.D. Child Survival priority country. Company selection criteria included business, financial, and pharmaceutical production, and distribution factors.

Modifications were made by PATH and A.I.D. in deciding to accept some sites not meeting all the guidelines. In some cases, they considered special circumstances outside the original guidelines which in a particular country appeared to offer promise of success. Among the special circumstances used in selection, the team found the following: (a) special enthusiasm on the part of a firm offering to work with A.I. D. and start local production; (b) USAID mission willingness to assign their staff in following-up and encouraging the local production effort; and (c), in cases where public demand for ORS was inadequate, the availability of technical assistance specialists from outside the project to address marketing and demand creation problems (such as the presence of a SOMARC or HEALTHCOM project activity giving attention to marketing and communications problems).

Project SUPPORT conducted assessments in countries representing all A.I.D. regions. The project has provided technical assistance in nearly 15 countries and participated in discussions about the possibility of entering local production in numerous others. The following summary suggests the scope of project field activities:

Ongoing Countries : Cameroon, Ghana, Guatemala, Paraguay,
Peru, Turkey and Uganda

Short-Term Technical
Assistance Requests: Philippines, Costa Rica, Ecuador,
Mexico.

Project Identification
Trips: Guinea, Honduras, Lesotho, Zaire and
Somalia

Transferred to PRITECH
or Postponed/Cancelled: Bangladesh, Yemen and Zambia

The five countries which have progressed the farthest toward completing the steps of local production start-up are: Ghana, Guatemala, Paraguay, Peru, and Turkey.

The team examined in detail the project experience for activities in Guatemala and Ghana. In both countries, some of the selection guidelines were not satisfied. Significantly, there existed very little demand for ORS in Ghana and only moderate demand in Guatemala. The companies selected in each case were active and interested in ORS. The Guatemala firm, ADAMED, Ltd., was three years old and only beginning to organize its production, quality control, and distribution systems. The Ghanaian firm, DANAFCO, was much older, engaged in production of many drugs, and operated an extensive network of product distribution, covering over 3,000 retail outlets. Neither firm had a mature marketing operation that was capable of planning and executing a wholly new ORS promotion without outside assistance.

F. Production of ORS Rehydration Salts

PATH has successfully reached most of the production objectives set by the cooperative agreement. PATH reached agreement with DANAFCO in Ghana and ADAMED in Guatemala to produce ORS (WHO Citrate formula), and both private companies were good choices.

PATH has advised DANAFCO and ADAMED on how to bring their buildings and production areas into compliance with GMPs. PATH procured manufacturing and quality control testing equipment and established quality assurance laboratories in both places. All the manufacturing and testing equipment and established quality assurance laboratories in both places. All the manufacturing and testing equipment, except the filling machines, are adequate and performing well. PATH has written and implemented manufacturing plans for producing ORS at DANAFCO and ADAMED. Both firms have registered their products as over-the-counter drugs (OTC) in their respective countries.

PATH has written quality control manuals for DANAFCO and ADAMED to assure the quality of locally-produced products. The document is implemented in the area of raw material testing, in-process testing,

and finished product testing. As required by GMP, PATH has attempted to validate mixing processes and developed several documents to control the quality of ORS. PATH has also developed a three-phase approach to ensure the quality of locally-produced ORS. This includes in-house testing by the local producers, testing by an independent laboratory, and testing of locally-produced ORS by an independent laboratory in the United States, whom PATH contracts with for such services.

In spite of successful production of 153 lots at DANAFCO and 30 lots at ADAMED, the filling machines procured for DANAFCO (ALL-FILL Semi-Automatic) and at ADAMED (M. Asteguita) have several problems and are not functioning to their optimum capacity. The problems associated with the filling machines should be resolved immediately. Within the pharmaceutical industry, start-up of production typically requires considerable time to complete a modification of processes. The team found the start-up problems of the SUPPORT Project manufacturers in most cases to be within the types expected during the early stages of production.

PATH needs to strengthen its assistance in the areas of GMP compliance and should also validate both filling and sealing operations, develop a sampling plan for content uniformity of the finished dosage, complete documentation for facilities and batch records, and provide GMP training for employees of DANAFCO and ADAMED. PATH should continue to provide additional technical assistance to DANAFCO and ADAMED to assure the quality of ORS.

G. Marketing of Oral Rehydration Salts

Marketing was investigated by PATH during the assessment visits to each country. The assessment documents contain data about marketing experience of the producer firm and available media resources. Market planning was also a necessary element in each site where Project SUPPORT assisted in starting production. The team found that insufficient study and planning had been done at an early enough stage to identify potential obstacles in an ORS marketing effort. There were no written marketing strategies and marketing plans developed for Ghana and Guatemala during the production planning activity.

The Ghana local firm, DANAFCO, produces and packages one common product and uses one brand name, ORS, for both the Ministry of Health and for distribution through private DANAFCO channels. A rather unique arrangement was developed where UNICEF imports raw materials to the Ghana MOH, which are then transferred to DANAFCO and bartered for a portion of the production output. The two products are priced at 25 cedis (or approximately .11 cents U.S. at the October 1988 exchange rate of 229 cedis to the dollar). Production costs have escalated since the price was set at product launch in April 1988. All promotion of the ORS products is planned jointly among donor agencies, including A.I.D., UNICEF, the MOH, and DANAFCO. Delays in the MOH promotional program and lack of national Pharmacy Board approval for DANAFCO to advertise ORS have conspired to slow all promotion and

sales efforts. Large overstocks of ORS packets now are accumulating in DANAFCO warehouses due to lack of progress with marketing and sales.

The Guatemala local producer, ADAMED, launched its product about six months before our evaluation in October 1988. There are several ORS products on the market in Guatemala; all but ADAMED's LITROSAL are imported products. The government with USAID/Guatemala assistance is preparing an ORS manufacturing plant at the University of San Carlos, which will make an additional competing ORS product, called SUPERSUERO. No specific target population was identified for the ADAMED product, it is sold in pharmacies and other private sector channels. The price to consumers for LITROSAL is 60 centavos per package (.22 U.S., US\$1 equalled 2.70 Quetzales in October 1988). This price is one of the lowest of the six powder-form products the team found being sold in pharmacies and other private sector channels. As in Ghana, the Guatemala producer now indicates that production costs have risen in this case to 62 centavos per packet, resulting in a corporate loss of 14 centavos per packet. ADAMED is able to distribute to pharmacies throughout the country, including 558 in Guatemala City and 476 in the interior. The promotion of LITROSAL had been planned to follow a heavy generic communication campaign by the government, encouraging ORS use; however the campaign remains delayed, and numerous changes in Ministry of Health top personnel have left the promotion and coordination efforts somewhat confused. Another A.I.D. project, HEALTHCOM, has a large program in Guatemala focused on promoting health-related products, including immunizations and ORT.

H. Finance and Business

Capital investment funds to start-up local production are provided from a special fund, known as the loan corpus, which A.I.D. granted to PATH for the purpose of making project loans. Specific criteria for granting of loans were designed for the project by PATH. Three types of loans were made available by PATH to potential producers, depending on financial, legal, and foreign exchange considerations: (a) loan incentives; (b) loan guarantees; or (c) direct loans. The core loan fund, or corpus, is administered by the PATH Comptroller's Department, and interest is accrued from the fund. The flexibility of the loan program responds well to the needs of local producers and the objectives of the project.

The business plans prepared for each local producer provide documentation of the business prospects of an ORS product. The business plan for Ghana was examined in detail, and it emphasizes mostly production issues to the near exclusion of financing and marketing factors.

Pricing of ORS products in each country is complex and fraught with many uncertainties. The pricing decisions of the firms' managers may be subject to review by government agencies. Pricing tests often are a valuable part of marketing plans, but they may not be permitted

by government price regulators. Both the Ghana and Guatemala producers now claim to be losing money at their present price point for ORS.

I. Impact and Sustainability

Project SUPPORT impacts can be divided into final impacts, such as changes in case management of diarrhea, and intermediate impacts, such as management, technical, and work efforts related to ORS production. An extensive plan for impact field studies was prepared for the project by consultant Dennis R. Foote in 1987. The evaluation team supports the conduct of such studies on a modified and reduced scale during the remainder of SUPPORT and more extensively in a follow-on project.

It was too early after product launch in Ghana and Guatemala for there to be evidence of final impacts. The products were first sold about six months before the evaluation, but delays in distribution and marketing have slowed the sales programs. Intermediate impacts included: management changes, production facilities renovations, and promotional program arrangements.

Sustainability, once production and promotion start-up is completed, is very important to the project. Among other factors, sustainability depends on: good program management and coordination, acceptance of ORT within the host country, continued and stable inputs of public funds, public promotional efforts to maintain the ORT program, and product profitability for the local producer. Both positive and negative signs concerning sustainability were uncovered by the evaluation team in Ghana and Guatemala.

J. Potential for Local Production of New Products

The evaluation team investigated informally the potential for products other than ORS to be developed for local production. A number of potentially viable products were found from the World Health Organization essential drug list together with a few other devices, such as AIDS diagnostic kits. Each technology would have to be investigated in detail to determine the exact nature of the production requirements and the present and future market outlook.

K. Central Procurement of Oral Rehydration Salts

Project SUPPORT was requested to provide advice and assistance to A.I.D. in its efforts to serve field missions with supplies of ORS packets. Throughout the period of the project, a debate raged within the Federal Government and other interested institutions concerning the proper arrangements to be used in controlling quality of ORS production. In part, this debate was a result of the sad deaths of several children in Peru in 1986 from over-concentrated doses of ORS, which had been manufactured by a U.S. firm and imported to Peru by USAID/Lima. The evaluation team found that PATH had provided appropriate and valuable assistance throughout the project as A.I.D.

grappled with the many procurement, legal, and programmatic issues related to providing ORS supplies.

L. Dissemination of Project SUPPORT Experience

Project SUPPORT, as with other A.I.D. projects, was required to prepare written reports and other forms of dissemination based on its experiences in development of local ORS production. The evaluation team reviewed the results of those efforts and was impressed with the dissemination effort, but believes that additional dissemination would be valuable. The project prepared manuals and reports concerning: volume and label of ORS products; guidance for local procurement of ORS (in preparation); and analyses of ORS quality assurance practices and standards. In addition, excellent publications were prepared and distributed internationally, under the Directions series, concerning PATH investigations of potential additional local products. Also, presentations concerning the development of local ORS production were made at national and international meetings.

M. Management

PATH follows a matrix organizational structure with project staff assigned by program area to work over time on several related projects. The Project SUPPORT staff was drawn from the pool of health professionals located at PATH headquarters in Seattle and the PATH communications office in Washington, D.C. Offices and equipment serving the project were found by the evaluation team to be functional and well-suited to the needs of the project.

Total budget for the project was \$1,973,000 in the original agreement. With amendments the actual expenditures after three years were \$2,152,195. Actual spending levels have consistently followed the budget levels, as amended.

Within the matrix structure of the organization, Project SUPPORT operated with a personnel level of effort as follows: 5.75 full-time equivalents in 1986, 13.27 in 1987, and 8.24 in the first nine months of 1988. Two positions at PATH were designated as full-time for Project SUPPORT. There were indications that in some cases delays in work and availability of staff members for project tasks was related to the considerable workload resulting from the expansion of this project's activities, and the other duties for which staff and the Project Director were responsible. The team found that many overseas participants in the SUPPORT activities, including USAID officials, were not clear on who at PATH provided backstop services and supervision over their country's project. The team was also concerned that PATH did not have senior specialists available in the areas of (a) pharmaceutical production and quality control and (b) private sector marketing. To a degree, the U.S. Federal pay ceiling presents an obstacle which bars PATH from obtaining the services of senior specialists in these areas.

Field implementation in the six countries in which comprehensive ORS production and marketing services are being provided has proceeded with many difficulties and delays, mostly related to complex host country bureaucratic and business procedures which are inherent in beginning an activity of this type. In all field reports and interviews, PATH personnel and consultants have been consistently praised for their professionalism and rapport. The staff of PATH is to be commended for its energy in pursuing solutions to the numerous obstacles facing the local production activities and for its willingness to respond to a greater number of production start-ups than was considered in the cooperative agreement. Coordination of Project SUPPORT activities in-country with national diarrheal disease control efforts has been a significant element pursued diligently by PATH. The project design placed responsibility on PATH also for coordinating its efforts with the several other related A.I.D. health projects operated in the project countries. Inter-project coordination has proved to be a highly complex process, and the team commends PATH for its efforts in this area but believes that additional effort is needed on this problem to ensure that efficient operations of the several projects are maintained.

Field work is monitored through visits and reports submitted by participating firms. It is critical that PATH remain continuously sensitive to indications that follow-up is needed for problems occurring in the field. The team believes that in general, the PATH staff have done well in serving host country client needs but is concerned that in some cases this highly important task is not getting sufficient attention. Information about project progress and problems is needed also by A.I.D. in Washington, D.C., across the American continent from Seattle. This information flow has been extensive but still additional resources seem to be required to permit more face-to-face meetings of project staff members with participating A.I.D. officials.

Summary of Recommendations

Production and Quality Control

- o Develop a uniform sampling plan for quality testing of all stages of production and quality control, including testing of finished ORS packets. Follow this plan at all project production sites;
- o Validate mixing, filling, and sealing processes used at DANAFCO, ADAMED, and other production sites; and
- o Develop specifications and testing methods for all levels of packaging materials (include primary, secondary, and tertiary packaging components, such as inner poly bag, outer poly bag, cardboard cartons, etc.)

Marketing of ORS

- o A.I.D. should provide what additional funding is necessary for PATH to recruit and assign personnel with experience in marketing;
- o Do not expand to new countries, companies, or product introductions until the experience in the initial projects has shown to be sound and reliable enough to warrant expansion;
- o In Guatemala, the first priority should be to provide a short term advisor who can provide consistent and continuous marketing assistance and program coordination to ADAMED; and
- o In Ghana, provide additional assistance with the same technical advisor to ensure that marketing decisions and plans are widely accepted and supported, and that actions are followed through with.

Finance and Business

- o Continue to offer similar loans mechanisms with the range of terms evidenced in SUPPORT I, that take into consideration the peculiarities of each country.

Dissemination of SUPPORT Experience

- o Provide for wider funding latitude in follow-on project in order to permit a greater variety of dissemination activities.

Impact and Sustainability

- o For monitoring and evaluation purposes, PATH should more rigorously pursue collection of key data from the firms it assists;
- o The evaluation team notes that due to delays in implementation of activities in some countries, and only recent initiation of activities in other countries, it is too early to assess the impact on ORS knowledge and use that may have resulted from this project. The team feels that efforts should be directed at collecting information more proximate to production and marketing; and
- o Conducting spot surveys of marketing outlets and consumers is an activity that should be budgeted into the follow-on project, in order to assess awareness, knowledge, and attitudes towards newly introduced ORS products.

Management

- o Incorporate higher levels of resource investment into follow-on project, to cover the greater level of time and technical assistance that has been shown to be necessary to sustain these activities;
- o Allow the project and follow-on projects to pay higher salaries to those consultants drawn from the private sector with experience in critical areas of production engineering, quality control, and marketing; and
- o Consider use of short-term resident advisors to be assigned during the most critical phases of planning, and implementation.

I. OBJECTIVES AND METHODOLOGY

A. Project Objectives

The primary goal of Project SUPPORT (Supply, Production, and Promotion of Oral Rehydration Salts) was to increase the availability, accessibility, and awareness of oral rehydration salts (ORS) through provision of technical assistance to private pharmaceutical companies in developing countries. A second goal of SUPPORT involves assessing the feasibility of forming beneficial partnerships between the private and public sectors in the pursuit of public health objectives. Once local production was organized and initiated, it was hoped that private sector dynamics would prove sufficient to sustain such an enterprise.

Project SUPPORT began as a three-year project in August 1985. It was recently extended for an additional 14 months with a new closing date of October 31, 1989. As specified in the original cooperative agreement, its main objective was to initiate or expand oral rehydration salts (ORS) production in four countries, with two of these being operational, and two more being in their final stages of development by the end of the project. Additionally, SUPPORT was to develop an efficient mechanism to procure and distribute U.S.-produced ORS packets to meet USAID requests; and conduct a series of technology reviews on key primary health care issues to help identify new opportunities for future commodity support interventions.

The project was developed jointly between the Bureau for Private Enterprise and the Office of Health in the Bureau for Science and Technology of the Agency for International Development (A.I.D.) in Washington, D.C. In the beginning, technical oversight was received from the Office of Health and the Cognizant Technical Officer and loan component oversight came from the Private Enterprise Bureau. At the end of the second year, all project oversight for SUPPORT was transferred to the Division for Health Services of the Office of Health. The Cognizant Technical Officer is Robert M. Clay. The project is being implemented by the Program for Appropriate Technology in Health (PATH), located in Seattle, Washington. The Project Director is John B. Tomaro, Ph.D.

This report provides findings and recommendations from a final evaluation of Project SUPPORT. Field work for the evaluation was conducted during September and October 1988. Final analysis of the data was prepared during November and December 1988.

B. Evaluation Team

A team of four people was contracted for the evaluation under funding from the Office of Health to the Office of International Health of the U.S. Public Health Service and through a contract to DEVRES,

Inc. The evaluation team consisted of: Professor Hridaya N. Bhargava, Ph.D., specialist in industrial pharmacy; Craig W. Carlson, specialist in public health and management; Robert C. Emrey, evaluation team leader and specialist in business and public health management; and James R. Messick, specialist in marketing and social marketing of health-related products and services.

C. Evaluation Objectives

The final evaluation summarized in this report was an element of the original project agreement. The project was started as an amendment to a previous A.I.D. private sector health project, called HEALTH-LINK. The team reviewed the cooperative agreement between A.I.D. and PATH and the accompanying documentation for background, as there was no separate logical framework or project paper design for Project SUPPORT.

The general intent of the evaluation was to assess progress made during implementation and to document lessons learned and obstacles encountered during project operation. Four specific objectives were provided to the evaluation team for its work:

- o To document the project's experiences in such a manner as to provide direction for the planning and development of any follow-on project to SUPPORT;
- o To contribute to the field's understanding of the potential for cooperation between public health and private sector organizations. In particular, the evaluation should address the questions of sustainability of such efforts and the possibilities for expanding the range of products and services provided;
- o To recommend new or revised project activities for the remaining period of implementation, because Project SUPPORT was extended for 14 months beyond its original completion date of September 1988; and
- o To address issues of project design, implementation and management, impact, and sustainability (see complete list in Annex 3).

The evaluation team was briefed on the meaning of these objectives by A.I.D.'s project officer during discussions in Washington, D.C.

D. Evaluation Methodology

The evaluation consisted of investigations made during September and October 1988. The team's observations and discussions began with officials in the U.S. with A.I.D. offices and with PATH in Seattle. Additional field observations were conducted at two project sites:

Guatemala City, Guatemala, and Accra, Ghana. The evaluation process consisted primarily of interviews and document reviews.

Numerous documents were accessible to the evaluation team in Washington, D.C., and Seattle. Midterm evaluations of Project SUPPORT were available to the evaluation team and focused on two areas. One evaluation assessed the financing component of the project (prepared by Jonathan Green); the second looked at operational issues (prepared by Dennis Foote). A full two meter-long bookshelf of notebooks was prepared for the team's use by PATH during the Seattle visit. This extremely useful collection of data consisted of: project documentation, correspondence, reports, and related materials. Other publications and memoranda related to production of oral rehydration salts were provided to the team by various experts during the evaluation process.

The team visited AID/W offices during the period September 26-30, 1988. Following a day and a half of team planning exercises, interviews were conducted with A.I.D. officials involved with health, private enterprise, social marketing, commodity procurement, and program planning. Additional interviews were conducted with other health-related projects based on the Washington area, including health promotion and social marketing specialists in the Washington, D.C., offices of PATH.

The team visited PATH headquarters in Seattle during the period October 10-12, 1988. The visit afforded an opportunity for the team to hear about progress made and problems encountered from the project staff members. The full scope of project field implementation activities across nearly 15 countries was reviewed in the written documentation and follow-up discussions with PATH staff members. In addition, the team was provided the opportunity to observe the operation of PATH's other several health services and research and development activities.

On-site visits in Guatemala (October 16 to 22) and Ghana (October 23-30) were used by the evaluation team to determine the progress made in ORS production and promotion. The visits consisted of interviews conducted in the offices of USAID, the local ORS production/marketing companies, and project-related international and business organizations. The ORS production companies were subjected to a systematic review of their production and promotion activities (see Annex 5 for a summary of the data collected).

E. Organization of the Report

The report contains findings from the evaluation team's analyses. The 14 chapters are grouped into five main aspects of Project SUPPORT.

- o Chapters two and three provide background information about oral rehydration and production of packets (or sachets);

- o Chapters four through nine focus on the field element-- technical, production, marketing, finance, business, impact and sustainability;
- o Chapters ten through twelve cover the three additional elements of SUPPORT--new products (10), central procurement (11), and dissemination (11);
- o Project management is discussed in Chapter 13; and
- o Recommendations are summarized in Chapter 14.

Annexes to the report contain background information on oral rehydration, salt production standards, the evaluation work scope, field mission reports, bibliography, and people contacted.

II. BACKGROUND TO ORAL REHYDRATION THERAPY

A. Overview

Since the beginning of the decade, Oral Rehydration Therapy (ORT) has been widely acknowledged by the international and domestic U.S. health communities to be an effective, inexpensive, and widely-applicable treatment for the dehydration that often accompanies diarrhea. Use of ORT to prevent or treat dehydration can often make the difference between life or death. This is particularly true for infants and children whose body fluids can be depleted more quickly than adults, thus endangering their lives. Babies who are malnourished are at an added risk from the effects of dehydration and electrolyte imbalances due to diarrhea. Certain Home-Available Fluids (HAV) or manufactured Oral Rehydration Salts (ORS) can be administered in the home during early stages of diarrhea to prevent dehydration. It can also be used in many clinic and hospital settings as an alternative to intravenous solutions and antibiotics. Rainfall and other environmental patterns produce in each country an identifiable diarrhea season. The pattern of demand for ORT in all forms will normally rise during that season of the year.

This very significant impact which ORS can have on mortality has resulted in it receiving very strong support from international groups, bilateral programs, and private voluntary organizations (PVOs). Control of Diarrheal Disease (CDD) programs (including policy, production, promotion, logistics and distribution, research, and training components) are increasingly common in developing countries' health portfolios as these countries target the more significant causes of morbidity and mortality. As of 1987, 112 countries had established operational National Diarrheal Disease Control Programs.¹

Acceptance of ORT as a high priority by national and international groups has contributed to increases in access and use rates, worldwide. WHO defines access as the percentage of population having reasonable access to a provider of ORS who is trained in its use and receives adequate supplies. The WHO estimates that as of 1986, 59% of children with diarrhea had access to ORS. ORT use is thought to give the better indication of projects' status because many countries promote ORT or HAV in the home setting and use ORS only when the child is brought to a health center. Use rates of ORS, worldwide, increased from 5% in 1983, to 14% in 1986. For ORT, use rates have increased from 12% in 1984 to 23% in 1986.

¹ World Health Organization. Sixth Programme Report, 1986-1987. Geneva: Programme for Control of Diarrhoeal Diseases, World Health Organization, 1988, page 4. (WHO/CDD/88.28)

B. Oral Rehydration Salts

The presently accepted formula for packaged oral rehydration salts is the result of many hundreds of scientific experiments and tests.² The formula contains sodium, potassium, glucose, chloride, and bicarbonate or citrate. The ORS dry material is mixed in water by a health worker or family member. It is critical that the users of ORS solutions know exactly how much to dilute the salts and how to proceed with safe administration of the solution to the child. Improper proportions of the ingredients may be harmful, even fatal to the recipient. Packaging materials, instructional aids, and educational classes are all a necessary part of the process for ensuring safe use of the ORS product.

The internationally approved formula for ORS is unsweetened, on the premise that infants' taste facilities are not yet able to discern that the formula is somewhat bitter. By providing unsweetened mixtures in ORT programs, public health authorities feel it may prevent overconsumption and the resultant hypernatremia in users who might try to drink large amounts of a sweetened mixture. Many developing country local ORS producers and some multinational pharmaceutical firms are producing sweetened oral rehydration mixtures for sale in developing countries even though they do not meet the present, internationally recognized formula.

C. Roles of International Agencies

1. Role of WHO

The World Health Organization (WHO) has played a major role in advising countries on CDD policy and programming. Since its initiation in 1980, WHO's CDD program has "provided technical and financial support to countries implementing national CDD programs and to researchers seeking ways to improve the delivery of control programs and new or improved tools for control".³ WHO's guidelines for ORS production and quality control have become the standard in many developing countries which manufacture their own ORS (see detailed description in Annex 2). Although WHO/UNICEF ORS is unflavored and uncolored, several studies are being done to assess the possible risks and benefits of adding such ingredients to ORS. If no problems are found, further studies will be done to find out if flavoring and coloring improves the acceptance of ORS.

² Norbert Hirschhorn. The treatment of acute diarrhea in children: An historical and physiological perspective. American Journal of Clinical Nutrition, March 1980, 33, 637-663.

³ Ibid., page 12.

2. Role of UNICEF

UNICEF has also played a critical part in CDD activities. It has incorporated these activities into many of its country programs. UNIPAC, the procurement, packaging, and shipping operation of UNICEF in Copenhagen, has procured and provided many countries with their ORS packet supplies. In 1987, UNIPAC provided 58 million packets to approximately 70 countries.⁴

3. Role of A.I.D

The worldwide health sector program of A.I.D. addresses oral rehydration therapy within an integrated set of health services and research projects covering many critically important developing country health care needs. These projects address health problems of developing countries related to: control of diarrheal diseases (CDD), immunizations of infants, children, and women of child-bearing age, and acute respiratory infections, among others. The A.I.D. program includes numerous country-specific projects in these fields, which are being implemented under agreements with host country governments, as well as centrally-funded projects which address high priority, worldwide requirements. Some of the centrally-funded projects that are relevant to oral rehydration include the following:

- o HEALTHCOM--communication and marketing
- o PRITECH--technical assistance, training, and policy making
- o PRICOR--operations research
- o ADDR--diarrheal disease research
- o SOMARC--marketing and promotion of contraceptives--but also ORS products in certain countries

These and other projects can provide services and research as needed to solve problems related to ORT.

While A.I.D. supports comprehensive CDD programming, it has begun to pursue activities beyond the usual domain of the public sector. One component of A.I.D.'s CDD efforts involves encouraging local production of ORS. Project SUPPORT, designed to complement larger CDD program efforts, provides technical assistance to local private sector pharmaceutical firms to initiate or upgrade their ORS production capacity.

⁴ Ibid., page 12.

III. STATUS OF ORS PRODUCTION

A. Issues in the Manufacture of ORS

ORS packets would seem to be a simple kind of pharmaceutical product to make, but in reality, it is not so. ORS formula presents many complexities that must be resolved by any multinational or local pharmaceutical producer. Among the properties of ORS ingredients that may pose production difficulties are the following:

1. Hygroscopic.--Ingredients will readily absorb moisture from the surrounding environment unless carefully handled, stored, and packaged;
2. Flow.--Ingredients do not flow freely, giving problems in filling of sachets;
3. Multiple Densities.--Four (4) therapeutically active ingredients of widely differing densities are used (sodium chloride, potassium chloride, trisodium citrate dihydrate, and glucose anhydrous);
4. Widely-Varying Proportions.--The amount of each ingredient in the formula ranges from 5% for potassium chloride to 72% for glucose;
5. Mildly Corrosive.--Ingredients can corrode many types of materials, thus requiring use of specially constructed equipment and construction for manufacturing;
6. Dust.--Ingredients produce a fine dust which may interfere with the sealing of packets during production;
7. Environmental Control.--ORS should be produced at controlled, low temperature and humidity; and
8. Cost Sensitivity.--For long shelf life, ingredients must be packaged in a relatively expensive package, yet should be produced at a low total cost to be affordable to as many users as possible.

The professional, social, and legal responsibilities that rest with the manufacturer of ORS or any other pharmaceutical are considerable. It is only through well organized, adequately staffed, and accurately performed process and dosage form control that adequate quality assurance of ORS can be achieved. These controls are needed before, during, and after the production process.

It should be realized that no amount of finished ORS testing and controls can assure the product's quality unless Good Manufacturing

Practices (GMP) are implemented systematically and process control is practiced vigorously. Product quality must be "built in," and not merely tested for, in the product.

GMPs encompass several aspects of pharmaceutical manufacturing processes. Each aspect is determinant in controlling the quality and purity of a pharmaceutical product. GMPs¹ govern each production phase, including:

1. Organization and personnel;
2. Buildings and equipment;
3. Drug product container and closure;
4. Production and process control;
5. Control of records and reports;
6. Packaging and labeling control;
7. Holding and distribution;
8. Laboratory control;
9. Returned and salvaged drug products;
10. Control and assurance of finished products;
11. Testing program and methods;
12. Quality of analytic methodologies; and
13. Associated activity, stability studies.

In order for the total quality control system to function effectively, certain operational rules should be established and should always prevail.

- o Control decisions must be based solely on consideration of product quality;
- o Production operations must adhere rigidly to the established standards or specifications, including systematic inspection and testing;

¹ U.S. Food and Drug Administration. "Good Manufacturing Practices." Federal Register, vol. 190, September 1978. Also found in: Code of Federal Regulations, 1988, Sections 210-211.

- o Manufacturers of ORS should strive constantly for improving the performance levels as measured by current standards or specifications; and
- o Quality control decisions should be administratively independent, and they must not yield to or be overruled by production or marketing personnel under any circumstances.

Because quality control decisions for ORS can involve the health and welfare of the child and the reputation of the manufacturer, creating and safeguarding the climate necessary for such decisions is essential. In times of major disagreement with the pharmaceutical firm over operational or quality factors, the quality control decisions should be subjected to review only at the highest level of management.

Quality assurance rests on the accepted specifications and testing procedures promulgated by national and international standard-setting bodies. There exists today a certain ambiguity among the various standards involving ORS products. The issues related to the ORS standards are significant and are discussed at length in an annex to this report (see Annex 2).

B. Local Production of ORS

1. Overview

In 1983, approximately 100 million packets of ORS were manufactured, worldwide. Current worldwide annual production volume is now over 300 million packets.² Locally produced ORS (that which is manufactured in developing countries for domestic or regional consumption) constitutes a growing percentage of this total production (see Figures 1 and 2). Developing countries' production now exceeds the amount produced in developed countries (this latter group being inclusive of UNICEF production). As of 1986, 55 developing countries were producing ORS, this constituting 65% of total world production. In 1980 only 13 countries were producing packets.³ While most of the ORS packets used in public health programs contained the unflavored WHO formula, sizeable amounts of flavored and colored ORS mixtures were produced, where permitted by local law, for commercial sales. Many commercial producers claim that sweetening and coloring the ORS powder mixture permits them to expand their market for ORS and ultimately to increase the appeal of using ORS in the home.

² World Health Organization. Sixth Programme Report, 1986-1987. Geneva: Programme for Control of Diarrhoeal Diseases, World Health Organization, 1988, page 14. (WHO/CDD/88.28)

³ M. Merson (WHO/CDD Program Director), speech at Fourth Consultative Meeting in Yamoussoukro, Ivory Coast, 1988.

2. Advantages

Some countries lack the manufacturing and quality control facilities necessary for ORS production, while others may have populations too small to realize sufficient economies of scale. But for many countries, the local production of ORS offers a number of advantages:

- o Label design, including languages and culturally-appropriate illustrations, can be custom tailored for the country, or even a region of a country. Package labels or inserts can also be used as a medium for other health messages such as breastfeeding or immunizations.
- o The packet dose can be readily adapted to any local container that is found to be widely available for mixing of the ORS. In Ghana, for example, the packet dose is designed for mixing in a 600 ml beer bottle, a container that surveys showed is available in most households.
- o If a disaster occurs (such as the flooding in Bangladesh in 1988) the country may be able to respond more quickly than if they had to order supplies internationally (assuming damage has not also affected raw material supplies, electrical power, production equipment, and related requirements).
- o In cases where countries buy ORS internationally (as opposed to receiving donations), local production can save precious foreign exchange.
- o Local production can serve as a way to develop or upgrade the capacities of local pharmaceutical firms and the country as a whole. Technical assistance provided for production, quality control and marketing can subsequently be applied to other essential drugs and pharmaceuticals.

3. Disadvantages

Certain conditions may not make it feasible or cost-effective to produce ORS locally. Among the disadvantages are:

- o Costs and difficulties involved with obtaining raw materials (that may need to be imported) that could drive product costs above those of imported finished products.
- o Less than satisfactory quality control (QC) during production could result in a product that is ineffective or even life threatening.
- o In small operations or where numbers of personnel are very limited, the managerial and oversight responsibilities of

local production could draw these scarce resources away from other program areas, compromising the latter.

- o If the marketing and distribution capabilities do not match the production capabilities, then the timing of the decision may be premature (and prompt the necessary development to make local production feasible).

IV. PROJECT CONCEPT, DESIGN, STRATEGY, AND PRODUCTS

A. Project Concept

Project SUPPORT was designed to extend previous A.I.D. project activity involving private sector firms in health-related services and products. The underlying concept according to project planning documents was to harness private initiative to replace what was a continuing public sector financial burden. The private sector would be assisted to establish a sustained production capacity which could take over, eventually, donor-financed manufacture of oral rehydration salts (ORS), as demand creation was developed.

The reduction of commercial risk and provision of financial resources at favorable rates were key elements of the project concept. The concept was to leverage private sector manufacturing capability by reducing their risks in entering the ORS market. Risk reduction can be seen in several project areas: research of market demand for ORS; evaluation of past performance on the part of manufacturers which were candidates to participate; advice to inform management decisions about profitable levels of production output, package design, product pricing, promotional advertising, and distribution mechanisms; training of staff members in all aspects of ORS manufacture, marketing, and distribution; selection and procurement of production and quality control equipment; and monitoring of product quality and cost controls to ensure the viability of the activity.

An innovative part of the project was the use of project funds to make loans for purchase of equipment required to enter ORS production in the participating developing country pharmaceutical firms. The implementing agency--the Program for Appropriate Technology in Health (or PATH), a nonprofit research and development organization in Seattle, Washington--was encouraged to tailor the loans to meet the differing circumstances of participating firms. Commercial loans are debt instruments which are considered by most businesses to be preferable to grants-in-aid typically used in funding public sector activities.

B. Project Design

The project design called for A.I.D. to enter into a cooperative agreement with an implementing organization. The cooperating agency was to begin its work by conducting assessments of possible manufacturers in countries where A.I.D. was already involved in child survival project activity. By the end of the three years of work, companies in four countries were to be actively arranging for ORS production, with two of those four having already reached the stage of active production. During the assessment and planning stages of the project in a particular country, any weak or missing areas of an ORS manufacturers' operations were to be identified and plans made to

remedy them. It was envisioned also that additional technical assistance could be made available on a worldwide basis by the project staff experts to advise other ORS manufacturers or potential ORS producers on isolated problems. A separate element in the project was the requirement to provide advice on the most appropriate central purchasing arrangement for use by A.I.D. in meeting the Agency's needs for ORS packets. Finally, the project participants were to study products and services other than ORS which might be adapted for later use involving local private businesses under the SUPPORT approach.

C. Project Strategy

As was mentioned in the preceding chapters, though less difficult than some other, more complicated drug products, the ORS product is not an easy one to produce in large quantities at high quality and low cost. Assuming that all problems related to the manufacture of ORS packets are being solved, the marketing of this product is also complex. There was no formal project paper developed specifically for SUPPORT so the HEALTH-LINK project amendment and the project agreement with PATH were the main source of concrete information provided to the evaluation team about project strategy. The project agreement contains very little discussion of strategy-related issues. It was recognized in the agreement that Project SUPPORT would have to coordinate its work within the combined public and private sector ORT activities and environment in a given country. As there was little experience on the part of A.I.D. in this area, there is not much discussion in the document about how private enterprise in ORS production would be meshed into an ongoing governmental educational and therapeutic campaign for control of diarrheal diseases.

The evaluation team would like to have had documentation of what strategies A.I.D. envisioned at the outset for SUPPORT to use where a country had either considerable, little, or no, oral rehydration therapy acceptance. Was SUPPORT intended solely, or primarily, as a means to replace A.I.D. and UNICEF imports of ORS packets from the U.S. and Europe with locally manufactured packets? Should SUPPORT funds be used for energizing a business to serve as catalyst for a new or slowly developing or dying oral rehydration therapy effort, which perhaps was foundering under host government management? Local production as replacement for imports might suggest a scenario where business risks are low, ORS user knowledge of safe use practices is well-established, and demand for packets is at continuing high level. Local production as catalyst for energizing a nation to accept ORT might suggest a scenario where business risks are high, health workers and family members are unconvinced and ill-informed about safe use practices for ORS, and demand for packets is low and unpredictable. There was no cost-benefit analysis concerning such strategy alternatives in the project documents provided to the evaluation team.

In addition, certain basic assumptions were made about how Project SUPPORT firms would operate, but the rationale for the assumptions was not explained or documented. For example, it was assumed from the

outset that drug companies agreeing to participate in Project SUPPORT would be required to produce and market only the unsweetened WHO formula for ORS. Firms also were encouraged to expect little or no ORS sales to host governments. A.I.D. did not explicitly identify or direct PATH to employ experienced marketing personnel nor to develop detailed marketing strategies, marketing plans, and marketing elements in country programs. A.I.D. believed, it seems, that sufficient marketing expertise would already exist in the local private firms selected by PATH.

The underlying concept of cooperative agreements in the Federal procurement system is to permit U.S. government agencies to do research and development of ill-defined or emerging problems. The ends being sought can be defined (locally produced, high quality ORS packets in the hands of health workers and family members), but the means to that end are, to a large degree, unknown. A great deal of exploratory cancer research is funded by the National Institutes of Health using this same type of agreement. The numerous possible scenarios facing Project SUPPORT, which were frustrating to the evaluation team, were undoubtedly also a factor in the original decision by A.I.D. to chose a cooperative agreement rather than a contract for this activity. If simple production advice for turn-key ORS factories was all that A.I.D. was seeking, then a contract instead of a cooperative agreement would have been the appropriate procurement vehicle. Under the cooperative agreement, both PATH and A.I.D. agreed to share experiences and problems, and to make joint decisions on all key elements of the project implementation as the project proceeded.

The evaluation team based its investigations of SUPPORT on the project agreement interpreted as a partnership effort between the two parties. The implementor (PATH) was responsible to use the best available expertise in its work and to inform A.I.D. fully as to obstacles encountered and lessons learned at each stage of SUPPORT. The funding agency (A.I.D.) was responsible to monitor closely the emerging experience, using the best available expertise, to guide the process of implementation toward the agreed ends. This evaluation holds both parties responsible for fulfilling their roles.

A separate agreement was negotiated by PATH with each participating firm agreeing to make ORS packets. The evaluation team considered these production and marketing agreements to be contracts. The contracts were construed by the evaluation team as establishing certain responsibilities for the parties throughout the life of the relationship.

D. Project Products

The SUPPORT agreement requires the completion of work on two ORS production units and substantial completion of work in two more sites. In addition, the project was to produce a written documentation of work accomplished. The documentation requirement has been adjusted in keeping with the flexible nature of the work under the cooperative

agreement. A key product from the project concerns the methods used in providing technical assistance, including guidance manuals and related materials. A series of studies was to be prepared exploring possible products other than ORS which would be developed using the SUPPORT approach. Workshop sessions, including participation in the ICORT Meetings in 1986 and 1988, were included in the set of SUPPORT products. The project implementors were also responsible for providing A.I.D. with regular and systematic reports about progress made at each site and their overall worldwide experience.

V. COUNTRY ASSESSMENT AND COMPANY SELECTION

Lists of guidelines for assessing and selecting appropriate countries and firms to work with were developed at the very beginning of the project. These guidelines were further developed and modified over the life of the project to aid in judging the suitability of candidate project sites. The number of sites considered suitable (i.e. that met the guidelines), which also had firms willing to participate in the project, was not especially large.

A. Assessment Guidelines

PATH prepared guidelines for assessing the appropriateness of countries for Project SUPPORT early during project development. These were modified over time, and at the time of the evaluation consisted of detailed assessment elements within the following four areas:

- (a) Existence of sufficient demand and need for ORS;
- (b) Degree of government support for ORS;
- (c) Level of technical feasibility and know-how available in the country; and
- (d) Designation as an A.I.D. Child Survival priority country.

Within countries that met these guidelines, companies were selected based on their expertise with pharmaceutical production and distribution, quality control and GMP, and financial standing. The process of site selection involved assessments by PATH and review and approval of each site by A.I.D. in Washington and the USAID mission in the host country.

Modifications were made by PATH and A.I.D. in deciding to accept some sites that could be successful as ORS producers but did not meet all the guidelines. In some cases, they considered special circumstances outside the original guidelines which in a particular country appeared to offer promise of success. Among the special circumstances used in selection, the team found the following: (a) special enthusiasm on the part of a firm offering to work with A.I.D. and start local production; (b) USAID mission willingness to assign their staff in following-up and encouraging the local production effort; and (c) in cases where public demand for ORS was inadequate, the availability of technical assistance specialists from outside the project to address marketing and demand creation problems (such as the presence of a SOMARC or HEALTHCOM project activity giving attention to marketing and communication problems).

The assessment guidelines concerning designation as an A.I.D. Child Survival priority country came under discussion within A.I.D. during the Project SUPPORT selection process. Some felt that there were non-Child Survival countries that needed more AID/W assistance because they were getting less bilateral funds. Also, there was a

mandate to give additional attention for increasing work in Africa for A.I.D. programming that came to effect the priorities given to countries such as Ghana.

B. Countries selected to participate

Project SUPPORT conducted assessments in countries representing all A.I.D. regions. The project has provided technical assistance in over 15 countries and participated in discussions about the possibility of entering local production in numerous others. The following summary of countries contacted by Project SUPPORT describes the scope of project field activities:

Ongoing Countries:	Cameroon, Ghana, Guatemala, Paraguay, Peru, Turkey, and Uganda
Short-Term Technical Assistance Requests:	Philippines, Costa Rica, Ecuador, and Mexico
Project Identification Trips:	Guinea, Honduras, Lesotho, Zaire, and Somalia
Transferred to PRITECH or Postponed/Cancelled:	Bangladesh, Yemen, and Zambia

The five countries which have progressed the farthest toward completing the steps of local production start-up are: Ghana, Guatemala, Paraguay, Peru, and Turkey.

The guidelines used in assessing and selecting countries and companies provided beneficial, although not complete, direction to the decision-making process. They helped to direct attention to necessary requirements which would be needed for successful implementation of local production. To the end, they were used flexibly by PATH and A.I.D. as a means of setting priorities and determining the most promising places to consider for inclusion among the project sites.

C. Application of criteria in Guatemala and Ghana

The team examined in detail the project experience for activities in Guatemala and Ghana. In both countries, some of the selection criteria were not satisfied. Significantly, there existed very little demand for ORS in Ghana and only moderate demand in Guatemala. The companies selected in each case were active and interested in ORS.

Guatemala did not qualify under the first guideline as ORS demand had not been demonstrated. However, there were indications that demand was being created or would be created because there were several commercial brands of ORS available in pharmacies. And through the HEALTHCOM Project, A.I.D. was committed to funding a large demand creation activity through the public sector. The government was indeed supportive of ORS, and the country also displayed sufficient levels of

technical capability in private sector pharmaceutical production. Finally, Guatemala also qualified under the final project criterion as it had been identified as an A.I.D. Child Survival priority country.

Demonstrated marketing capability was missing from the company selection guidelines. The team found that the Guatemala firm, ADAMED, did not demonstrate all the necessary marketing skills and experience to create the demand for their ORS product--particularly in the face of slowly developing national demand for the product. However, it is also evident that the marketing effort also lacked strong funding support. The firm was very enthusiastic and eager to succeed with LITROSAL but required additional training and experience base. During the first year of PATH's work with ADAMED and prior to beginning actual production of ORS, ADAMED lost several key people, particularly a marketing manager who had worked rather singlehandedly on the LITROSAL product plans. Even without that setback, the team concluded that the firm would require some assistance in developing marketing strategies and a complete marketing plan to help guide them into good product marketing of LITROSAL.

Ghana was selected although there were even fewer indications of sufficient ORS demand than in Guatemala. The government supported ORS as one of its major health needs, and PATH did find a necessary level of technical feasibility. However, the fourth guideline along with the first guideline was not met: Ghana is not an A.I.D. Child Survival priority country. As was discussed previously, A.I.D. officials at the time were persuaded that there were factors, such as the mandate to direct available resources toward African countries, that should be considered in the case of Ghana.

The selection of Ghana seems to have been made at least in part because there was a local firm, DANAFCO, who seemed fully capable and interested in the local production of ORS. DANAFCO had already been selected for the social marketing of contraceptive products by an A.I.D. contract, Social Marketing for Change (SOMARC), through The Futures Group. DANAFCO had not yet demonstrated their ability to market contraceptives at the time of their selection by PATH, but it is understandable that PATH was persuaded by the assumption. Six years earlier (1980), DANAFCO had served as distributor for contraceptives while a local advertising agency created a large and well-funded promotional campaign for the Ghana Contraceptive Retail Sales (CRS) Project. Some implementation problems might have been avoided if the technical assistance base in developing social marketing programs had been stronger, or, perhaps, if PATH had followed its selection guidelines and chosen a country with established demand for ORS.

Based on the evaluation team's experience in visiting the two countries, additional company selection guidelines may be needed in marketing and GMP. With marketing, either the production firm or a separate firm should have demonstrated ability to successfully plan, develop, and implement a marketing strategy and campaign for new products such as ORS. In Ghana, and to a lesser degree in Guatemala, the PATH assessment gave the two firms high ratings for their extensive distribution and wholesaling networks. The team concluded that the

existence of such channels was not, in itself, a substitute for an adequate marketing capability. With quality control and GMP, the country and firm must have the infrastructure to produce quality drugs in compliance with GMP. Selection teams for SUPPORT projects should include technical experts to assess the marketing and GMP capabilities available in the country and firm.

VI. PRODUCTION OF ORAL REHYDRATION SALTS

A. Objectives

The primary goal of the cooperative agreement to PATH was to increase the availability and accessibility of ORS in order to reduce infant mortality and morbidity due to diarrheal dehydration. The objectives of Project SUPPORT in the area of local production of ORS as provided in the cooperative agreement were as follows:

- o Reach agreement with private companies in at least four developing countries to manufacture and/or distribute ORS;
- o Develop series of guidelines for local production of ORS through private sector companies and revise them over the life of the project;
- o Provide technical assistance and other support so that new or expanded production facilities are operating in at least two countries and at least the final stages of preparation in two other countries.
- o Provide exact formula either WHO bicarbonate or WHO citrate and characteristics of the formulation in terms for example, its flow properties in terms of packaging.
- o Provide specifications for quality assurance and procedures and equipment.
- o Desirable factory layout, assistance in upgrading existing facilities and specifications for air conditioning and humidity control [to comply with GMP].
- o Advise on options for procurement of raw materials.
- o Advise on packaging requirements.
- o Provide information sources, prices, and availability of machinery and quality control equipment.
- o Once production was started, provide technical assistance as appropriate to any problem areas.
- o By the end of three years, at least two individuals will have been trained who could provide assistance in local ORS production.

In the remainder of this chapter, the evaluation team presents its findings on ORS production, quality control, and technical assistance.

B. General Findings

To date, PATH has accomplished most of their objectives and, in most cases, have surpassed them. This is a commendable achievement in as much as PATH worked in two continents with differing cultures, unpredictable levels of knowledge, technical abilities, and limitations of work force; unanticipated complications in communications, difficulties with the suppliers, shipment inspection delays, customs clearance delays, shipping errors and machine operation difficulties.

PATH has successfully reached agreement for production with private companies in several developing countries. PATH has been working at various levels of project assistance in different countries. Their assistance is most extensive with the projects in Ghana, Guatemala, Paraguay, Peru, Turkey, and Uganda.

PATH has successfully initiated production of ORS in Turkey, Ghana, and Guatemala and is scheduled to initiate production in Paraguay and Peru. In Ghana, PATH selected DANAFCO, an established pharmaceutical manufacturer with 3,000 distribution centers and in Guatemala, PATH selected ADAMED Laboratories, a young but aggressive pharmaceutical company to produce and distribute ORS.

C. Ghana and Guatemala Production Activities

The evaluation team visited the ORS production facilities in Guatemala and Ghana, where the most extensive involvement by PATH was provided under Project SUPPORT. In both of those sites PATH has developed and prepared:

1. Manufacturing plans for ORS production; and
2. Quality control procedures for manufacture of ORS;

The evaluation team noted that the Manufacturing Plan document developed by PATH for Ghana in August 1987 and for Guatemala in June 1987 now need several changes. The document for Ghana is not consistent with current production.

The WHO citrate formula has been chosen for all sites by PATH. The WHO formula (27.9 grams/liter) packaged in foil-laminate package was chosen for production in Guatemala, and the WHO formula modified to a reduced size (16.74 grams/600 ml) packaged in polyethylene was selected for production in Ghana.

PATH extensively used the WHO manual (WHO/CDD/SER/85.8) entitled "Oral Rehydration Salts: Planning, Establishment and Operation of Production Facilities," in preparation of its production planning manual for Ghana and Guatemala. The facilities were modified and climatized and renovated at ADAMED, as well as DANAFCO, to comply with Good Manufacturing Practices. Quality control laboratories were established to perform testing on raw materials, in-process tests and testing of finished dosage form.

PATH ordered various equipment for quality assurance laboratories, as suggested in WHO/CDD/SER/85.8). Manufacturing and filling equipment has been procured and installed. Drum hoop mixers of 200 liters capacity were selected for both facilities, and provisions were made to procure a dryer, platform scales, and screening machine. All manufacturing equipment was procured to make about 100-120 kg batches (approximately 4000 packets of 27.9 grams/liter). This capacity would be adequate to produce 1.5 million to 2 million packets per year.

Filling equipment is semi-automatic for Ghana and automatic for Guatemala; equipment was selected in-country to seal the two different types of packages in Ghana and Guatemala.

Raw materials procured to date in Guatemala are of U.S. Pharmacopeia (U.S.P.) medium granular or fine crystalline grade. Raw materials for Ghana were supplied by UNICEF under special agreement, which are British Pharmacopeia (B.P.) grade. The WHO manual approves the use of materials conforming to specifications of either B.P., U.S.P., Food Standard (F.C.C.), or International Pharmacopoeia (I.P.).

Packaging components were selected by PATH with careful consideration for economic factors facing each country. The WHO manual provides specifications for foil-laminate as well as polyethylene. According to the WHO manual, the specifications are:

<u>Polyethylene bag:</u>	Gauge of Low Density Polyethylene (PE)
Inner bag containing ingredients	minimum 0.04 mm
Outer bag holding label	minimum 0.05 mm
<u>Laminated Aluminum Foil</u>	
Polyethylene PE (inside)	minimum 0.04-0.05 mm or 36.9-46.1 g/ml
Aluminum (ALU)	0.009-0.015 mm or 24.3-40.5 g/ml
Polyester (P)	0.012-0.015 mm or 12.9-20.9/ml

It is not known if the packaging components used in Guatemala and Ghana conform to the these specifications. The Production Planning Manual fails to provide either specifications or methods for testing these types of packaging components used in Ghana or Guatemala.

In selecting filling machines, PATH did not prepare adequately for the problems of ORS manufacturing or other related operations, or quantities produced in Guatemala. The filling machines in Ghana as well as Guatemala have serious problems. In Guatemala, a locally assembled automatic filler from M. Astequida was chosen. The machine is too tall for ADAMED facilities, was not made of proper quality of steel, cannot vacuum fill, and cannot print lot number and expiration date on foil-laminated packages. Secondly, to produce 2 million packets a year the semi-automatic filler would have been adequate. The current filler is under-utilized, thereby adversely affecting the cost of the final product.

In Ghana, the filling machine from ALL-FILL vibrates once the hopper is only 10-20% full. This is a potentially serious problem and should be resolved immediately. DANAFCO claims to have informed PATH of these problems by letter and telex, copies of which were presented to the evaluation team. PATH officials notified the team that they were unable to find records of having ever received copies of these communiques. The team acknowledges that difficulties of initial start-up of a machine are common in the transfer of technology. Careful and frequent observations by the technical assistance specialists are critically important during the first year of production to solve such problems.

Some of the equipment selected was high speed automated, but other pieces are manual and slow, such as: the torsion balance, stapling of outer package (printed match book type cover) in Guatemala. Equipment in the analytical laboratory is also only suited for semi-automated equipment. This makes coordination of the various operations difficult with several bottlenecks in the entire production operation.

D. Quality Control

PATH has attempted to establish an independent quality assurance program at DANAFCO and ADAMED with technically qualified staff in the respective quality assurance departments. Quality control procedures for the manufacture of ORS developed by PATH has two sections:

- o Quality control procedures used in testing of chemical raw materials, in-process tests, and finished product tests. These test procedures are adapted from:
 1. WHO guidelines, WHO/CDD/SER/85.8;
 2. United States Pharmacopoeia;
 3. Association of Official Analytical Chemists; and
 4. Analytical Procedures
- o Good Manufacturing Practices is based on guidelines of U.S. Food and Drug Administration, which are legally binding for all manufacturers of pharmaceuticals in the U.S.⁸ (see Chapter 3 for a background discussion of GMP).

The quality control manual is well written but does not distinguish the fact that the two products in Guatemala and Ghana are in different size packets. (Guatemala 27.9 grams/liter and Ghana 16.74 grams/600 ml).

PATH has developed a program calling for three-phase approach to ensuring the quality of locally produced ORS. The program consists of:

⁸ U.S. Food and Drug Administration. Good Manufacturing Practices. Federal Register, vol. 190, September 1978. Also found in: Code of Federal Regulations, 1988, Sections 210-211.

- o In-house testing by the local firm for ORS produced by said firm;
- o Testing of the locally produced ORS by an independent laboratory based in the project country; and
- o Testing of locally produced ORS by PATH or independent laboratory in U.S.

In spite of well-written documents, the implementation of quality assurance and GMP needs improvement. In Ghana as well as Guatemala the execution of quality assurance is not consistent with the written guidance provided by PATH. This suggests the need for additional follow-up by PATH to ensure compliance with the established guidelines.

Some examples observed by the team of these inconsistencies were:

1. Validation of the mixing operation at ADAMED involved analyzing only chloride ions though the manual suggests testing for all ions and glucose.
2. ADAMED tests only five (5) packets of finished ORS when determining whether to accept or reject a batch. The PATH quality assurance manual does not specify the number of samples to be tested.
3. Processes of filling and sealing have not been validated at either DANAFCO or ADAMED; though DANAFCO has already produced 153 batches and ADAMED has produced 30 batches of ORS.
4. The batch record form does not provide manufacturing directions, e.g., order of addition of ingredients, or guidelines on what to do if the batch does not conform to in-process specifications.
5. Neither of the two manufacturers of ORS uses "geometrical mixing," which is the preferred way to mix powders and is recommended by Dr. Jensen⁹ and WHO guidelines.
6. DANAFCO has not developed inventory numbers for raw materials used in the production of ORS.
7. The PATH Manual specifies humidity and temperature in filling area, but there is no instrument to monitor humidity even after six months of production.
8. Though the manual recommends GMP training, the people interviewed by the evaluation team in quality control and production seemed unfamiliar with certain precepts of GMP, suggesting they had not received such training.

⁹ Erik H. Jensen. Quality Assurance of Oral Rehydration Salts. Seattle: Program for Appropriate Technology in Health, 1988.

9. Certificates of analysis from some vendors give only specification and not the test results, even though the manual recommends to obtain certificates of analysis with test results.

Additionally, the quality control manual developed by PATH for use by these firms does not include:

(1) Specifications and test methods for packaging components, either primary package, secondary package or tertiary package for DANAFCO. DANAFCO accepts packaging components unless a visible defect is observed. This is their only test.

(2) Sampling plan for raw materials is not based on statistical considerations;

(3) Standard operating procedure for cleaning the manufacturing equipment and facilities.

E. Technical Assistance

Based on observations made during the evaluation team's visit to the manufacturing facilities, it is apparent that technical staff at PATH need to increase its attention to details and specifics, as noted in the previous sections of this chapter. PATH, as possibly others in this field, appears to have underestimated the difficulty of GMP monitoring and the level of assistance necessary, including initial training of staff, establishment of documentation, and being constantly responsive and sensitive to the needs of DANAFCO and ADAMED.

The Project SUPPORT firms may, in some ways, be burdened with a requirement to perform better work than are other firms in their countries. On a worldwide basis, firms in the pharmaceutical industry must consider many factors when determining how they will go about quality assurance and quality control (QA/QC). The QA/QC function can be expensive, and its cost must be borne by revenues from its product sales operations. Factors such as: licensing agreements to make drugs developed by other firms, local food and drug regulations, and requirements of major purchasers may induce firms to adhere to QA/QC standards. For Project SUPPORT participants, the funding agency, A.I.D., also has an interest in ensuring that QA/QC standards are being met and that A.I.D.'s reputation will not be affected negatively by poor quality ORS production.

Deficiencies on which numerous recommendations are made (see Chapter XIV of this report) indicate a need for more qualified technical expertise in the area of pharmaceutical production and quality assurance. The evaluation team is concerned that in the area of pharmaceutical production and quality assurance, technical staff of PATH may not possess enough education, experience, and expertise to be responsible for transfer of ORS production technology. It is unlikely that this lack of senior-level specialists can be remedied by PATH under Project SUPPORT without an A.I.D. waiver permitting payment of higher level salaries or fees in this area of expertise. These

observations are made after reviewing curriculum vitae and work experience, and personal interviews with PATH staff.

VII. MARKETING OF ORAL REHYDRATION SALTS

A. Objectives

A primary purpose of Project SUPPORT is to increase availability and accessibility of oral rehydration salts (ORS) in order to reduce the mortality of children. The Project Agreement includes the following section on Distribution and Marketing:

The Recipient shall plan and provide, as necessary, assistance for distribution and marketing. It is expected that extensive coordination will take place at this stage with PRITECH, the Mass Media and Health Practices (MM&HP) [later called HEALTHCOM] and the SOMARC projects. MM&HP will be launching new activities in five countries and could potentially assume responsibility for such communication efforts.

The major components of market development efforts shall cover such items as package design, instructional and promotional material development, and mass media campaign planning. Use of focus group discussions and in-depth interviews shall be incorporated as appropriate.¹⁰

A.I.D. included a background statement for the Scope of Work in Amendment 2 which included the following section on marketing:

Finally, we have learned the importance of marketing and promotion in private sector work. Increasing the availability of ORS is difficult, but making the product available at prices affordable to those most in need as well as presenting the product in an easily understood manner are very difficult exercises. Marketing through the private sector must be defined and resolved in the context of national program activities before production can be launched. Critical issues such as pricing, appropriate container size, effective distribution channels and consistency with national ORT program goals must be explored fully before a program can be initiated. The project plays a challenging and critical role in making the private sector companies conscious of the need to define promotional activities within the broader scope of the National ORT program.¹¹

¹⁰Agency for International Development. Cooperative Agreement with the Program for Appropriate Technology in Health. Washington, D.C., Agency for International Development, August 1986, Attachment 2, p. 11.

¹¹ Agency for International Development. Amendment 2 to Cooperative Agreement with Program for Appropriate Technology in Health. Washington, D.C., Agency for International Development, 1987.

The evaluation team used the original Cooperative Agreement and its amendment as the terms of reference and developed data through examination of documents and interviewing project participants in Washington, D.C.; Seattle, Washington; Guatemala City, Guatemala; and Accra, Ghana. These activities and subsequent analysis of the design and all other available information formed the basis for judging PATH's marketing efforts to date. Marketing design, marketing plans, actual marketing operations and activities, program coordination, sustainability, and technical assistance performance comprised major segments of the marketing evaluation.

The background and environment for Project SUPPORT within the Agency for International Development merits some review in order to gain perspective on the project design. The AID/W Office of Health had limited previous marketing or social marketing experience with private firms on which to draw for the design of the marketing portion of the SUPPORT agreement. The A.I.D. Office of Private Enterprise (PRE), which initially co-managed Project SUPPORT, was to contribute its private sector experience; though their experience in the health field was limited. The Mass Media and Health Practices Project was in place and the new health communications project, HEALTHCOM, was in operation, but these projects had worked largely with government-run health education units in ministries of health. The AID/W Office of Population had developed social marketing programs since the early 1970's and there was some discussion between the two offices regarding the role of social marketing. Nonetheless, the SUPPORT Project Agreement Scope of Work and Terms of Reference lack explicit guidance and requirements as to the need and schedule for important marketing components such as marketing plan, selection criteria, target population market segmentation, marketing research, package, price, promotion, and other marketing elements for the private company. The companies would be expected to carry-out these functions through their own marketing programs.

The Project Agreement, as shown in the excerpt above, also called for PATH to coordinate the needs for distribution and marketing with other AID/W centrally-funded programs. PATH was encouraged to coordinate closely with the HEALTHCOM contractor group. The evaluation team contacted and met with representatives of PATH, AID/W, the USAID Missions, PRITECH, HEALTHCOM, and SOMARC during the course of this evaluation; and found that PATH had communicated with and tried to coordinate its activities with these groups.

Assumptions were made by A.I.D. as to the appropriate degree of assistance to provide local private firms in the area of marketing, based on experience in projects focused on small and medium-size business enterprise development. The philosophy taken by A.I.D. was that they should not provide too much assistance so that companies would become dependent on A.I.D. The project was seen as a catalyst to get companies to mobilize their resources and expertise, so the effort could be better managed and also sustainable. To some extent, this assumption may not have been clearly explained to the local companies, or, these companies may not have had sufficient awareness of what technical assistance they needed.

B. Marketing Planning

The evaluation team believes that marketing must be a part of an integrated set of country and company selection criteria conducted in Project SUPPORT. A marketing strategy and subsequently a marketing plan need to be developed with the selected ORS firm early in the development process, when country selection and company selection have been confirmed. Marketing segmentation and target population are essential steps in creating the marketing strategy and plan. The ORS product to be produced by the local company has to be targeted to a particular segment of the entire population, including sex, marital status, age group, socioeconomic group, and a few more specific characteristics. The product's package, price, promotion, and distribution should be developed to appeal to that special group, the target population. The economic concept of stratification of population is useful in this type of analysis. For purposes of discussion, the target population could be defined as mothers of child-bearing age, in socioeconomic groups C or D (on a hypothetical scale where A is the wealthiest and E is the poorest).

An additional factor that must be considered by ORS producing companies is the seasonality of diarrhea incidence and the demand for ORS. Rainfall patterns and other environmental factors produce significant swings up and down in ORS usage. Producers of ORS must also consider these patterns as they plan manufacturing and marketing of the product.

PATH conducted an assessment of marketing capability as part of the company selection process. In some cases, firms were rejected from consideration based on marked deficiencies in marketing. For the firms selected to join the project, there needed to be prepared, from the start, a marketing approach, which included both strategies and plans. It appears to the team that PATH did not develop a marketing strategy and a marketing plan with the selected local companies. Within these, the Guatemala and Ghana projects did not clearly define their target populations.

In Guatemala, there was no marketing plan in use at the time of the team's visit and the company, ADAMED, was uncertain about their target population for their ORS product, LITROSAL. ADAMED is very enthusiastic and eager to succeed, but needs marketing technical assistance to help develop and implement marketing elements for their product. The team was informed by PATH that a marketing plan would soon be provided to ADAMED, but it would arrive a long time after project launch.

In Ghana, DANAFCO has been developing increased marketing knowledge and experience. The Ghana Social Marketing Program (GSMP) Program Coordinator attended a consumer marketing course in Boston recently. However, the program has evolved away from the basic marketing principles and does not follow the same pattern as the GSMP. The local manufacturer in the private sector, DANAFCO, is producing ORS for both the public as well as private sectors. This could be a very

economic and efficient production model. However, the government and DANAFCO are selling exactly the same product, in the same package, at the same price to their respective distribution systems, and neither is using a strong promotional campaign.

The reasons behind the establishment of the common product and marketing approach are rather complex. PATH provided advice and assistance to DANAFCO aimed at preparing the firm to do its own, independent marketing effort. A decision was made unilaterally by the Ministry of Health that forced DANAFCO to make its product and marketing approach identical to the government's. This move by the government is recognized by the team as being an example of one of the realities of working in coordination with governmental programs.

The Ghana Ministry of Health has approximately 600 outlets whose clientele might represent a portion of hypothetical socioeconomic group E in rural areas and groups C, D, and E in urban areas. DANAFCO has approximately 3,700 outlets, pharmacies and chemical sellers whose customers most probably represent socioeconomic classes A, B, C, and D in urban areas and large proportions of all rural groups. The positive effect of using the same product everywhere is that all people are being exposed to the same oral rehydration therapy (ORT) concept and ORS packets that are easily recognizable. During the stage of ORT awareness-building, the single national product can give users confidence that they can get good rehydration results whether they use the public or commercial suppliers. The population is treated as one mass and there is no provision for differentiating products, packages, prices, or promotional appeals to the different segments of the population. The negative effect of the single national product lies in the restrictions placed on the potential of commercial marketing processes: brand names, package, promotions, and distribution channels each of which may be oriented to certain segments of the target population. DANAFCO might, in the future, continue to support the ORS product and add a commercially branded ORS product using the normal private sector marketing strategies and elements.

The Government of Ghana and USAID/Ghana are committed to a successful ORT program and to promoting ORS. It is probably their joint agreement and commitment which has led to the present shared marketing arrangements. However, a private and public sector agreement might perform better for both to allow each to distribute, promote, and market in their own most natural ways. A example is found in the existing agreement for the Ghana Social Marketing Program within the Ghana Contraceptive Supplies Project where DANAFCO markets certain product brands and the government distributes their own products.

C. Marketing Accomplishments

There are marketing accomplishments in both of these countries. Guatemala's ADAMED company lost its marketing manager in June 1988 and the management responded quickly to appoint a new person who is enthusiastic and capable in handling many of the duties vacated by his predecessor. Medical promoters have been trained and a series of promotional materials have been developed for LITROSAL. Some

collaborative technical assistance to help develop an overall marketing strategy, an annual marketing plan, and general marketing and program coordination for good relations with the Ministry of Health, HEALTHCOM, and the USAID/Guatemala Mission would still be beneficial. ADAMED seems enthusiastic, eager, and capable of developing and managing an excellent ORS program.

In Ghana, DANAFCO's marketing program coordinator and management team are working in an extremely difficult environment. The economy is slowly emerging from a period of severe stagnation and weakness but remains in the "intensive care" stage. Tight government regulations on import, exports, and currency exchange have been loosening. The greatest care must be exercised by DANAFCO in managing its resources. Governmental directives on raising salaries and other unforeseen costs have caused serious business problems in pricing and profit/loss conditions. During this period, DANAFCO managers are showing great resolve and resourcefulness and are working hard in their distribution and sales of ORS. They are coordinating promotional activities with the Health Education Division (HED) of the Ministry of Health and preparing for retailer training activities with the subcontractor, Pharmahealth Center, Ltd., scheduled to begin in November 1988. DANAFCO is doing a good job at marketing ORS with the resources that are available. With the recommended addition of experienced technical assistance in social marketing, plus an increased promotional budget, the Ghana ORS program may recover from a slow start and develop into a successful and sustainable program. In view of DANAFCO's present condition, including a large overstock of ORS product, both of these needs (funding and technical assistance in marketing) are urgent.

At the time of the evaluation team visit, only a few months of sales had been completed. The early sales figures can provide only a rough idea of the eventual sales levels and cannot be used for definitive judgments about the causes of positive or negative sales trends. In Ghana, current stocks number 520,000 packets, while average monthly sales reach only 25,000 packets. The imbalance is not quite as great in Guatemala, where stocks are about 60,000 packets and sales have totaled 72,000, but average monthly sales are only about 11,000 sachets and the sales pattern is flat, at best. Both countries require experienced marketing consultancies, effective marketing and promotional campaigns, and a larger budget to provide for the new designs and assistance.

D. Basic Marketing Elements

1. General Concepts

Basic marketing principles include five key elements, among others: product, package, price, place, and promotion. In the discussion that follows, the evaluation team's findings are presented in terms of these elements for the SUPPORT field activities in Ghana and Guatemala, respectively.

2. Ghana

a. Product and Package

DANAFCO produces and packages one common product and uses one brand name, ORS, for both the Ministry of Health and DANAFCO. Earlier, in 1987, a series of brand names were created and tested by the marketing research group of a local advertising agency. However, after the brand names testing was completed, all candidate names were dropped and the name, ORS, was adopted without further testing. The Ministry of Health, (MOH), seems to have played a major role in the areas of the brand name and package. Earlier, DANAFCO's package was blue and white with red letters with ORS at the top. MOH officials explained to the evaluation team that they insisted that DANAFCO produce the MOH package in the same way, as people might find the red-lettered ORS packet more attractive and therefore not buy the MOH ORS product. In this way, both packets became virtually identical in contents, package design, and colors.

b. Pricing

Pricing to the public for the ORS product is set at 25 Cedis, (with US \$1.00 equalling 294 Cedis in October 1988). When DANAFCO set their original price, this structure provided a margin to DANAFCO of about two (2) Cedis. However, government-driven salary increases and other unpredictable factors, have driven total costs to around 46 Cedis. If this figure is correct, DANAFCO loses 21 Cedis with each ORS packet sale. DANAFCO believes that a price increase would be a dangerous strategy since there is no demand for the ORS product yet and plans to submit a request for a price increase to the Ghana Price and Income Board (PIB) after new promotional activities create greater public demand (by Spring 1989, DANAFCO officials hope).

The original price for the product was not tested in any areas of Ghana. Price testing requires several months of controlled distribution where different prices may be tested in different locations. The pressure to "launch" the product frequently forces brand or product managers to omit the price-testing step; the omission, however, can cost time, money, and effort later if the untested price is identified as a possible culprit in poor consumer sales or low-return for product sales. It is not known by the team just what latitude DANAFCO would have from PIB to conduct pricing tests.

The decision to use the same product and the same package almost guaranteed that both DANAFCO and MOH products would be sold at the same price. This element becomes the first real financial deficit for the program as DANAFCO is presently locked into a price which, according to their calculations, causes a loss to the company. Some elements of the present loss situation, however, are related to unpredictable government policy changes and other factors outside the separate product issue. Nevertheless, instead of having a profit as a sustaining force for Project SUPPORT, the inability of DANAFCO to market its own product in its own package to its own target population

at its own price now looms as a threat to the Project SUPPORT sustainability in Ghana.

The team concluded that neither A.I.D. nor DANAFCO could have predicted or exercised control over the direction taken by government officials in making policies about the ORS product and its pricing. Assessments made by PATH at the outset were intended to select a firm which met criteria indicating promise for success in implementation of local production. Factors outside the basic selection criteria, such as these government actions discussed here, can and did intervene to change the direction of the intended technical steps.

c. Place

DANAFCO's distribution system includes access to distribution centers in the country's ten regions. The target audience of DANAFCO's commercial distribution system is comprised of most of the country's population with cash (the hypothetical socioeconomic groups A, B, C and D) through a national network on 3,000 chemical sellers and 700 pharmacies.

The MOH claims to reach its clients through 600 health outlets. It is believed by the team that the MOH outlets reach some of the urban part of socioeconomic group E. The team did not find data assessing the overlap in population groups of the two provider channels. The fact that MOH and DANAFCO appear to have different clientele is a positive factor in reaching more segments of the population. To the extent that the same product is marketed to both, there may be greater recognizability and opportunity to create consistent widespread messages about instructions for how to safely use the product. On the other hand, the lack of product differentiation and targeting the product, package, price, and promotion to the different audiences probably represent a missed opportunity to motivate more people to buy and use the product.

d. Promotion

In Ghana, the promotional approach shared between the government's Health Education Division (HED) and DANAFCO's advertising seems to be coordinated in a fashion but is not entirely coordinated in an agreed message and media plan. At present, HED is handling all mass media, although their messages are all generic messages which do not promote the purchase of the ORS packages. More importantly, the overall funding seems far too insufficient even if there were an excellent, well-coordinated communication and promotion plan.

DANAFCO's promotional efforts have been placed mostly in print media. Since September 1988, these have been stopped altogether by the country's Pharmacy Board, which suddenly demanded review of DANAFCO's ORS advertising. Even before the September interruption, DANAFCO's budget and campaign seemed to be quite limited (a total of the equivalent of US\$30,000, including training). The overall concern now is that the promotion for the ORS product is not sufficient, in quantity or impact and must be increased to create demand as huge

overstocks are being held in DANAFCO's warehouse. At the time of the team's visit, DANAFCO's Managing Director indicated he would probably have to reduce ORS production rates in December 1988 because of the situation.

3. Guatemala

a. Product and Package

LITROSAL is the brand name selected for ADAMED's ORS product. The Ministry of Health (MOH) has selected a brand name of SUPERSUERO for its product, which is supposed to be produced by its university-based parastatal firm, LAPROMED. There have been prolonged delays in the government's production unit. The target population for LITROSAL was not clearly stated in the documentation from the team's meetings with PATH or ADAMED although it was the impression of the evaluation team that the government's product was intended for people in lower socioeconomic groups than the ADAMED LITROSAL product.

Development of the LITROSAL package could not be reviewed by the team as the former marketing manager's records were not available. The package consists of an inner foil and a cardboard outer cover. In the commercial market, ten other ORS products were found: five liquids in bottle form and five other packets or envelopes. Four of the six (including LITROSAL) powder form products were colored in bright red or orange. LITROSAL's packet is produced in a more subdued blue and white design. Additional market research on package styles and colors with additional pretesting of these package elements might have produced a different, more attractive package. ADAMED's personnel indicated they would like to be able to redesign the LITROSAL pack. ADAMED indicated that they were interested also in selling ORS to the Ministry of Health during the interim period when LAPROMED was not yet capable of producing the SUPERSUERO ORS product. During the October visit, USAID/Guatemala indicated that such interim sales may, in fact, be possible. In December, USAID/Guatemala indicated that such sales from ADAMED to the MOH were very unlikely.

b. Pricing

LITROSAL is sold by ADAMED to pharmacies at 48 centavos and the consumers then pay the retail price of 60 centavos per package. A brief survey of prices by the evaluation team showed that LITROSAL is one of the least expensive of the six powder-form products available in pharmacies. Based on price and other economic factors, it would appear that ADAMED was targeting the hypothetical socioeconomic group D. There is no reason why a broader and higher socioeconomic group, including C and even B, might not be targeted. The issues in this matter: first, to decide the target audience for the product (or, alternatively to select a target audience and create the product and elements accordingly); second, to position the product (package, brand name, color, size, shape, price, and promotion), among the competition to match the target population, and third, to test two or three prices in test markets for several months to discover the elasticity of the

test prices. With that information, a more confident and informal pricing decision can be made.

ADAMED's interest in selling its ORS product to the Ministry of Health may have been the reason for its LITROSAL pricing structure. The problem is that ADAMED provided its cost elements, which reveal that average cost for one LITROSAL pack is 62 centavos--a loss of 14 centavos for each sale to pharmacies. If the costing elements are true where ADAMED incurs such a loss, the sustainability of Project SUPPORT in Guatemala is threatened. The team suggested that ADAMED develop two different products with different pricing structures for the two markets: government and commercial.

c. Place

ADAMED has a good distribution system of pharmacies, including 558 in Guatemala City and 476 in the interior, where LITROSAL had reached as of September 30, 1988. Sales through September 1988 to those outlets (distribution pipeline and sales) totalled 72,825 packets of LITROSAL. Total production since sales began in May 1988 was 130,000 packets. These early production and sales figures appear encouraging, but at the time of the team's visit it was as yet too early to determine the full meaning of these trends.

d. Promotion

The medical and health communities and the pharmacy sales personnel represent the country's basic provider system for ORS. The physicians, nurses, midwives, and pharmacists must be informed, instructed, and enlisted to support the ORS program. In the case of ADAMED, they must be persuaded that LITROSAL is a good ORS product to recommend to potential users. This public relations and training work is important in order to avoid conflict and potential jealousy within the provider group and also to engender the support and momentum needed to reach the target population.

ADAMED received assistance from the Nutrition Institute of Central America (INCAP), an international research and educational institution in Guatemala City, which conducted an investigation about the feasibility and kinds of pharmacy training that might be held. Their finding was that training of pharmacy sales personnel was not feasible without a very large budget since the capital city itself had over 500 pharmacies and the task of coordinating the training would be complex and expensive. As an alternative, INCAP assisted ADAMED by providing training to the company's medical detailers who, in turn, were instructed to train pharmacy sales personnel on LITROSAL. A physician's conference was held at the time of product launch, which served, to some extent, as a public relations activity to promote support for ORS and LITROSAL in the medical community.

Both the training and the conference are commendable activities which help to promote the ORS concept and the LITROSAL product. The evaluation team believes that more funding and greater efforts be invested productively in actual training and promotional meetings with

pharmacy sales personnel in order to convince them to actively recommend the product to the customers. The ORS training and promotional meetings can also serve the pharmacy by including training on sales and marketing techniques so that pharmacy salespersons may improve their skills and that the pharmacy owner is motivated to allow time off for the salespersons' training. Certificates of recognition for participants and one for the pharmacy will help to commemorate and solidify the experience. A special venue with refreshments or snacks provided can further promote goodwill and associates with the LITROSAL product. An additional campaign to reach health and medical personnel will also add supporting insurance to the sound foundation of ORS and LITROSAL.

Demand for ORS in any form, including the ORS products sold through commercial outlets, are subject to seasonal fluctuations. The patterns of rainfall and related environmental effects cause a diarrhea season in each country during which the use of ORS should be expected to rise. The public demand for LITROSAL at the time of the team's visit, as reflected in the sales figures for May through September 1988, were too new and short to discern a pattern of growth.

The ORS demand situation is assessed that although a great deal has been accomplished, the public needs more of everything: information, education, and motivation. The assessment, design, production, and delivery of a motivating campaign will require technical assistance in information-education-communication (IEC) and brand advertising, plus sufficient promotional funding to support these efforts.

The total national cost of developing a successful ORT program can be very high. The team concluded that a serious reexamination may be needed by A.I.D. and PATH in Guatemala to consider several issues: (a) to what extent is it the role of the private sector to launch a national public education effort?; (b) should private firms involved in ORS production concentrate only on pharmacies and private physicians or should they address other marketing areas?; and (c) what is a reasonable promotional budget which a commercial firm should be expected to invest for the development of public education and demand for ORS?

VIII. FINANCE AND BUSINESS

A. Capital Investment

1. Capital Funding Criteria

The start-up investments in oral rehydration salts (ORS) production and promotion include feasibility studies, preparation of physical plant, purchase of equipment and raw materials, training of workers, and marketing activities. The cooperative agreement for Project SUPPORT provided for use of loans and grants to be made available to ORS producers for start-up purposes. The loan program is available for production equipment, quality control instruments, and raw materials. Grants are available also for use with marketing-related costs in situations where the feasibility study and business plans indicate that such outside funds are needed by the producer. Businesses are experienced with loans and usually not with grants. The underlying rationale for providing loans to producers builds on their experience with credit instruments in their day-to-day work.

The design of loan packages for Project SUPPORT aims to ensure that certain criteria are met. As stated by PATH, the loan arrangement in a Project SUPPORT field activity should meet the following criteria:

- o The total loan amount and repayment terms are linked to projected sales volume;
- o Disbursements coincide with the purchase of approved equipment;
- o The borrower is able to negotiate credit terms with a party who understands the social as well as the commercial objectives; and
- o Repayments are designed to promote and sustain existing activities and/or to launch new projects in a developing country.¹²

The evaluation team found these criteria to be reasonable for purposes of meeting Project SUPPORT needs for capital investment funds. Collecting data required to decide on approving a given loan appears in many circumstances to have involved a great deal of creativity. In its role as financier, PATH takes a considerable responsibility for investigating the background and present situation surrounding a given loan application. The data collected by PATH field assessment teams in the Project SUPPORT cases examined by the team were well documented but contained many gaps and estimated figures. Risks appeared to be high

¹² Program for Appropriate Technology in Health. Project SUPPORT Loan Program. Seattle: PATH, August 1988, p. 3.

that in some cases that the underlying circumstances affecting a potential ORS producer and its credit worthiness could turn unfavorable rather quickly. This comment is not intended as a negative reflection on any particular case examined by the team but rather to suggest that in a developing country setting the above-stated criteria cannot fully be investigated and risks can only partially be evaluated.

2. Loan Mechanisms

PATH selected three types of loan mechanisms for use in Project SUPPORT. They decided on the three based on previous experience under other private sector technology transfer projects. The three basic types of loan mechanisms are as follows:¹³

- o Loan Incentive.--This is lending at below-market terms. Usually, this mechanism uses a buy-down of interest rates to level that the firm agrees to participate in the project. The Turkey loan program used this arrangement.
- o Loan Guarantee.--This is a loan made by a local bank to the producer where PATH guarantees the credit risk of the producer to the local bank. The local bank provides the funds and administers the loan. If there is default, PATH would provide funds to the local bank to offset the loss. A stand-by letter of credit (SBLC) is issued by PATH's U.S. bank to a correspondent bank making the loan. The Guatemala loan program used this arrangement.
- o Direct Loan.--This provides loan funds in the host country. The loan funds may be used for imported equipment purchases or may be converted to local currency for promotional programs. This mechanism carries the highest risk of the three used by PATH. The direct loan mechanism permits the project to operate in countries where the economy is all but closed to any financing. The project loan program provided direct loans to the firms in Ghana and Guatemala.

The repayment process for these loans was beginning at the time of the evaluation in October 1988. No real data were yet available to the team concerning the loan repayment prospects.

3. Loan Corpus

A.I.D. provided the loan corpus used for Project SUPPORT capital investments. This loan program was reviewed and approved by A.I.D.'s Offices of PRE, S + T/H, and SER/OP at its inception. It is maintained in a separate, interest-bearing bank account in PATH's name. The loan corpus can be used to provide funds for any of the different types of loan mechanisms. Repayments can be used for additional loans for production or for promotional programs. In cases where repayments are

¹³ Ibid., pp. 11-16.

not in U.S. dollars, the funds are to be recycled as determined by A.I.D. and PATH.

The loan corpus is administered by a loan officer employed in the PATH Comptroller's Office. Under an agreement with A.I.D., the interest proceeds of the loan corpus will be used to fund continued administration of the loan repayment activity after conclusion of the Project. The accounting and credit approval activities of the Project are separated from the staff members who are engaged in investigating the technical aspects of the deals. This separation of functions provides a positive check and balance in the loan-making process. It is noted, however, that loan officers assigned to the Project SUPPORT activities are not afforded the opportunity to visit project sites during their involvement with loan decisions and administration. No problems were detected by the team in having loan officers work only in Seattle to date. The evaluation team can imagine situations in the future where a loan officer might need to be on the spot overseas to properly assess the circumstances surrounding a proposed loan or loan amendment.

4. Guatemala and Ghana Loan Programs

The financing experience of Project SUPPORT was investigated by the team in Guatemala and Ghana. In both cases, the financing arrangement had successfully resulted in equipment to be provided for production and quality control. In Guatemala, the financing was used also to purchase the first year's raw materials for ORS. In both countries, PATH prepared with the producers business plans at the time of the assessment investigations. The business plans concluded that there were favorable prospects for production and marketing of ORS products in those countries. The evaluation team's visits to these sites came at about six months after product launch. Considerable difficulties were being experienced at that time in the joint arrangements by which host governments and local producers had agreed to share promotional activities and expenses. Both local producers expressed a concern to the evaluation team that their expectations for levels of product sales were not going to be realized. The viability of the loan programs in those two countries could be threatened if delays in the joint promotional activities continued over a long period of time. At this stage, it would be premature for the evaluation team to conclude that anything alarming is involved in the situation but rather to underscore the difficulty of the endeavors and the need for continuing vigilance (see also Chapter IX on project impact and sustainability).

The flexibility of the loan mechanisms has served the project well. The loan arrangements require somewhat longer to finalize than would be required to make direct grants. The benefits of the loan arrangements examined by the team appeared to outweigh the difficulties involved in preparing them. Jonathan A. Green evaluated the financing component of Project SUPPORT for A.I.D. in August 1987. His conclusions were that the financing approach used in SUPPORT was "useful and appropriate for an investment promotion program designed to stimulate private sector production and the sale of socially desirable

goods."¹⁴ The evaluation team concurs with Green's assessment. The loan program in Project SUPPORT represents a novel and effective arrangement for addressing difficult financing problems in the health sector. The continued success of this unique approach should be given consideration for its possible use in other USAID projects.

B. Product Costs and Business Plans

The product costs for ORS are somewhat difficult to analyze with data available from accounting records. Accounting practices and standards differ from country to country. Cost centers and other accounting systems used in some countries to identify the underlying cost of a product or a service are not usually available for a new product, if at all. The assignment of indirect costs varies even from firm to firm within the same city, making comparison of cost experience extremely complex.

Business plans for local ORS production prepared by PATH advisors contained estimated cost rates and levels of effort, based on available local and international sources. The plans examined by the evaluation team contained reasonable cost factors and calculation methods. The plans were prepared in each case against a backdrop of great uncertainty about changes in international markets, currency exchange rates, and host government policies affecting salaries, interest rates, and taxes and tariffs. The plans contain many of the elements of business planning documents usually associated with commercial ventures.

For example, the ORS Business Plan for Ghana contained the following sections in its analyses:¹⁵

- o Summary;
- o Background, containing a summary of the business situation in Ghana;
- o Organization, covering the structure and key personnel of DANAFCO;
- o Manufacturing Facilities, describing the firm's buildings and renovations required for ORS production;
- o Production Equipment, outlining the equipment required for ORS production;

¹⁴ Jonathan A. Green. Mid-Term Assessment of Project SUPPORT's Financing Component. Sewickley, Pennsylvania: Green International, Inc., August 1987, p. 13.

¹⁵ Program for Appropriate Technology in Health. A Business Plan for Manufacturing Oral Rehydration Salts at Danafco Mfg. Co. Seattle, Washington, PATH, 1986.

- o Quality Control, describing quality control practices at DANAFCO and outlining required new instruments;
- o Procurement of Raw Materials, describing the proposed arrangement with UNICEF participating in the importation of materials;
- o Preliminary Cost Projections, covering expected demand for ORS (which is stated without other documentation of its origin), and a cost projection based on the cost formula provided in the WHO ORS production handbook¹⁶, including: cost of raw materials and packaging, cost of fixed assets and depreciation, and fixed annual cost of personnel.
- o Actions Required, containing actions for: (a) raw materials, (b) loan/grant agreement, (c) product artwork, (d) quality control, and (e) drug registration; and
- o Annexes, including background information on the Ghanaian economy, a map, a table of organization for the firm, a floor plan drawing of proposed production equipment and layout, a letter from an accounting firm offering its services, and letters confirming prices for equipment required.

The business plan for Ghana emphasizes the manufacturing aspects of ORS production. The plan does not contain either financial analyses (that is, projections of income and expense over future time periods) or marketing analyses (such as assessment of market demand, product distribution, promotion, or pricing). Given the ever changing situation for any business venture in a place facing the economic upheaval of Ghana, it seems only prudent to consider several scenarios for the future of ORS products. The scenarios could take into consideration factors such as the following:

- o Production factors (including quality control, labor, and raw materials);
- o Financing factors (including overall financial situation of the firm, cash flow affecting the ORS product specifically over an adequate time horizon, and analyses of possible changes in factor costs due to outside influences such as delays or government policy changes); and
- o Marketing factors (including present and expected market demand, experience with oral rehydration therapy education and promotion, and promotional plans).

The evaluation team was unable to find documentation which presented the results of such analyses in the case of Ghana or Guatemala. In the

¹⁶ World Health Organization. Oral Rehydration Salts: Planning, Establishment, and Operation of Production Facilities. Geneva: World Health Organization, 1986. (WHO/CDD/SER/SER/85.8)

absence of such documentation, the risks and possible remedies for problems affecting the ventures there are unknown.

To its credit, the PATH assessment team gave considerable attention to finding solutions to the difficulty of projecting financial information. Cost projections were discussed in some detail in the Ghana business plan. The plan notes that costs for administration, contingencies, and profits were known to be difficult to document, based on experience with a previous USAID/Ghana project for distribution of contraceptives. The plan suggests that those cost elements would require sensitive negotiations with the local producer and proposes the hiring of outside accounting advisors to document the cost projections. The evaluation team was unable to determine if such accounting studies were conducted.

C. Product Pricing

Pricing of the ORS products must be considered and developed with regard to the sustainability of the program. Prices must include the costs of raw materials, indirect costs of administration, sales, and production, and finance costs. In addition, promotional costs must be included. In addition to these pricing elements, the consumer must be able and willing to pay the product price. Setting the price to the public is frequently done by deciding on a strategy to position the product in relation to other products already being sold in the market. In a case where the product is new and there are few or no other competitive products, and as a sound means to evaluate a pricing strategy, price testing may be employed. The product may be priced at two or more levels in separate geographical markets where all other marketing components are treated equally. Sales results after about two or three months can then be analyzed considering volume, profit margins, and special goals. Management can then finalize a pricing structure considering all available test results and known market factors.

Pricing levels established by Project SUPPORT companies in both Guatemala and Ghana present anomalous situations. In Guatemala, the pricing structure of ADAMED for the LITROSAL product to the commercial sector shows a loss of 14 centavos with each product sale. In Ghana, DANAFCO received an approval for its pricing of ORS from the Pricing and Income Board (PIB) at the beginning of the project. However, since then the government has imposed several obligations on private industries including mandatory pay raises and the net result is that the ORS price no longer covers DANAFCO's costs (they are incurring a loss). However, since the product is new and demand has not yet been created, DANAFCO does not feel it can raise the price without losing the market.

In the Guatemala case, ADAMED seems to accept the estimated 14 centavo loss per product sale in the interest of hoping to sell the product to the government; in addition, ADAMED has already stated that their interest in ORS is a social and national one and not exclusively for profit. Nevertheless it was pointed out that by creating two packages and price structures, ADAMED could market to both segments of

the market without losing in either one. Certainly the commercial product pricing structure needs change.

IX. IMPACT AND SUSTAINABILITY

A. Impact

1. Impact Evaluation Approaches

Investigation of project impact provides participants and funders with a picture of changes brought as a result of project activities. The evaluation of project impacts is of great interest for Project SUPPORT, due especially to its pioneering role in combining private and public sector initiatives for public health purposes. The impacts of Project SUPPORT can be divided into at least two types: (1) final impacts, to include changes in case management for infant diarrheas from use of ORS; and (2) intermediate impacts, to include effects on organization, management, technical capacity, and work efforts related to ORS production and promotion.

Responsibility for tracking project impacts is shared by both A.I.D. and PATH. Both organizations have been involved already in the planning and execution of various types of impact evaluation related to Project SUPPORT. These evaluations have been focused on the individual steps of planning and implementing the local production efforts. Through funding of various market research and anthropological studies in Project SUPPORT sites, A.I.D. has provided baseline data for the assessment of progress made in a variety of Child Survival Activities, including Project SUPPORT. For its part, PATH has encouraged a serious monitoring activity to be put in place by the local ORS producers which can serve as an indication of progress made in the intermediate impacts already mentioned.

A plan was prepared by Dennis R. Foote¹⁷ in October 1987 outlining an extensive series of field studies for Project SUPPORT to use in tracking impacts. The plan is divided into three parts:

- o Field Study of the Corporate Managers. This study would collect data concerning the following areas: (1) descriptive information about the corporate environment and personnel; (2) considerations underlying decision-making; (3) Project SUPPORT's role; and (4) the effects of participation.
- o Summative Evaluation of Outcomes. This study would analyze impacts in the following three areas: (1) availability of ORS and knowledge of its use; (2) knowledge changes resulting from communication activities; and (3) annual progress (as outlined in the A.I.D. Child Survival Action Program indicators). The detailed research protocol includes collection of data at four levels of analysis: the

¹⁷ Dennis R. Foote. Draft Summative Evaluation Plan for Project SUPPORT. Menlo Park, California: Applied Communication Technology, October 1987.

individual, the population, the organization, and the societal level.

The evaluation team supports conducting such impact studies. The team believes that the Foote protocols discussed above can serve well to guide the preparation of such investigations.

2. Final Impacts

There was effectively no final impact from Project SUPPORT activities in Ghana or Guatemala as of the evaluation team visit. There had been very little active oral rehydration therapy practiced using packaged packets in Ghana and only a moderate amount used in Guatemala. The distribution of locally-produced packets is now beginning to occur so that actual purchase and use of them will occur during the end of 1988 and beyond.

3. Intermediate Impacts

Significant progress within the local producer organizations is being made in the two countries visited. These intermediate impacts of the project are the subject of much of the previous chapters in this report. It is noted that spillover effects beyond the ORS product-line are likely to be produced within the firms from the project activities to develop production, quality control, and marketing capacity.

B. Sustainability

1. General Situation

Many factors suggest that a sustained local production could continue to operate at the two local producer firms as a result of Project SUPPORT efforts. There are unfortunately certain disturbing elements in the arrangements for joint public-private marketing which could negatively effect progress made in those programs.

On the positive side, the evaluation team confirmed the findings of the Project SUPPORT assessments showing a favorable business capability in the two local firms visited. They both have active management groups which are willing to direct their business skills to the production and promotion of an ORS product. The general economic situation is supportive of the business activities of local producers, although problems such as availability of foreign exchange have required special attention.

On the negative side, several factors have been mentioned already in the earlier sections of this report which are disturbing when considering the long-term viability of local production of the ORS product. Some of the evaluation team's concerns over sustainability are outlined below in three specific areas.

2. Specific Factors

a. Acceptance of ORT

Unlike other pharmaceuticals or foods, the oral rehydration salts packet has not been understood quickly or easily in any country where ORT programs were started. Both Ghana and Guatemala have made an effort to gain professional and household understanding of oral rehydration therapy. The results of those efforts are reported to have been slow to progress toward a successful program. Many competing therapies for management of diarrheas are still considered to be more effective in the eyes of a large proportion of health professionals of the two countries. Guatemalan researchers with participation from INCAP have produced several surveys and anthropological studies of professionals attitudes and public understanding of diarrheal diseases. The available studies in Ghana are not as extensive but do indicate that much remains to be done in educational efforts to develop a successful ORT program. Without a sizeable "momentum" of public and professional acceptance for the therapy, the private sector firm producing the salts may not consider ORS production to be a viable business proposition. Production volumes could remain low and production costs would rise as a consequence.

b. Availability of Public Inputs

A considerable investment is needed by public agencies in the training and promotion of ORS to develop and maintain a successful program. Many organizations, both public and private, must contribute their support and expertise to develop a successful ORT program. In Ghana, the evaluation team found a consortium of public agencies working together to ensure the viability of the ORT program. The local ORS producer was also invited to participate in the group's meetings. In Guatemala, there is an effort being made to develop an ORS Coordinating Committee to bring together and ensure the involvement of important public agencies in the program. The key international donor agencies also are needed to provide funding and support for the program. In the event that there is a loss in the continuity of funding or leadership on the part of the public agencies, the situation will prove especially difficult for the local producer firm. The firms visited in Ghana and Guatemala both are dependent on the participation of public agencies in the educational-awareness marketing efforts of their respective countries. Delays and other discontinuities in the public agency inputs to the control of diarrheal diseases program in general and the ORT program in particular are proving to be especially difficult for the firms.

c. Product Profitability

Profitability is necessarily a critical factor affecting the sustainability of local ORS production in each participating country. The initial assessment of feasibility for a locally produced ORS product considered the profitability of the product. All subsequent business decisions by the firms have been taken within the context of achieving a stable and profitable production and sales level. There are several interrelated factors which influence the profitability of the product. These include:

- o Cost of production and sales (including advertising) must be controlled where possible by the local producer firm to achieve a stable product cost structure.
- o Production output levels and sales must match the designed range of operation for the manufacturing process.
- o Governmental purchases of the local product should be established on a clear, predictable basis so that expectations for production and sales can be met and relations between the firms and their public sector counterparts remain conducive to further cooperation.
- o Quality production and safe use of ORS must remain a paramount factor in the minds of all involved in local production of ORS. It is essential that the build-up in production and sales never be permitted to outdistance efforts to control production quality and user understanding of safe use for ORS. No ORS production activity is likely to withstand even one event involving either ORS production errors or inaccurate mixing and administration of oral rehydration solution in the household.

An additional point should be made concerning profitability of ORS products. The cost structure of any manufactured product includes both variable and fixed cost elements. Variable costs include those cost elements which are added directly to the production and sales of the product in proportion to the amount of product made. Fixed costs are those other cost burdens which would be spent by the firm whether the product was made or not. In general, the revenues from sales of ORS are favorable to the firm if they at least cover the variable costs of the product and make even a small contribution to the firm's fixed costs. By this standard, the profitability of ORS products can be seen to offer considerable leeway as to the matching of costs and revenues in the short term. Occasional shortfalls in total recovery of all variable and fixed costs are not necessarily bad business propositions for local producers.

X. POTENTIAL FOR LOCAL PRODUCTION OF NEW PRODUCTS

For purposes of planning a possible follow-on project to SUPPORT, the evaluation team discussed potential public and private health products for local production other than oral rehydration salts with various respondents during the field visits. The products could be produced in the private sector and complement a child survival intervention strategy. The results of those informal discussions are summarized in this brief section.

There are several essential drugs that Project SUPPORT might consider producing in developing countries. The following are some products which are worthy of consideration:

1. Acetyl Salicylic Acid (aspirin)
2. Acetaminophen tablets (Tylenol(R))
3. Acetaminophen elixir
4. Chloroquine phosphate tablets
5. Ferrous sulphate tablets
6. Mebendazole tablets
7. Folic acid tablets
8. Benzylbenzoate emulsion concentrate
9. Vitamin A

A.I.D. may want to consider any of these that respond to the needs of the developing country. All products noted above are in the World Health Organization list of essential drugs.

Since A.I.D. has provided equipment to manufacture ORS (powder), a tablet formula would need little additional equipment or training in quality assurance testing of tablet products.

Numerous other products were suggested as candidates for local production. Most of them, including midwife kits, infant and baby scales, and various medical items, could be of interest to selected local producers. The underlying technology of many of those items is fairly simple so would require relatively easy processes for transfer.

Among the interesting but somewhat more sophisticated devices suggested for local production were the following:

- o AIDS diagnostic kits;
- o Low-cost disposable syringes; and
- o Weaning foods and other supplements.

The evaluation of these and other products for viability in local markets would require a considerable amount of market research.

XI. CENTRAL PROCUREMENT OF ORAL REHYDRATION SALTS

A. Tasks

The agreement for Project SUPPORT contained a task for the development of plans for procuring ORS packets on a centralized basis. The purpose of this central purchasing arrangement was to ensure the availability of packets to USAID Missions to meet requirements of their host country programs.

Several specific work elements were included within the central procurement task, in summarized form:¹⁸

- o Develop a proposed mechanism to quickly and efficiently procure and distribute U.S.-produced packets to USAID missions;
- o Request funds, outside of Project SUPPORT, to implement the approved mechanism, including possibly subcontracting the production and stockpiling of packets; and
- o Develop a system for estimating ORS demand for future years.

Progress on these tasks is summarized in the following section.

B. Findings

Studies to prepare an effective central purchasing arrangement for ORS packets were made by PATH and other groups under other A.I.D.-funded activities even before the initiation of Project SUPPORT. The considerable history to this task is best understood through a recitation of the events:

- o Ms. Veronica Elliott, for Westinghouse Health Systems, produced a report concerning ORS requirements and potential central procurement arrangements [September 1984]; she later produced a Strategy document based on the results of the first report [March 1985];
- o PATH proposed that A.I.D. consider long-term purchasing arrangements through the worldwide UNICEF production system with the A.I.D. products to bear a special custom label; statues concerning source and origin of A.I.D. purchases were cited as obstacles to the acceptance of this proposal [1985];

¹⁸ Agency for International Development. Cooperative Agreement with the Program for Appropriate Technology in Health. Washington, D.C., Agency for International Development, 1986, p. 15.

- o AID/W cabled USAID missions to survey their 3-year requirements; results showed a total requirement of 12 to 15 million liter-equivalents of ORS [October 1985];
- o Several children in Peru were given over-concentrated solutions of ORS salts produced in the U.S. and purchased by the USAID mission; several of the children died as a result of the incident [February 1986];
- o Discussions were held between the A.I.D. Administrator and the U.S. Commissioner of Food and Drug over the Peru incident and consequent problems of quality control associated with central purchase of ORS packets; discussions resulting from those initial meetings are continuing to the time of the evaluation;
- o Central procurement system concept was proposed by PATH [April 1986];
- o Letter sent to ORS vendors in the U.S. from PATH soliciting their interest in participating in A.I.D. purchases [October 1986];
- o Revised version of central procurement system proposed by PATH [February 1987];
- o Meetings held between A.I.D. Office of Health and Office of Procurement to prepare for formal bidding [July 1987];
- o PATH prepared a Request for Proposals (RFP) document for ORS purchases by A.I.D. and visited firms to evaluate their capacity to produce ORS packets [September 1987];
- o Commerce Business Daily published announcement of A.I.D. intent to make central purchases of ORS [September 23, 1987];
- o Pre-Solicitation Conference for ORS purchase held in Washington, D.C. [November 10, 1987];
- o Revised Project Implementation Order for Commodities (PIO/C) for ORS purchases by A.I.D. prepared by PATH [January 1988];
- o Bids received by A.I.D. for ORS from U.S. producers; subsequent U.S. Food and Drug Administration inspections of two firms bidding [1988];
- o Report on quality assurance in ORS production prepared by Erik Jensen [August 1988];

The recent history in this chronology is focused on discussions over quality assurance, involving various technical specialists, the U.S. Food and Drug Administration, and A.I.D (see Annex 2 to this report for further discussion of the underlying problems of quality control).

Four questions will require attention as the various parties involved with the quality assurance issue come to closure in their discussions:

- o What role should A.I.D. play in CDD?
- o Does A.I.D. need access to an ORS stockpile?
- o Should A.I.D. get its packets from a U.S. firm instead of UNICEF?
- o What level and type of quality control is sufficient for ORS packets that are provided and/or financed by A.I.D.?

The decision as to use of UNICEF as a source for the ORS purchases lies outside the scope of the team's data or expertise.

The rapidly changing circumstances surrounding the various quality control issues, including high level discussions within the Federal Government, made the task considerably more difficult to complete than could possibly have been envisioned at the outset of the Project. This resulted in a much greater level of assistance being asked of PATH by S + T/H than had been initially anticipated. In some cases, this exceeded the in-house expertise of PATH, requiring outside consultants to be hired. The team acknowledges PATH for its continued efforts to help A.I.D. resolve these issues.

XII. DISSEMINATION OF PROJECT SUPPORT EXPERIENCE

As with most A.I.D. projects, Project SUPPORT has contractual obligations to disseminate information or "lessons learned" from its field experience. The project's cooperative agreement calls for SUPPORT to "test the feasibility of the proposed collaboration between the commercial and public sectors and their combined abilities to meet public health objectives". Per this agreement, PATH was to present its experience at conferences and meetings. SUPPORT facilitated a workshop (following the ICORT II Conference), which addressed private sector ORS production. SUPPORT staff have also presented papers and organized panels at annual meetings of the American Public Health Association (APHA) and the National Council of International Health (NCIH). In addition, staff of the project have made several presentations to A.I.D. staff and other interested parties concerning project methodology and implementation.

SUPPORT, like other AID/W Office of Health projects, submits periodic draft reports to the Office of Health that are included in latter's Weekly Activity Reports (W.A.R.). This document is circulated throughout the Health Office and to higher levels of the Science and Technology Bureau. SUPPORT has also submitted a text for an article on the production efforts in Ghana and Guatemala that will be published in an upcoming issue of A.I.D.'s newsletter, Frontlines.

In addition to the activities noted above, SUPPORT is also developing a number of documents pertinent to private sector ORS production. These include:

- o ORS Volume and Labeling Manual, developed with assistance from the HEALTHCOM project. This document addresses the issues of determining the most appropriate packet volume and label design for ORS sachets. UNICEF has voiced interest in distributing this manual to its field personnel once completed.
- o ORS Local Procurement Manual. Currently being developed, this manual is designed to help explain the various issues and concerns to be considered when procuring ORS, and it provides guidance to personnel making procurement decisions.
- o Report on ORS Quality Assurance. Developed at the request of S&T/H by a consultant to PATH, this report offers alternative standards and recommendations for the manufacture of ORS.

This project has received greater attention recently within A.I.D. due to its private sector approach to health objectives. With this attention has come additional requests for information and materials. Lack of funds though limits the amount of additional dissemination that can be done during the project's final year.

In review, given the level of funding provided, the project is well on track towards satisfying the Cooperative Agreement's requirement of disseminating its lessons learned. It will be important in this final year of the project to ensure that documents currently being developed are completed to A.I.D.'s satisfaction. Certainly more can be done to document this work if desired. But it will require funding, beyond what is currently available. With any follow-on project, A.I.D. should consider providing greater financial latitude for dissemination.

Project SUPPORT funds have also financed seven issues of Directions, a PATH publication. These issues were not intended to address ORS matters but instead were to help identify other health-related commodities that address or deal with child survival interventions. These issues have addressed: essential drugs, tuberculosis, childhood accidents and injuries, iodine deficiency, traditional media, intestinal worms, and sexually transmitted diseases.

XIII. MANAGEMENT

A. Organizational Structure

PATH follows a matrix organizational design. Project staff are organized, not by geography or project, but by program area. Staff members usually work on a number of projects rather than one. In the case of SUPPORT, only two staff members are working exclusively on this project.

Operations within the organization seem to be very well managed. Internal communications are well established, including periodic staff meetings. Project SUPPORT staff noted that the Project Director made a special effort to keep them well informed of the pertinent developments.

There are an ample number of personal computers available for staff to use and the office appears to be well staffed with clerical personnel. Filing systems are comprehensive, well organized, and well maintained. PATH has centralized both the SUPPORT project's communications flow (cables, telexes and correspondence) and records maintenance under one staff person. This person spends 100% of her time on SUPPORT activities. This same person also monitors each staff persons' assigned work tasks and responsibilities by monitoring monthly activity reports. She alerts the Project Director to upcoming deadlines and action needed as necessary. This is a creative way to ensure the work tasks are covered and deadlines are not overlooked.

The office working environment is very pleasant, with sufficient space and offices for existing staff. Staff members say they readily confer with one another on program decisions. A team spirit is evident, and morale seems good.

B. Budgeting and Level of Effort

Financial matters are handled by the organization's Financial Department. Financial reporting seems to fit managerial needs and be responsive to requests. Monthly budget reports are provided to the project staff, disaggregated by project and by functional sector. At present, PATH's information and reporting system is not set-up to generate expenditure reports by country, or by buy-in. This is likely to be required of contractors by AID/W for all projects in the future.

The project staff and managers have done a commendable job of keeping costs close to budget. The estimated budget (as it appeared in the cooperative agreement in 1985) projected total expenses for the three years to be \$1,973,000. Actual expenditures after three years are \$2,152,195, less than 10% difference. Monthly expenditures in the last 18 months of the project have been averaging \$60,000. The Cooperative Agreement estimated monthly expenditures would approximate \$55,000.

There have been a number of reallocations of funds between the different line items of the budget. These changes were decided and agreed upon by the A.I.D. Cognizant Technical Officer (CTO) and PATH Project Director.

A key issue pertinent to budgeting that will be raised in several parts of this report concerns the level of funding provided for field activities, specifically whether it was sufficient to achieve the objectives. Please refer to earlier report sections on production, marketing and sustainability, and the sections on staffing that appear below for elaboration.

C. Staffing and Personnel

While many PATH staff members may contribute a portion of their time to SUPPORT, the number of full-time equivalent positions is noticeably smaller. The number of full-time positions that would be filled, if all the part-time positions are combined was 5.75 staff positions in 1986, 13.27 in 1987, and 8.24 in 1988 (prorated from the first nine months of 1988).

Only two staff positions have been designated as 100% committed to SUPPORT, one project officer and one administrative coordinator/assistant. The three other major project officers' time devoted to SUPPORT activities ranges from 23% to 70%. Similarly, the Project Director has spent only a portion of his time on SUPPORT. This amounted to 61%, 65%, and 48%, respectively, for project years one, two, and three.

The concerns that can arise with a staffing configuration such as this are twofold: are there sufficient staff to do the work and secondly, is there sufficient managerial oversight? The evaluation team is concerned that PATH's staff may be working beyond their capacity. Indications of a possibly too heavy work load include delays with the submission of trip reports, delays in submission of periodical reports, the rough state of draft in which some materials have been delivered, and the need to postpone SUPPORT travel due to other staff commitments. The team's concern is further raised by the Project Director's other commitments that limit the attention he can give this project.

To PATH's credit it should be noted that SUPPORT Project Staff have been very responsive to requests for assistance that have come from A.I.D. missions and Washington, D.C. offices. The number of country activities, both short term and long term, is significantly higher than what was originally planned. And it is this expansion that has increased the workload on project staff.

To alleviate this overload and to ensure prompt and thorough handling of issues, the team recommends that additional staff be designated for SUPPORT. A key position that may contribute to this would be a Deputy Project Director position, 100% dedicated to Project SUPPORT. It would probably be helpful to increase the portion of time

that the key project field staff have to spend on SUPPORT activities. An alternative to this would be to hire a new project officer to share the work load. While a greater amount of staffing is a must for any follow-on project, attention should also be given to this area for the remaining year of this project.

The other aspect of staffing that the team found to be of concern was the lack of extensive experience and knowledge in the areas of (a) pharmaceutical production and quality control (QC), and (b) private sector marketing of consumer products. Visits to project sites in Ghana and Guatemala showed these areas needing considerable more attention and technical assistance. While the existing project staff have been able to make significant contributions in these areas, full and proper execution of the project in the field requires personnel with more thorough experience in these crucial areas. This concern is expanded on more fully in the report's Marketing and Production chapters. It is of the utmost concern both for the success of current projects, and any others attempted in the future.

Outside consultants are relied upon by this project to provide additional personnel and the specialized skills currently not found among the staff. More extensive use of consultants has been limited by the very small pool of consultants available in these fields. In its Cooperative Agreement, PATH was given the task of expanding this pool of consultants. One training seminar was held for four individuals, early in the project. But retention of these four was hurt by the many competing offers available for people who have received these specialized skills.

Further complicating the difficulty with acquiring such consultants is the considerable salaries they normally receive for work in the private sector, normally ranging from \$1,000 to 1,500 per day. It is understandably difficult for PATH to entice such consultants with the comparatively low rates that A.I.D. allows (up to a maximum of \$285/day).

PATH has made an effort to communicate the assignments of staff members to A.I.D. and host country parties involved in the Project. In both countries visited, however, the USAID staff were unsure if PATH had designated a particular person to function as backstop for activities (responsible leader) in their respective countries. This confusion was fueled somewhat by PATH's practice of sending different consultants or staff as the project progresses through its assessment, production, quality control, and marketing phases. The team recognizes it may be necessary to use people having a variety of backgrounds for a project such as this. Nonetheless, PATH must find a way to deal with the possible confusion of the present arrangement and provide more continuity. While PATH may already be operating under this arrangement, it was not perceived to be in effect by A.I.D. and others in the field.

D. Implementation

PATH has initiated more than the Cooperative Agreements' specified number of country start-ups. In all field reports and interviews, PATH personnel and consultants have been consistently praised for their professionalism and rapport.

This is particularly commendable given the complexity of this project and the variety of players involved with its implementation. While touted as a pure private sector venture by some, SUPPORT's field implementation is, in fact, influenced and dictated to a considerable degree by public sector decisions. For these firms, ORS production and marketing is not a purely market-driven activity. Firms that PATH works with are told what formula to use in its preparation, what size packet to use (they are required in some instances to use the same size packets as those of the public sector), and what price to ask. They must maintain the product price within a certain percentage range of actual production cost.

SUPPORT must ensure that its project activities fit into and complement the larger Control of Diarrheal Diseases (CDD) program activities of the countries visited. This close cooperation is necessary because of the suspicions held by some public officials here, and also because of the fact that in many countries a private sector activity such as this could be immediately suspended or cancelled if so chosen by the government. Suspicions and rivalries among the public and private parties are common. Thus, the delays that often are common with developing countries' public sector programs can end up delaying the private sector as well. This was clearly the case in both Guatemala and Ghana. Public sector promotion campaigns with which the pharmaceutical firms were to coordinate, had been delayed considerably and their future initiation dates had yet to be firmly established.

A number of other delays resulting from SUPPORT's unique components have also been experienced. These have included delays with the procurement and shipping of production equipment, and delays with the banking and loan arrangements that accompany this project.

Affecting implementation has been the project's level of effort. While PATH should be credited for keeping expenditures close to what had been originally budgeted, this team's impression is that this may have compromised the effort's success. Technical support has been less than sufficient in the areas of production, quality control, and marketing. Additional trips or trips of longer duration are called for in order to effectively train staff and ensure correct execution of these activities.

Also requiring continuing attention in the two countries we visited is general liaison and coordination. Assessments of this situation differed amongst those interviewed. USAID Mission staff noted that additional "time on the ground" by PATH consultants would have been beneficial to the project. In the case of Guatemala, USAID staff felt this had resulted in additional work for its own staff and the HEALTHCOM resident advisor (RA). In Ghana, the USAID Population

Development Officer felt that PATH may have relied too much on the local ORS company's marketing representatives to fulfill the job of coordination and liaison. The PATH staff felt that it had made a concerted effort to provide and exchange information with people in the field. They felt they had not requested any of the other parties to coordinate parts of the program on PATH's behalf.

Thus, additional resources and support are needed. One form this might take is to use RAs for moderate periods of time, perhaps three to six months around the time of the product launch. The concern expressed by PATH staff, that use of such personnel would foster dependency amongst the key players, seems of far less concern with this project since private sector pharmaceutical firms can be far more independent, adaptive, and resourceful than some public sector groups typically assisted by RAs.

Another option suggested during the evaluation would be for PATH to hire a local facilitator to organize and follow up on matters in between visits by PATH representatives. Alternatively, a regional representative, perhaps with experience in private sector marketing, could be hired to cover all countries in a region and would visit for longer periods of time.

It is recognized that it would also be necessary to raise the project ceiling to accommodate this higher level of assistance or to reduce the number of new project sites that were being planned under Project SUPPORT.

E. Monitoring of Project Field Work

Project monitoring will be addressed as two dimensions. First is PATH's awareness of and ability to monitor its field activities. Second is AID/W officials' awareness of field activities based on reports it receives from PATH.

Without personnel based in the host country, PATH's data collection is limited to whatever reports the pharmaceutical firm may provide, correspondence with parties involved, and what its consultants report following in-country visits. The agreement that PATH establishes with a pharmaceutical firm requires the firm to provide PATH with periodic reports containing certain information. These reports are to include copies of production batch records, sales records and profits, and samples of packets for testing. Once PATH has provided the loan, established the ORS production units and trained company staff, there is little control they can exercise over the firm - short of claiming possession of the equipment. This latter action was incorporated into the agreements to give PATH some leverage should the firm default on its loan or produce inferior quality packets.

In Seattle, PATH was able to present only a limited collection of records on ORS production volume, distribution, sales, and quality control monitoring records. This information must be monitored on a continuous basis, especially batch records for quality control.

Efforts should be made to improve this situation and expand the monitoring process.

Also at issue is PATH's responsiveness to reports it receives from the firms with which it works. In Ghana, DANAFCO showed members of the evaluation team telexes that had been transmitted by DANAFCO to PATH several months earlier, describing problems being experienced with production equipment. DANAFCO said there had not been any acknowledgement or reply to these letters. PATH staff were unable to find a record of having received copies of the requests. Such communications, between production firm and PATH, is an issue that PATH needs to pay much closer attention to. No matter what actually happened in this DANAFCO case, the need to ensure reliable exchange of messages and follow-up of telexes is potentially very serious and should not be overlooked.

The second dimension of monitoring, as noted earlier, is PATH's reporting to A.I.D. on country activities. For monitoring of country activities, this reporting takes a number of forms including trip reports, routine monitoring of cables and telexes, and discussions held during Semi-Annual Project Review Meetings (SAPRMs). The A.I.D. Cognizant Technical Officer relies on the contractor to keep him fully informed of all developments of significance that occur in all project countries. It was the team's impression that the CTO was not fully aware of a number of crucial events that had occurred in Ghana and Guatemala. These include the problems experienced with the equipment in Ghana, and the low or stymied level of activity of the marketing programs in both countries.

This suggests that PATH provide more information to A.I.D. PATH's location in Seattle does seem to preclude a sufficient number of face-to-face meetings frequently held between CTOs and their projects' staff because meetings like these provide more opportunities for information to be presented, understood, and discussed. Budgeting for more exchanges like this, with project staff coming to Washington, may be necessary if the Recipient is to be based outside Washington, D.C.

It should be pointed out that the CTO for this project has increasingly had to divide his time among a number of projects, thus limiting the attention he can give to SUPPORT. Recognizing that this monitoring is a two-way process puts some burden on A.I.D. to recognize its responsibility to provide sufficient oversight.

F. Coordination

There are many organizations which work in CDD/ORT, including A.I.D., contractors, international donors, host government ministries, private, public and private voluntary organization (PVO) groups which present coordination among them very difficult, both in countries where work is being done, and among groups' headquartered in the U.S.

As noted earlier, PATH staff have been consistently complimented by AID/W, and overseas personnel for their professionalism and good rapport. AID/W staff (including PFC and regional bureau staff) who

have had occasion to deal with PATH have also complimented the contractor's responsiveness.

Interviews with contractors involved with CDD/ORT also brought mostly complimentary words, but the potential for overlap and confusion among projects and contractors was recognized. The overlap is greatest within marketing and promotion of ORS. HEALTHCOM, PRITECH, and SUPPORT are all actively involved in this area. SOMARC has also been involved in Ghana. PRITECH's recent hiring of a private sector pharmaceutical marketing expert, further blurs the distinctions between these providers of technical assistance. Missions may be confused as to which project should be accessed for technical assistance. The task lies with the AID/W Office of Health to clarify roles for these projects. It may not be realistic to expect that universally applicable guidelines could be developed. The Office of Health should pay close attention to developments in individual countries as contractor involvement is being planned to ensure these activities are well coordinated. This requires close coordination and discussion between A.I.D. Cognizant Technical Officers who manage these projects.

PATH and other contractors have developed ways to expedite coordination. PATH, for example, has one staff member who is assigned to work in the PRITECH office. They have also helped to facilitate coordinating meetings among the contractors. Creative mechanisms such as these should be continued and encouraged.

Another dimension of coordination that is somewhat ambiguous concerns the extent to which PATH should take the initiative (or be responsible) for coordinating the many groups in-country who play a part with CDD/ORT programs. It was difficult for the team to decide to what standard SUPPORT should be held. On one hand, coordination is so clearly a prerequisite for project success that PATH should obviously play a part. But, on the other hand, comprehensive CDD programming is clearly the prerogative of the public sector. In countries where a more public-sector oriented contractor (i.e., HEALTHCOM or PRITECH) is also working it would seem more appropriate for one of these groups to take the responsibility for assisting the host government and donors in organizing the coordinating committees. The private pharmaceutical firm working with Project SUPPORT should be a member of this committee.

G. Submission of Reports, including Deliverables

Documents and reports for which PATH is responsible have been listed on the Project Monitoring Assistance (PMA) sheets that are provided with this report. The agreement on these deliverables and what each is to contain has evolved over the three years of the project as the CTO and Project Director have agreed on more expeditious ways of reporting the project's status. PATH has been instrumental in helping to evolve a more efficient and appropriate reporting format. Periodic submissions include Monthly Activity Updates, Quarterly Reports, Semi-Annual Progress Review meetings and Annual Progress Reports. SUPPORT's field activities are covered in trip reports, and documents on specified concerns of implementation such as loan agreements, marketing plans, and manufacturing/quality control manuals.

Other special reports being prepared include: the Volume and Labeling Manual, ORS Local Production Manual, and five issues of Directions, PATH's technical review periodical.

There have been cases of trip reports and periodic reports being submitted late. An extreme example was an Ugandan trip report that was sent to AID/W five months after the trip was taken. There is also the concern, that at times the development of these documents was not adequate when some draft versions of reports were submitted in very rough form. They should have been developed further before being submitted, even though considered to be drafts.

Marketing plans for Ghana and Guatemala should have been co-developed with the local production firms early in the project development process. Instead they were submitted in September 1988 and had not been developed with the local firms. PATH must assist the local firms so that they may be able to plan and implement product marketing activities.

H. Evaluation

As mandated in the cooperative agreement, a midterm evaluation was done in 1987. These documents listed in the references of this report, were prepared by Dr. Dennis R. Foote and Mr. Jonathan Green.

PATH has also submitted a proposal to AID/W for final evaluation of its field projects. As requested by Office of Health, work plans for this evaluation have been developed at two budget levels, \$36,000 and \$65,000. Given delays with implementation that have been experienced in several project sites and the only recent initiation of implementation in other sites, attempts to assess impact may be difficult during the remaining year of the project. This limitation should be taken into consideration when doing this evaluation. It may be more helpful to designate some funds in a follow-on project to be used for evaluation of SUPPORT's impact. For the duration of this Project SUPPORT should concentrate on collecting more immediate data such as numbers of packets manufactured, distributed, and sold by cooperating firms. Even this most critical data is unavailable in some cases.

XIV. RECOMMENDATIONS

A. Production and Quality Control

1. Remainder of Project SUPPORT

- a. Respond at once to problems associated with filling machines at DANAFCO and ADAMED, as noted in the evaluation report.
- b. Validate mixing, filling, and sealing processes in DANAFCO, ADAMED, and other project production sites.
- c. Establish SOPs for all quality control test methods and operation of manufacturing equipment and laboratory equipment (including mixing, filling, and sealing process validation) at all project production sites.
- d. Develop a uniform sampling plan for quality testing of all stages of production and quality control, including testing of finished ORS packets, and use the plan at all project production sites.
- e. Develop standards and specifications for glucose analysis by polarimetry.
- f. Develop specifications and testing methods for all levels of packaging materials (include primary, secondary, and tertiary packaging components, such as: inner poly bag, outer poly bag, cardboard carton).
- g. Develop a protocol for retention of raw material and finished product samples.
- h. Add the following items to the list of essential equipment required for production, and procure the items for all project production sites: temperature/humidity monitor; sampling thief; plastic covers for stainless steel equipment housed in the filling room; and polarimeter for quality control laboratories to measure specific rotation of glucose.
- i. Develop protocol for salvaging batches that are found not to conform to in-process specifications, as required by GMP.
- j. Develop SOP for maintenance and calibration of production and quality control equipment.
- k. Develop SOP for cleaning of manufacturing equipment and facilities.
- l. Develop manufacturing directions for mixing process for DANAFCO, ADAMED, and other project production sites.
- m. Provide flow characteristics of WHO citrate formula to DANAFCO, ADAMED, and other project production sites.

n. Conduct tests on the value of adding silicon dioxide to the product to improve the flow characteristics. This would be done as a research activity, preferably in-house or at a collaborating center, prior to incorporating its use into standard production practice.

o. In the early stages of production, introduce additional in process testing during filling operation (10 samples may be taken every hour (or 1000 packets) and individually analyzed for sodium and potassium. The frequency of tests may be loosened or tightened based on the information received from experience. From each hour of dosing operations, keep the packets in a separate container. Mix the packets from all containers after the results from the laboratory have been received.

p. Monitor the data from production and quality control closely and pay attention to details and specifics of production and quality assurance. For example, SUPPORT must continue to insist that producers forward copies of master batch records for all batches produced during the first six months of production, and at established intervals thereafter. Other relevant QC documentation should also be forwarded and reviewed closely during the first six months of production, and periodically thereafter.

q. SUPPORT staff should develop a standardized training curriculum for QC and production that can be adapted for the needs of each producer. The curriculum should contain clearly stated objectives, instructional materials, hands-on exercises, review time, and pre/post-tests to check comprehension. Training should be considered as successfully completed only upon achievement of criteria specified by SUPPORT staff.

r. SUPPORT should develop a Drug Master file that can be adapted to the needs of each collaborating producer.

s. SUPPORT should establish a timetable for requesting samples for analysis during the initial months of production. Samples from each released batch should be tested to ensure that the results have meaning. Such a timetable should follow ISO and MIL rules. If test results on the product drawn from the large samples at frequent intervals at the outset of production confirm that the product is within specification, firms should be allowed to reduce the sample size and intervals.

t. Recruit a senior consultant with proper education and several years of experience in formulation, processing, and quality assurance in the pharmaceutical industry.

u. SUPPORT should send a production/quality control specialist to visit each producer for at least one week roughly three months after the start-up of production.

2. Potential Follow-on SUPPORT Project

a. Allocate additional human resources with proper education and experience in technical assistance, as starting of production of a drug product is extremely time consuming in any setting or culture.

b. WHO guidelines WHO/CDD/SER/85.8 were prepared for planning purposes and should not be considered a final quality control manual. In initial stages, perform additional tests on raw materials, not just percent purity, moisture, heavy metals and identification. These tests may follow USP, BP, FCC or WHO guidelines, especially bulk density and particle size distribution.

c. Learn from experience with raw materials, processes, equipment and select the appropriate raw materials, processes and equipment. Monitor the bulk density and particle size distribution of all raw materials.

B. Marketing of Oral Rehydration Salts

1. Remainder of Project SUPPORT

a. Technical Assistance

As necessary, A.I.D. should provide additional funding support so that PATH can recruit and assign technical assistance personnel with experience in developing marketing programs, including the establishment of coordinating and advisory bodies, market planning, all marketing elements: product development, marketing research, market segmentation, target populations, packaging, pricing, promotion, distribution, sales, public relations, IEC, training, and institutionalization of social marketing programs. Promotional programs for ORS are especially needed to create greater awareness and demand for the products.

b. Guatemala

First priority should be to try to place a short-term resident advisor in Guatemala to provide consistent and continuous development assistance to ADAMED in order to support and coordinate program activities in the country. Additional funding is urgently needed for the placement of the advisor and for promotional activity to create demand for the LITROSAL product.

c. Ghana

Resident advisors are not politically feasible in Ghana, so the next best alternative is to provide continuity by using consistently the same technical advisor and providing for sufficiently long visits to ensure that the solutions and the learning process are accepted, incorporated, and reinforced. The technical advisor should be experienced in developing social marketing programs. Promotion of

the ORS product should be a high priority for the subsequent technical assistance and funding.

d. Collaboration

Collaborate and interact with existing consulting organizations having relevant experience in social marketing. These may include Contraceptive Social Marketing II (CSM II), the SOMARC Project, to the maximum extent possible for the benefit of utilizing their resources of marketing and social marketing in all countries to successfully diffuse ORS products of Project Support. (PATH is a subcontractor to the Futures Group, which was recently announced to be the contract award winner of CSM II.)

2. Potential Follow-on SUPPORT Project

Do not expand to new countries, companies, or product introductions until the experience in the initial projects has shown to be sound and reliable enough to warrant expansion. Strive to improve and develop projects in existing Project SUPPORT countries.

C. Finance and Business

1. Remainder of Project SUPPORT

a. Guatemala

Increase promotional activities in order to create demand for LITROSAL in Guatemala. After product demand is demonstrated by increased sales over three to six months, increase the price of the product in order to reach a break-even point, estimated to be at a consumer price of approximately 75 centavos.

b. Ghana

Increase promotion to create demand for ORS in Ghana. After product demand is demonstrated by increased sales over a three to six month period, submit the necessary request for a price increase to the P.I.B., the amount of the price increase over the present 25 Cedis is yet to be determined.

2. Potential Follow-on SUPPORT Project

Continue to offer similar loan mechanisms with the range of terms evidenced in SUPPORT I, that take into consideration the peculiarities of each country.

D. Dissemination of Project SUPPORT Experience

1. Remainder of Project SUPPORT

Continue distribution of materials already developed.

Consider use of a buy-in to PRITECH if there is the interest in further documenting SUPPORT's implementation experience.

2. Potential Follow-on SUPPORT Project

Provide for wider funding latitude in follow-on project to permit a variety of dissemination activities to be pursued.

E.1. Impact and Sustainability

1. Remainder of Project SUPPORT

For monitoring and evaluation purposes, PATH should more rigorously pursue collection of key data from the firms it assists.

The evaluation team notes that due to delays in implementation of activities in some countries, and only recent initiation of activities in other countries, it is too early to assess the impact on ORS knowledge and use that may have resulted from SUPPORT. The team feels that efforts should be directed at collecting information more proximate to production and promotion (i.e., number of packets produced, number distributed, number sold, inventory status, sampling of product prices, other ORS products on the market, etc.).

2. Potential Follow-on Project SUPPORT

Terms and agreements that the contractor makes with firms should encourage, as best as possible, accurate, full and prompt reporting on the types of production, inventory and sale issues noted above. The team appreciates the difficulty there can be with getting firms to comply with reporting requirements. But such information is essential, and means must be found to obtain it on a regular basis.

Conduct field studies on project impact.

Spot surveys of marketing outlets and consumers should be budgeted into the follow-on project in order to assess the target populations awareness, knowledge, and attitudes towards newly introduced ORS products.

F. Project SUPPORT Management

1. Remainder of Project SUPPORT

a. Commit a greater portion of key project officers' time to SUPPORT in this final year to help ensure sufficient attention to country monitoring and reduce delays with report submission.

b. Consider reducing the number of new starts in the final year so that energy and funds can be focused on a few new ones and the existing efforts.

c. Recognizing that A.I.D. Cognizant Technical Officers must take responsibility to oversee coordination of their respective

contracts when two or more projects operate in a country, establish operating procedures that constantly update all staff members as to the plans and activities of other related projects in-country.

d. Identify ORS coordinating committees and/or project advisory boards as desirable groups through which to attempt to organize in all project countries; ensure that some group takes responsibility for pushing these committees (this would fall to PATH if no other group is deemed more appropriate).

e. Additional detail on field projects' implementation (particularly with any delays or problems encountered) should be reported to A.I.D.

f. Ensure that all current deliverables are developed and finished to A.I.D.' satisfaction in the remaining year of SUPPORT.

g. Given that local production is only now beginning to start in project sites, attempts to assess impact may be difficult during the remaining year of the project. This limitation suggests to the team that the final reevaluation proposed by PATH, based on the evaluation plan by Dennis Foote, be funded at the lower budget level of \$36,000, if available. Additional funds should then be designated in a follow-on project to be used for evaluation of SUPPORT's impact.

h. SUPPORT staff should communicate the name of the country backstop person to the management of each producer and the local USAID health officer. At the same time, SUPPORT should ask each firm to designate a principal contact for production, quality control, and promotional issues. Other SUPPORT personnel may participate in responding to requests, but for the sake of clarity, the key contacts should remain constant.

i. SUPPORT should establish and maintain a log system to track all requests and responses regarding technical assistance required by the producer. This should include date of receipt, date of response, person(s) responsible, and status. This log should be maintained regularly and checked on a regular basis, perhaps biweekly, by knowledgeable personnel. In addition, the requesting party should be asked to forward the request by two methods (e.g., letter backed up by telex).

j. SUPPORT should develop a method for updating production and quality control manuals, and marketing plans in a timely and systematic fashion. This includes putting the manuals in a looseleaf binder format that permits the ready replacement and recall of numbered pages to ensure that only current information is used.

2. Potential Follow-on SUPPORT Project

a. Consider establishing a staff position of Deputy Director for the project that would be dedicated full-time to the project.

b. Revise financial reporting to allow for expenditure attribution by country and by buy-in source of funds.

c. Recognize and incorporate into project designs the SUPPORT experience suggesting the need for a higher level of resource investment than was budgeted for the 1986-1987 start-ups (including funds for field visit time, program support, and technical expertise).

d. Allow for project to pay higher salaries or fees to those consultants with needed experience and expertise so that they can be available for appropriate assignment to in-country projects.

e. Consider use of short- to mid-term resident advisors (RAs) to be assigned during the most critical times of market and production planning, product launch and other identified periods.

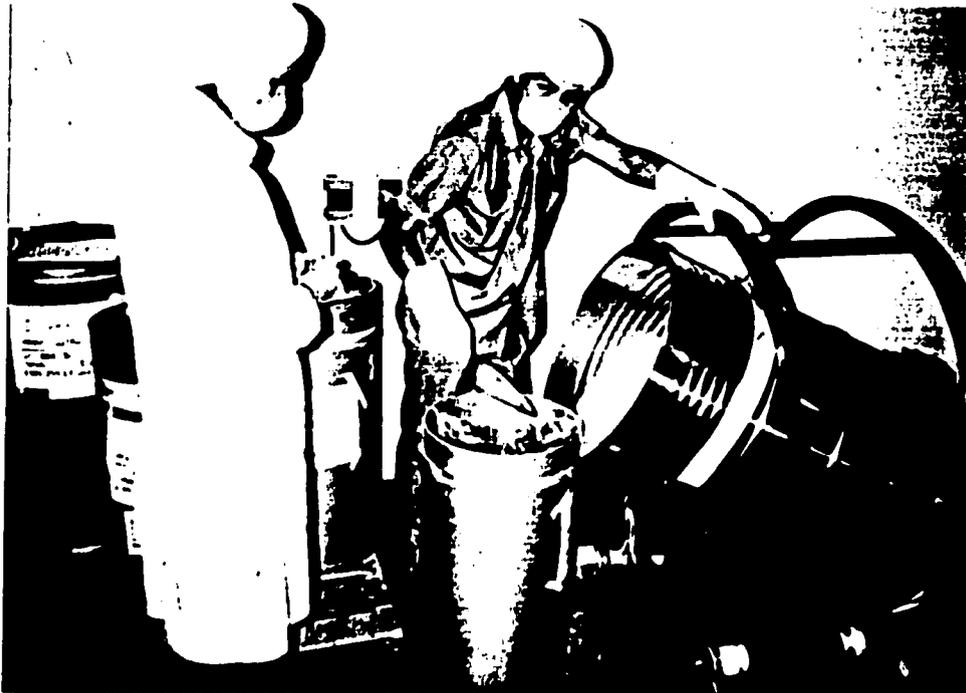
ANNEX 1

Photographs

Guatemala

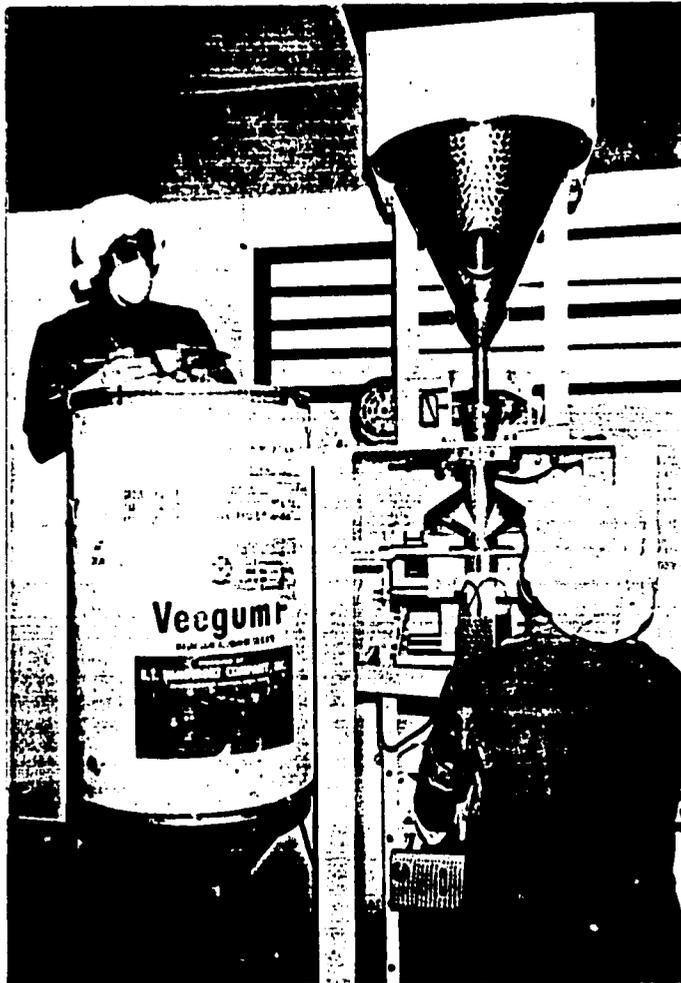


The main factory site of Adamed S.A. Laboratories, Guatemala City, Guatemala.

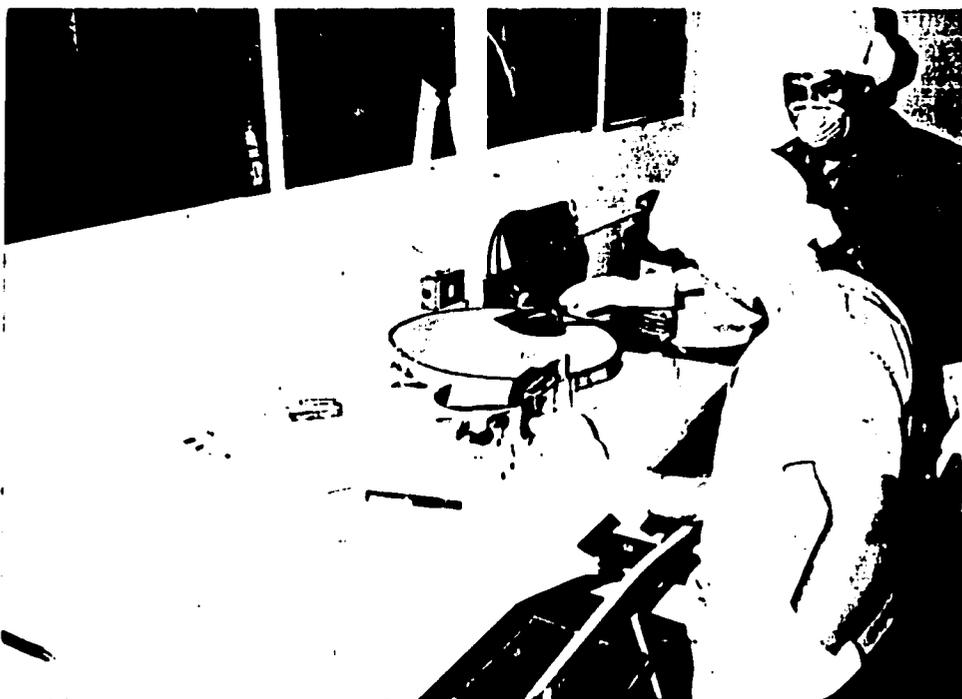


Following a predetermined time in the rolling blender, ORS is removed for transfer to the filling/dosing machine.

Guatemala



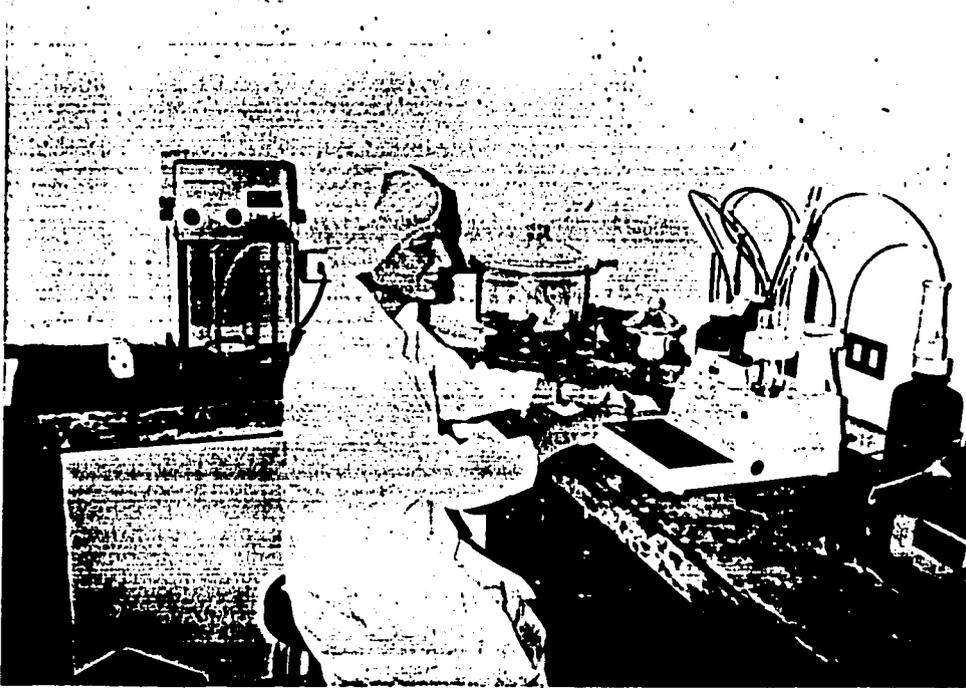
A semi-automatic filling/dosing machine fills the packet with a specified amount of ORS, then seals laminate package.



Assuring quality of ORS involves sampling during production to verify correct weight of packets.

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Guatemala



Samples of the finished product are tested for composition of ingredients--most crucially, sodium and potassium.

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Ghana



Danafco, Ltd. Factory in Accra, Ghana.



Polyethelene bags are filled individually from dosing machine, then handed down production table for sealing, after which they are placed inside a second polyethylene outer bag and instruction inserts are added.

Ghana



Outer bags are heat-sealed, packets are placed in holding trays, and then in cartons for shipment.



Packets drawn from production are mixed with water and tested for composition of ingredients.

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Ghana

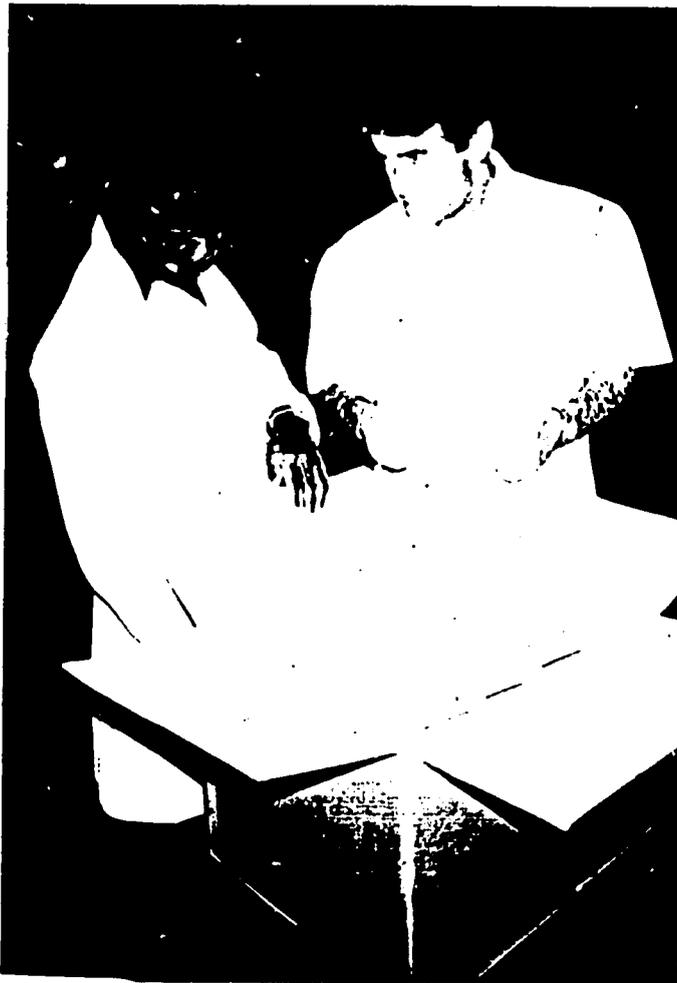


Facilities and equipment for ORS quality assurance are specified by PATH staff, who work with the local firm to establish these.



The degree of automation of production equipment varies from country to country. In Ghana, considerable availability of labor deemed less-automated equipment more appropriate. Heat sealing tools are shown here.

Ghana



Finished packets are inspected before shipment to sales points. This private firm's regional warehouses and established product sales outlets help compliment public sector distribution and improve overall availability of ORS to consumers.

ANNEX 2

Issues in Quality Assurance for ORS Production

ANNEX 2

Issues in Quality Assurance for ORS Production

A. Problem

Oral Rehydration Salts (ORS) are now manufactured in over 40 countries. As yet, there does not exist a sampling plan for content uniformity which is acceptable to all parties involved with ORS production. Any plan that is accepted by USP, BP, and WHO would be practiced by most manufacturers of ORS. This discussion provides a review of the present status of quality assurance standard setting arrangements for the ORS product.

B. Background

The approval of a chemical as a safe and efficacious therapeutic agent in the prevention of diarrheal dehydration is a function of government regulatory agencies, such as the Food and Drug Administration (FDA) in the United States or the Pharmacy Board in Ghana. Most countries have approved ORS (either the WHO citrate or the WHO bicarbonate formula) as over-the-counter drug product. An additional function of these agencies is also to monitor the quality of the drugs produced through implementation of Good Manufacturing Practices and by requiring pharmaceutical manufacturers to practice them vigorously.

Official compendia, like the United States Pharmacopoeia (USP), British Pharmacopoeia (BP), International Pharmacopoeia (IP), and others, provide guidance in control of quality of therapeutically active chemicals and other excipients used in formulation of pharmaceuticals. A chemical which is included as a monograph in the official compendia, such as USP, must conform to all physical, chemical, and microbiological specifications contained in the compendia. These compendia also have monographs of finished dosage forms of most commonly used drug products. The pharmaceuticals that constantly need to be monitored for their quality are also included in official compendia.

ORS has been approved as a drug in many countries. The U.S. Pharmacopoeia has also recently published a monograph¹ on it, categorizing it as an over-the-counter drug product in the United States. Additionally, many other pharmacopoeia, including the B.P. and the I.P., have also published monographs on ORS, and consider it an

¹ United States Pharmacopoeia Supplement. Pharmacopoeal Forum. November-December 1987, pages 3150-3155.

OTC drug. However the F.D.A. has, as of yet, failed to rule definitively on how it will classify ORS.

The World Health Organization (WHO) ORS formulae are most widely used, and WHO has published guidelines for planning the establishment and operation of production facilities for the production of ORS to encourage local production of ORS. This document was published by the WHO Program for Control of Diarrheal Diseases (CDD) in 1985 and is titled, Oral Rehydration Salts: Planning, Establishment and Operation of Production Facilities. It often is referred to as publication number WHO/CDD/SER 85.8. This is the only manual of its kind and is very well written. It includes specifications on raw materials, formulas, manufacturing directions, inprocess controls, finished production specifications, manufacturing and filling equipment descriptions, and documents to monitor manufacturing quality control of ORS.

Even though USP and BP are the most widely-used compendia in the pharmaceutical industry, the WHO document (WHO/CDD/SER 85.8) is widely used for its specifications of raw materials, in-process testing, and finished product specifications in production and quality assurance of ORS. The WHO document specifications were adopted by most manufacturers of ORS worldwide, and they even advertize their product as UNICEF/WHO formula on package labels to gain public confidence and trust in their formula.

The quality of ORS, including the homogeneity of all ions and glucose, is extremely important. Considering the problems associated with production of the ORS formula and the potential for toxic effects of sodium and potassium ions, it is imperative to maintain the homogeneity of the mix in each sachet so it contains the specified quantity of each ion. In the absence of testing for all the sachets for chemical composition (which is not possible as testing of ions is destructive testing), a test called "Content Uniformity" is widely used. Content uniformity is widely included in various compendia, in quality assurance of heterogeneous solid pharmaceutical products like tablets, capsules, powders. This is the only test that would validate the quality for an ORS product.

Of the three publications cited, only BP has a test of "content uniformity" for ORS. Neither the WHO/CDD/SER 85.8 nor the USP have included content uniformity as one of the specifications for an ORS product (see Table 2-1).

Recently, Project SUPPORT contracted with Dr. Eric Jensen to develop a document to provide acceptance evaluation techniques for ORS. Jensen's report is based on inspection by attributes and includes criteria for dealing with critical defects, major defects, and minor defects in product. The sampling plan in the Jensen document uses U.S. Military Standard (MIL STD) 105D, General Inspection Level I.

Considering the wide and growing use of ORS and its availability from multiple sources, it is essential that guidelines now be developed for manufacturers and users to guide quality assurance activities. It is necessary to maintain trust in the integrity of the product. It is, perhaps, even more important after the 1986 tragedy in Peru that quality assurance guidelines be developed.

C. Recommendation

It is recommended that scientists from USP, BP, WHO, the U.S. Food and Drug Administration, and donor agencies like UNICEF and USAID agree on a sampling plan for ORS production. The sampling plan must assure the quality of ORS consistent with the accepted standards for product quality of the pharmaceutical industry (meaning minimal or no risk to the user) and the sampling plan should not increase the production cost of ORS significantly.

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TABLE 2-1
ORS Specifications for WHO Formula

Item	WHO ²	USP ³	BP ⁴
1. Content Uniformity Sampling Plan	--	--	Dual Sampling
2. AQL	--	--	--
3. No. units to be tested for content uniformity	Takes samples at beginning, middle and end of filling process	--	10 packets, if one fails take 20 more
4. Labeling	10 packets	--	--
5. Moisture	2.0% maximum	2.0% maximum	2.0% maximum
6. Seal Integrity	10 packets /10-15 min	--	--
7. Net Weight (10 packets combined)	--	10 packets not less than 279 grams	--
8. Minimum fill individual packet	95-105	95-105	--
Number of packets:	10 packets	10 packets	--
9. Package	If bicarbonate formula, separate package	If dextrose monohydrate with bicarbonate or citrate formula package in separate packages	--
10. Packaging Components	Polyethylene or laminated foil	--	Laminated foil protected from moisture

² World Health Organization. Oral Rehydration Salts: Planning, Establishment and Operation of Production Facilities. Geneva: Program for Control of Diarrheal Diseases, World Health Organization, 1985. (WHO/CDD/SER/85.8)

³ United States Pharmacopoeia Supplement. Pharmacopoeal Forum. November-December 1987, pages 3150-3155.

⁴ British Pharmacopoeia. London, 1988, page 873.

TABLE 2-1
ORS Specifications for WHO Formula (continued)

Item	WHO	USP	BP
11. Storage	--	Preserve in tight container and avoid exposure to temperature in excess of 30° C	Protect from moisture
12. Sodium	93%-105%	90%-110%	90%-110%
13. Potassium	93%-107%	90%-110%	90%-110%
14. Chloride	93%-107%	90%-110%	90%-110%
15. Citrate	93%-107%	90%-110%	90%-110%
16. Glucose	93%-107%	90%-110%	90%-110%
17. Moisture:			
a. Sodium Chloride	1.0% max	0.5% max	1.0% max
b. Potassium Chloride	1.0% max	1.0% max	1.0% max
c. Sodium Citrate Dehydrate	10%-13%	10%-13%	10%-13%
d. Glucose Anhydrous	1.0% max	1.0% max	1.0% max
18. Flavor	--	Yes	--
19. Flow agent	Allow use of flow agent like silicon dioxide	Not Specified	Allow use of flow agent like silicon dioxide

ANNEX 3

Major Issues to be Addressed in
Evaluation of Project SUPPORT

ANNEX 3

Major Issues to be Addressed in
Evaluation of Project SUPPORT

Prepared by AID/W Office of Health
September 21, 1988

A. Project Design

1. Are current activities in agreement with the project's original mission and scope of work?
2. How do the features of the countries selected for long-term assistance compare with the selection criteria originally proposed?
3. At the outset of this project, it was anticipated that a standard format of activities that would be applied in each country. But the actual work has involved a wide variety of responses - due to widely varying needs in different countries. How has this affected the project's design, rationale and objectives? Has this compromised or lessened the impact A.I.D. hoped to produce with this project?
4. Address the issue of SUPPORT's evolving or expanding S.O.W. from production T.A. to that of product marketing and promotion. Does it suggest a demand for different or additional types of T.A.?
5. SUPPORT was initially developed in the A.I.D. Office of Private Enterprise. Later it was transferred to S&T/H. What affect has this had on the project, particularly on those facets that require more business and economic oversight?
6. What are the criteria used to measure project performance? How sensitive and accurate are these measures? To what degree can they be used to suggest "success"?
7. Is the policy decision of having SUPPORT work with only private sector firms a valid one? Should this policy continue? Note cases where SUPPORT has worked with public/parastatal firms.

B. Project Management and Implementation

1. The project's number of activities (including use of buy-ins) and level of effort have significantly exceeded original plans. Has this had any affect on the project's ability to do its original S.O.W., and to do the additional tasks that have been requested? Has this had any affect on quality of work, staff workload and morale, etc.? Have resources and staff been sufficient to accomplish these activities?

2. How do actual spending patterns and levels, overall and by budget category, compare to what had been planned? What, if anything, does this suggest about implementation?
3. Are there sufficient number of staff with the appropriate skills to successfully accomplish the project's objectives?
4. Has SUPPORT been able to obtain the consultants it needs, when it needs them? Have they been able to train new staff/ consultants when necessary? Comment on this 'pool' of consultants - their numbers, background, skills, etc.
5. What ORS-related political and legal events/issues have occurred during the L.O.P. (e.g., Peru, protracted QC dialogue with FDA) and how have they affected implementation?
6. Has the project submitted the deliverables specified in the cooperative agreement and subsequent documents? Have these been received by A.I.D. on time? (Refer to the PMA deliverables tally sheet developed for the S&T/H Office.)
7. What role was SUPPORT originally to play with development of the CPS? Describe the activities it has actually carried out. What additional resources did this require of SUPPORT? Has A.I.D. been satisfied with the assistance SUPPORT has provided?
8. Has SUPPORT been responsive to field requests for T.A.?
9. Has SUPPORT been responsive to requests and instructions from the CTO? How have these requests been made and followed up on?
10. Assess the history of project implementation in countries: how do initial plans and implementation time schedules compare to actual ones? Have there been delays? What has caused any delays experienced? Has SUPPORT noticed a difference in implementation rates between private versus public/parastatal firms?
11. Describe and assess how SUPPORT has developed its production, quality control, marketing, distribution, and promotion T.A.
12. Has A.I.D. given sufficient mandate and authority to SUPPORT in order for SUPPORT to carry out its responsibilities?
13. Has A.I.D. been responsive to SUPPORT's need for direction, prompt decision-making, funding changes, etc.?

C. Project Coordination

1. Regarding coordination with other contractors (especially HEALTHCOM and PRITECH), when has it been done, how has it been

orchestrated, and are there any problems that have arisen with this (for example, ambiguity as to project jurisdiction)?

2. How has SUPPORT's distance from the A.I.D. office affected communication/liaison?
3. Describe what and how SUPPORT reports to A.I.D.; has A.I.D. been satisfied with this?
4. Has SUPPORT's relationship with PATH's Washington, D.C. office been effective and appropriate? Can it be utilized differently to enhance communications or management of SUPPORT?
5. How effective and responsive have A.I.D. missions been with helping coordinate and expedite SUPPORT's activities?

D. Impact

1. Assess the project's impact in the following areas, (comparing, where possible, what existed prior to the project, what the project intended, and what has been actually realized):

- Number of production sites assisted,
- Scope of services/T.A. provided,
- Number of packets produced,
- Number of packets distributed,
- Type and number of sources/outlets from which ORS is sold,
- Changes in the type/frequency of product promotion and marketing,
- Population with access to product.

2. Recognizing PATH's stated expertise and aptitude for appropriate technology and the technology of ORT, note any innovations, and operational or systemic efficiencies that SUPPORT has learned from this experience.
3. Part of SUPPORT's mission is to disseminate the lessons learned from the field. Mechanisms for doing this have included presentations at conferences and workshops, and periodic releases of short publications entitled Directions. Comment on the effectiveness of these mechanisms. Can this dissemination be improved upon?
4. What impact has SUPPORT's T.A. had on the firms it's worked with?
 - Have firms realized a profit on the product?
 - Would firms consider producing other essential drugs because of this involvement?
 - What impact has SUPPORT T.A. had on the skills and competency of the firms' staff (e.g. QC competency)?
 - Are firms conducting their marketing/promotional activities any differently as a result of SUPPORT's

assistance?

5. Has SUPPORT's work with private firms affected host governments' attitudes about the role the private sector can play with public health endeavors (e.g., the government's willingness to purchase from the private sector)?

6. How has SUPPORT's work impacted on the CDD/ORT efforts of other A.I.D. contractor efforts?

E. Sustainability and Recommendations for the Future

1. Earlier plans considered regional marketing of ORS as a possible way to meet ORS needs of countries too small to do their own manufacturing. Has the project explored the feasibility of this? State this work and findings. What are the implications of these findings?

2. Assess the prospects for sustaining the private sector activities SUPPORT has helped initiate; are the profits and other benefits realized from ORS production sufficient to keep these firms involved with the product?

3. Assess the project's strategies for 1) production T.A., 2) financing, 3) market research, 4) and distribution and promotion; are these considered appropriate in light of project experience to date?

4. Comment on the potential of replicating the SUPPORT-private sector working relationship to other essential drugs or medical supplies.

5. What factors are likely to undermine the success of these efforts following the departure or conclusion of Project SUPPORT. What steps could be taken to insure that the operations started or expanded by SUPPORT in various countries can continue?

6. What is needed to manage the loans that will still be outstanding, when the contract ends? How should this work be handled?

7. The task of consumer training (pharmacists, mothers, health workers) was recognized earlier as a need; does it continue too be? What new directions might this take?

8. Describe what need for business skills training there may be amongst the firms with which SUPPORT works. How has these firms' level of business expertise affected SUPPORT's project success? Does SUPPORT have the ability to address these business skills needs? Should it? What might this assistance consist of?

9. Based on what Project SUPPORT has learned to date, and what is anticipated for worldwide ORS demand, what role can be anticipated for

a SUPPORT-like project (i.e. project demand for production, marketing, QC and promotion T.A.), with ORS work in the future?

10. An earlier semi-annual review meeting report (SAPRM) suggested that SUPPORT develop a list of questions that could guide future research activities. Has the project completed this? If yes, what do the questions suggest about future directions for ORS and SUPPORT?

11. What does Project SUPPORT's experience suggest about the viability of applying this approach (private sector production/promotion assistance) to other essential drugs, pharmaceuticals, or medical supplies?

ANNEX 4

Results of Survey of USAID Missions
Concerning Experience with Project SUPPORT

ANNEX 4

Results of Survey of USAID Missions Concerning Experience with Project SUPPORT

A. Survey of Project SUPPORT Sites

In order to collect additional impressions of the project's field activities in places other than the two countries visited, a cable was sent in October 1988 to all USAID missions in countries where Project SUPPORT had provided assistance of one sort or another. Six countries (Costa Rica, Paraguay, Cameroon, Uganda, Ecuador, and Yemen) responded with replies; two countries (Mexico and Peru) had not yet replied as of this writing.

This cable asked missions questions on the following concerns:

- o The nature of services provided by SUPPORT;
- o Perceived appropriateness and effectiveness of that assistance;
- o Opportunities for applying the SUPPORT approach to other essential drugs or medical products;
- o Comments on the impact this assistance has had (e.g., number of packets produced, numbers distributed, numbers of sales outlets developed, and type and extent of promotion used; and
- o Impressions on the sustainability of this private sector endeavor.

The majority of these countries are places that SUPPORT has initiated but completed its T.A. for ORS production testing and distribution. Comments made are quite brief. When discussed, satisfaction with the work done by SUPPORT staff is consistently well thought of. In almost all cases, these countries require continuing technical assistance as most of these projects are at a very early stage. It follows that there is no mention of impact, it being too early in implementation to assess this.

Only a few comments were made as to other drugs or products that could be produced with this approach. These included, antibiotics for acute respiratory infections, parasite medications, prenatal vitamins, condoms, and other essential drugs. These suggestions seemed to have been made in a tentative, casual context--without a great deal of certainty.

B. Survey of Future Interest in SUPPORT

A second cable was sent worldwide to ascertain the level of interest that existed for a follow on project similar to the current SUPPORT project. It also asked if there were other services or products that could be offered by such a project that may be more appropriate to country needs.

A total of 31 missions responded to this cable. Of these, 16 missions had no interest in such a project, three said with certainty they were interested, and twelve countries gave qualified 'maybe' answers. These countries are listed in Table 4-1.

TABLE 4-1

Cable Responses Expressing Interest
in Project SUPPORT for the Future

<u>Response</u>	<u>Latin America/ Caribbean</u>	<u>Asia/Near East</u>	<u>Africa</u>
No Interest:	Barbados Dominican Republic El Salvador Jamaica	Nepal Burma Jordan	Lesotho Madagascar Mauritania Niger Rwanda Swaziland Togo Zimbabwe Mozambique
Interested:	Haiti	Indonesia	Guinea
May Be Interested:	Bolivia Ecuador ROCAP/Guatemala Honduras	India Tunisia Philippines Morocco Egypt	Chad Senegal Sudan

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C. Buy-Ins

Regarding interest in buying in to the project, of those who voiced strong interest in the project, Haiti was willing to buy-in, Indonesia and Guinea were not. Of the twelve maybe-interested countries, eight mentioned they would be willing to use buy-ins to get SUPPORT's technical assistance.

D. Other Services Needed?

Missions were asked to mention any other services that would make such a project more suitable for local private sector producers in host countries. Responses to this included reiteration of services already provided by SUPPORT and also operations research in the area of ORT, and marketing of contraceptives.

ANNEX 5

Evaluation Team's Assessment Questionnaire Concerning
Local Production and Marketing of Oral Rehydration Salts

ANNEX 5

Evaluation Team's Assessment Questionnaire Concerning
Local Production and Marketing of Oral Rehydration Salts

Prepared by Evaluation Team

H. N. Bhargava, Ph.D., Craig Carlson,
Robert Emrey (Team Leader), and James Messick

September 30, 1988

PART I. PROJECT HEADQUARTERS SECTION

1. Country Selection
 - A. Provide criteria
 - B. Review of actual function
 - C. Recommendations
2. Selection of Private Sector Firms and Organizations
 - A. Selection of Manufacturing and Distribution Firm
 1. What criteria used?
 2. What selection process?
 - B. Selection of Marketing Research Firm
 1. What criteria used?
 2. What selection process?
 - C. Selection of Advertising, Promotion, IEC firm
 1. What criteria used?
 2. What selection process?
 - D. Selection of Training Firm for Pharmacies, Physicians, Nurses, Traditional Birth Attendants
 1. What criteria used?
 2. What selection process?
 - E. Private Sector-Public Sector Coordinated Efforts
 1. Project history and outcomes
 2. Lessons learned
 3. Present status, directionality
 4. Future prospects for additional public-private efforts
 5. Sustainability of present efforts

F. Product Review
(Please provide description, samples, pack, size, price, distribution data, availability, consumption.)

1. Locally produced ORS product--private manufacturer
2. Locally produced ORS product--public manufacturer
3. U.S. provided ORS product
4. UNICEF provided ORS product
5. Commercial ORS (local product)
6. Commercial ORS (imported product)

3. Project SUPPORT Operations

A. Project SUPPORT Human Resources

1. PATH Seattle--Who and how many and what coverage where--adequacy
2. PATH Washington, D.C.--Who and how many and what coverage where--adequacy
3. Recommended changes for last 14 months of project
4. Recommendations for follow-on project
5. PATH Consultants--Data and descriptions and adequacy)
6. Any recommendations for future use of consultants?
7. HEALTHCOM resident advisors--describe and evaluate actual use and desired use of resident advisors
8. Local manufacturers' representative--describe and assess use of any local representatives to assist project. What recommendations?
9. Other recommendations regarding the use of local representatives or advisors to follow-up and coordinate work.

B. Coordination with Missions and AID/W
(USAID Mission--AID/W--Project SUPPORT coordination and cooperation)

1. Describe the functions
2. Assess and situation and potential for coordination and communication of Project SUPPORT
3. Any recommendations for the future?

PART II. HOST COUNTRY SECTION

1. ORS Manufacturer--Part 1: Production

A. Physical Plant

1. Plan site and size
2. Sanitation

3. Ventilation
 4. Segregation
 5. Warehousing
 6. Climatization
 7. Power generation
 8. Water supply
- B. Equipment
1. Production
 2. Packaging
- C. Quality
1. Labor force--Technical quality
 2. Machine
 3. Methods
 4. Materials
 - a. Raw Material, chemicals, packaging size
 - b. In-process
 - c. Finished product
- D. Quality Control
1. Sampling plan
 2. Specification and test method
 3. Guidelines to improve on rejected batches
 4. Retain
 5. Stability studies
 6. Label
- E. Material Sources
1. Status with FDA or other regulatory body
 2. Cost of raw materials
 3. Processing cost--size of batch
 4. Q.C. Cost
- F. Good Manufacturing Practices (Compliance)
2. ORS Manufacturer--Part 2: Marketing Firm/Department
- Key points:
- o Company organization and structure
 - o Human resources and staffing
 - o Function view of department
 - o Structural view of department
 - o Physical resources
 - o Strengths
 - o Needs and plans

- A. Marketing Research
 - 1. Who, how, what, where, how many
 - 2. History
 - 3. Quality
 - 4. Success
 - 5. Strengths and weaknesses
 - 6. Plans
 - 7. Recommendations
 - 8. Have any marketing research results contributed directly to marketing success?

- B. Packaging Information and Review
(Package and mixing container)
 - 1. Design
 - 2. Labeling
 - 3. Pretesting
 - 4. Present status
 - 5. How many and how works on packaging? On mixing containers?
 - 6. Recommendations

- C. Information/Education/Communication (IEC)
(Please review materials, design, message)
 - 1. Testing
 - 2. Media selection
 - 3. Results
 - 4. Plans
 - 5. Recommendations
 - 6. Any successful examples of efforts of IEC?

- D. Promotion
(Review and describe promotional plans and results)
 - 1. Messages
 - 2. Media
 - 3. Results in product sales

- E. Training
(Who has been trained?)
 - 1. Describe programs
 - 2. Situation
 - 3. Needs
 - 4. Activities
 - 5. Results
 - 6. Recommendations
 - 7. Plans

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- F. Pricing
(Review pricing environment, history, rationale)
 - 1. Method for price setting
 - 2. Constraints
 - 3. Present status
 - 4. Recommendations
 - 5. Plans

- G. Evaluation of Program
 - 1. Methodology
 - 2. Results to date
 - 3. Plans
 - 4. Recommendations

- H. Management Information Systems (MIS)
(Describe the MIS Component)
 - 1. Design
 - 2. Set-up
 - 3. Implementation
 - 4. Results
 - 5. Present MIS outputs
 - 6. Recommended changes
 - 7. Plans

- I. Distribution
(Describe distribution system and history)
 - 1. Network structure
 - 2. Function
 - 3. Components
 - 4. Incentives
 - 5. Records
 - 6. Actual sales data
 - 7. Number of personnel and vehicles
 - 8. Other resources

- J. Prospective Health Products for Follow-up Projects
(Please list and describe briefly which of these seem to be most promising and why?)

- K. Project Coordination
 - 1. HEALTHCOM
 - 2. PRITECH
 - 3. SOMARC
 - 4. Enterprise
 - 5. Local UNICEF/WHO/PAHO
 - 6. MOH
 - 7. Other Host Government Ministry or Office

8. Private Sector Firm
9. Other commercial firms
10. Others

L. Impact

(Documented successes in the increase of ORS availability, access, awareness, and sustainability)

1. Packets produced
2. Packets distributed to wholesalers
3. Packets distributed to retailers
4. Estimate of packets distributed to consumers
5. Number of ORS wholesalers
6. Number of ORS retailers (Pre/Post)
7. Training conducted
8. Promotional activities completed
9. Promotional activities planned
10. Awareness measures (research results)
11. Reaction/plan for private manufacturing firm to continue production

M. Governmental Perceptions

1. Perception of host government toward Project SUPPORT
2. Perception of host government toward private firm
3. Perception of host government toward future policies potentially affecting the ORT program and ORS production

N. Project Perceptions

(Perception of CDD/ORT-related contractors toward Project SUPPORT)

3. ORS Manufacturer--Part 3: Investment and Operational Financing

4. Ministry of Health

- A. Status of ORS
- B. Interest in CDD
- C. Resources budget
- D. Budget for pharmaceuticals
- E. Budget for CDD
- F. Supply and distribution system of health care
- G. Cost of imported ORS

5. Food and Drug Administration or similar body

- A. Regulatory status of ORS
- B. Registration of drugs
- C. Safety assessment
- D. Efficacy assessment
- E. Difference between Over the Counter and Ethical Drugs
- F. Powers of FDA

6. UNICEF
 - A. Government attitude to CDD and ORS
 - B. Allocation of resources by Government
 - C. UNICEF contributions--supply distribution
 - D. Program in health care

7. USAID Mission
 - A. MOH relationship
 - B. Reputation of company selected
 1. Drug manufacturer
 2. Quality product
 3. Philosophy of management
 - C. Morale of MOH employees
 - D. Physical infrastructure for transportation, energy, dispensaries, etc., in country.

PART III. EXPERIENCES OF PROJECT SUPPORT

1. Lessons Learned
(Please provide 1 or 2 written examples or anecdotes relating to the local development and implementation of project support)

2. Sustainability Factors
 - A. Profitability of ORS

 - B. Regional Marketing

 Are there possibilities of marketing the local ORS product in other countries of this region? Which countries?

 - C. Strategy

 Are the presently use strategies sufficient to sustain continued success and expansion in these areas:
 1. Production
 2. Financing
 3. Marketing research
 4. Distribution
 5. Promotion
 6. Training

 - D. Replication with other products likely? What products?

 - E. Loan management following end of PATH role?

- F. To what extent may this local ORS product be sustained without USAID support?
 - G. Consumer information and training--if continued at present levels, will consumer interest and use be sustained?
 - H. Business skills--Are they sufficient now to sustain the ORS product success?
3. New Project
- A. To what extent is a continuation or follow-on project needed?
 - B. In a follow-on project, what changes would improve performance and objectives? (In production, in market research, in IEC/Training, in promotion, in personnel, in funding, in quality control, in product development?)
4. Future Project/Follow-on Model
(To what extent will the present Project SUPPORT serve as a model for expansion to new health products and/or services in your country?)

ANNEX 6

Summary of Project SUPPORT Field Activities

ANNEX 6

Summary of Project SUPPORT Field Activities

Prepared by PATH, September 1988

Ongoing Countries:

Cameroon: Cameroon is considered an ongoing project country (receiving assistance in all areas of the project--production, promotion, loan financing) though in a very early stage. An assessment visit was conducted in April, 1988. Since the visit, project development work has been initiated with a private sector firm, Plantecam. A Manufacturing Plan has been drafted and sent to the firm for review. Project SUPPORT assistance will be provided in the following areas: production and QC training, equipment selection, loan financing, and product promotion and marketing. J. Tomaro will visit Cameroon in October to draft a Memorandum of Understanding and outline a course of action.

Ghana: A successful national product launch of the Ghanaian product, "ORS", took place in April and received enthusiastic support and representation from the medical community. A feature article on the launch was submitted for publication in Frontlines. Major follow-up/tracking issues include: 1) monitoring product sales and distribution, especially repeat purchases, and 2) advising UNICEF of concerns regarding the status of the remaining UNICEF one-liter bicarbonate packets and the need to monitor distribution. The key element of the Ghana project that should be highlighted is the successful coordination and cooperation carried out by the various agencies involved in arranging for the production and promotion of "ORS".

Guatemala: The private sector ORS product, "Litrosal" was launched by Adamed on March 24, 1988. Product distribution to pharmacies and private physicians began in May. Promotional activities for "Litrosal" continue being closely coordinated with HEALTHCOM, USAID/Guatemala, and the Ministry of Health. Major follow-up tracking issues include: 1) determination of an appropriate container and volume size for ORS in Guatemala, and 2) monitoring product distribution and sales. The lessons learned in Guatemala are largely due to the local situation where both public and private sector efforts to produce and promote ORS were initiated at the same time. Project SUPPORT has demonstrated that 1) the decision on ORS packet size should be a national effort based on valid research, and 2) in a country where ORS will be manufactured by a private company and a government production facility, the private sector firm has moved ahead with the effective and efficient introduction of a public health product. (Details on coordination with the HEALTHCOM project are provided in Section I).

Paraguay: Launch of Laboratorios Asuncion's (L.A.) ORS product, "Sueroral", will take place in October/November 1988. Prior to production start up, R. Arce will visit Paraguay in August/September to provide L.A. staff with quality assurance training and to validate blending and mixing procedures. L.A.'s new product, "Sueroral", will be promoted at seminars for physicians and community leaders with the assistance of local HEALTHCOM staff. Major follow-up action includes: 1) additional QC testing of L.A.'s product by an outside lab in the U.S.; 2) developing promotional materials for distribution at the upcoming seminars; and 3) preparing for product launch. The main issues to note with the Paraguay project are the cost reduction in the product price, the change in the presentation from a glass vial to a polyfoil laminate packet, and the extensive time and effort involved in making the technology switch. (Details on coordination with the HEALTHCOM project are provided in Section I.)

Peru: It is anticipated that the LUSA product, "Nueva Salvadora", will be available by December 1988, before the diarrhea season begins in Peru. Additional production assistance will be provided by R. Arce after LUCA receives all the materials and equipment. The promotional plan, currently being finalized, includes the development of print materials and a three-month mass media promotional campaign that will be initiated in November. Major follow-up action includes: 1) providing additional production technical assistance; 2) processing of the loan documentation; and 3) implementing the promotional plan. In Peru, the challenge for Project SUPPORT has been to develop strategies on how to promote and reintroduce a product that in recent years was publicized as harmful to infants.

Turkey: Bilim began production of their ORS product, "Litoral", in June 1988. The marketing plan and samples of the promotional materials will be sent to Project SUPPORT and forwarded to S&T/H. Samples of the product will also be tested for conformity with WHO specifications. Major follow-up issues include: 1) monitoring product distribution and sales; and 2) finalizing renegotiations of the financial arrangements with Bilim due to the country's high rate of inflation. The Turkey project demonstrates how a financial incentive to a private firm motivated it to produce and promote a public health product.

Uganda: Following an assessment visit in February, a five-party agreement and a PIO/T were developed outlining project implementation and responsibilities for launching a new ORS product in Uganda. Pending completion of these documents, Project SUPPORT will begin activities in Uganda. Follow-up action includes: 1) processing of the loan for the purchase of equipment and materials; 2) procuring equipment and materials; 3) developing a manufacturing plan; and 4) conducting an operations research study on the most effective means of ORS distribution. At this stage of the project in Uganda, it is too early to note major lessons learned or country highlights. The project will, however, be similar to the Ghana model of multi-agency coordination.

Short Term Technical Assistance Requests:

Costa Rica: At the request of USAID/San Jose, Project SUPPORT staff reviewed a proposal for assessing the feasibility of producing and marketing a pre-mix ORS concentrate. Project SUPPORT staff visited Costa Rica in September 1987 to evaluate the potential safety issues of using an ORS concentrate. The field tests with Costa Rican mothers suggested that there is a significant degree of risk that the concentrate solution may accidentally be taken directly, without dilution in water. For this and several other reasons, Project SUPPORT recommended that introduction of a new ORS concentrate product not be pursued.

Ecuador: In response to a request from USAID/Quito, Project SUPPORT reviewed the disposition of imported ORS stockpiles, and assessed the feasibility of local ORS production.

Mexico: Project SUPPORT has assisted the private firm, Protein Latinoamericanos to promote its commercial ORS product. During the year Project SUPPORT reviewed Protein's ORS marketing plan and assisted in the planning and implementation of a pharmacy KAP/ORT survey. The survey findings suggest future directions that ORS promotion can take for sales through pharmacies. In addition, Project SUPPORT worked closely with the HEALTHCOM project on the development of pictorial instructions for the government ORS product and in collaborating with the public sector ORT program.

Philippines: Recent discussions with HEALTHCOM indicate that there is substantial private sector and Mission interest in receiving Project SUPPORT production assistance. R. Clay noted that the Philippines is a USAID priority country and should be included in Project SUPPORT's Year IV work plan. It was agreed to reclassify the Philippines as a potential project country warranting a project initiation trip in the fall. Arrangements will be made for Project SUPPORT staff to visit in September to conduct assess private sector needs and capacity for ORS production.

Project Identification Trips (Potential Project Countries):

Guinea: Observation of the Guinean Soguipharm plant and unfavorable test results of the firm's ORS product have prompted requests from USAID/Conakry and the Africa Bureau for Project SUPPORT technical assistance. A visit is scheduled for 1989.

Honduras: USAID/Tegucigalpa and the MOH have requested Project SUPPORT's assistance in assessing the production and quality assurance equipment and procedures of two private pharmaceutical firms that will be producing ORS for the private sector. Arrangements have been made for R. Arce to carry out the assignment in early August.

Lesotho: Earlier communication with USAID/Maseru indicated an interest in receiving Project SUPPORT assistance later in the year. Due to budget constraints for Year IV, if an assessment visit is requested, it will need to be made in conjunction with another visit to Africa.

Somalia: Following an initial visit in February 1988, no requests for Project SUPPORT assistance have been received from the Mission. Due to project funding constraints, no activities in Somalia have been budgeted for Year IV.

Zaire: PATH is scheduled to visit Zaire in February to assess the prospects for local private sector manufacture and marketing of ORS. Since it is very probable that additional follow-up assistance will be required during Year IV, it was suggested that the Project SUPPORT budget include funding for ongoing activity in Zaire.

Transferred to PRITECH or Postponed/Cancelled:

Bangladesh: In response to requests for Project SUPPORT assistance in studying the feasibility of ORS production by the local social marketing program, a two-week visit will be conducted by R. Fields and M. Fry in late August. Due to budget constraints, the team assessment visit will be funded by the PRITECH project.

Yemen: An agreement has been signed by the MOH, UNICEF, and Yedco for the initiation of local ORS production. Implementation of this activity will be carried out with Mission buy-in funds through the PRITECH project.

Zambia: As a follow-up activity to a Project SUPPORT assessment visit conducted in September 1987, the PRITECH project sent a Project SUPPORT consultant to Zambia to provide the private firm, Interchem, with communications assistance for product promotion and advertising. No additional activities are anticipated in Zambia during Year IV.

ANNEX 7

Bibliography

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ANNEX 8

List of People Contacted

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List of People Contacted

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