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PROJECT SUPPORT II

PROJECT PAPER

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Supply, Production, and Promotion
of Oral Rehydration Salts

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Division of Health Services
Office of Health
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TABLE OF CONTENTS

	<u>Page</u>
Project Summary	iii
I. Background	1
A. The Problem	1
B. Project Strategy	6
C. Findings from Project SUPPORT Evaluation	9
D. A.I.D. Policies	9
II. Project Description	11
A. Goal	11
B. Purpose and Specific Objectives	11
C. Project Components	13
D. Expected Accomplishments and Achievements	18
III. Financial Plan	19
IV. Implementation Plan	20
A. A.I.D. Management	20
B. Contractor Services	21
1. Contractor Activities	23
2. Gray Amendment Considerations	24
3. Project Staffing	25
4. Relationships with Host Countries and Firms	28
C. Project Monitoring	28
1. Contractor Reporting	28
2. Technical Advisory Group	30
D. Project Evaluation	31
E. Implementation Schedule	32
V. Project Analyses	33
A. Technical Analysis	33
B. Social Soundness Analysis	35
C. Administrative Analysis	37
D. Financial Analysis	38
 Annexes	
A. Findings from Project SUPPORT Evaluation	39
B. Logical Framework	42
C. Implementation Plan	43
D. Concept Paper and Waiver of PID	
E. Summary of Mission Responses	
F. Financial Plan	

Project Summary

Background and Problem

Diarrheal diseases remain one of the leading causes of morbidity and mortality among infants and children in developing countries. The dehydration caused by diarrheal diseases kills an estimated 2 and a half million children every year. Oral rehydration salts (ORS), a very effective, inexpensive, and easy to use therapy is available to combat this dehydration. But access to ORS continues to be a problem in most developing countries.

Strategy

To address this problem, A.I.D. is pursuing a number of strategies. One of these, which Project SUPPORT II addresses, involves encouraging local, private sector production, marketing and distribution of ORS. There are a number of advantages to be gained by pursuing this strategy. Involving private sector pharmaceutical firms means their commercial distribution and sales networks can be utilized to supply and sell ORS. This greatly increases the number of ORS outlets, which previously were limited to public health clinics and hospitals. Secondly, private sector production is far more likely to become a sustained activity when firms, selling the product for a price, can cover their production and investment costs. Private firms typically demonstrate greater efficiencies in all facets of production and sales, thus keeping costs to a minimum. Well established firms have considerable interest in assuring that all their products are of acceptable quality.

A.I.D.'s strategy is to tap the dynamics of the private sector, investing the minimum amount of resources needed to launch these production facilities. Following a list of criteria, appropriate countries and firms are identified that can benefit from such enterprises, and who are interested in receiving such assistance. Close coordination between the public and private sector players is a necessity. Working with reputable, well-established firms, ORS products specially developed for local markets and consumer tastes are manufactured and distributed. Depending on the situation in each country, the private firm may provide ORS to the public sector, or may sell its product in addition to the public sector's version.

Activities

Project SUPPORT I, which initiated this strategy and activities in 1985, will be ending in October 1989. A follow-on SUPPORT II project is needed to continue this technical assistance. SUPPORT II will provide the necessary continuing assistance and monitoring of project sites initiated under the first project, until they are able to operate without assistance. This project will also initiate comprehensive assistance delivery to approximately four new sites. Technical assistance includes feasibility studies, market research, product development, production set-up, equipment selection, establishing quality control measures, labeling and packaging, marketing strategies, and distribution and logistic concerns.

Short term assistance in various facets of these technical areas will also be provided by SUPPORT II in up to 12 countries over the life of the project.

Policy dialogue, where appropriate, will be pursued by this project to encourage the revision or adoption of policies and regulations conducive to appropriate private sector involvement. As with SUPPORT I, this project will continue to promote and require close coordination between public sector CDD/ORT programs (where they exist) and private sector production/distribution activities.

SUPPORT II will have a operations and pharmaceutical research component that will address issues pertinent to local production/marketing, and the ORS product itself. While most of this research will focus on ORS concerns, a limited amount of attention will be provided to address questions pertaining to other essential drugs, their manufacture, distribution and use.

An increased amount of effort will be put into collecting, documenting and disseminating the experience of this project, and new developments in this field that are of broad interest to the health and economic development communities.

Financial Plan

This will be a five year project with total funding of \$10 million. Approximately half of this will originate from mission and regional buy-ins. These will be used for the majority of sustained country programs, regional training efforts, loan funds for the sustained sites' equipment and capital improvements, and some of the short term technical assistance work. Central funds will cover the balance of the sustained and short term field work, and the research and information dissemination components.

Implementation Plan

The project will be carried out through a cooperative agreement. The substantial amount of involvement to be provided by the CTO, and the flexibility that should be designed in to field work and research components of this project make this the most appropriate mechanism to use.

This project will be managed by an S&T/Health cognizant technical officer (CTO) who will be involved in all stages of the agreement and subsequent implementation. This will include selection, approval, and review of all research and information dissemination activities. The CTO will also play a key role with coordinating the activities of this project with those of the other S&T/H projects active in CDD.

Technical capabilities of the agreement recipient will be very important, and challenging to collect given the diverse areas of expertise called for. These should include child survival programming experience in developing countries, and consulting experience with for-profit production and marketing enterprises, industrial pharmacy and marketing, and small enterprise development. Staff background should reflect these general and specific technical needs. Monitoring of activities will rely on the usual reports as well as technical advisory group reviews held periodically through the life of the project. Evaluations will be conducted at the midway point, and at the end of the fourth year of the project.

I. BACKGROUND

A. The Problem

1. Limited Access to ORS

Diarrhea is one of the most serious health problems facing infants and young children throughout the developing world, killing an estimated three to five million children each year. This constitutes as much as one-third of mortality from all causes among 0 to 5 year-old children in LDCs.

In most cases it is usually dehydration resulting from the diarrhea that causes death. Dehydration involves losses of water and electrolytes (sodium, potassium, chloride, and bicarbonate) beyond what the body can tolerate. The typical child growing up in a third world country experiences on average two to five episodes of diarrhea every year and has diarrhea on 20 to 30 days of every year. About 10% of diarrhea episodes lead to dehydration. One to two percent of these cases are serious enough to be life threatening, which, UNICEF estimates, results in two and a half million children's deaths each year.

Rehydration therapies to replace lost fluids and electrolytes can eliminate a large proportion of these deaths. Two of these therapies are: intravenous (IV) administration of fluids and oral rehydration. IV fluids are very effective in those areas where such supplies and medical personnel are available to administer it. However, it is expensive and must be administered under close supervision of a health professional in a hospital or clinic setting. This greatly limits the number of patients who have access to it. For the vast majority of people with diarrheal diseases, IV therapy is not an option.

Oral rehydration therapy (ORT) became available in the last two decades. ORS is an inexpensive and easily used therapy for dehydration. The key problems with ORT are their limited availability and lack of user knowledge in many countries.

In the long run only sanitation, clean water and safe food, better nutrition, and improved living conditions can prevent or reduce the incidence of diarrhea among infants and children. Accomplishing such programs can be very expensive, taking perhaps decades of effort, and is dependent on considerable infrastructure development. In the meantime, ORT and ORS can provide mothers and families with a means to prevent many of the deaths that would otherwise occur.

Oral rehydration therapy has become widely recognized and

appreciated as effective for dehydration. The general term, "oral rehydration therapy" can refer to home available fluids, solutions of salt and sugar prepared in the home, or commercially prepared mixtures (that include key electrolytes as well as sugar and salt). ORT has been found to be an effective and appropriate alternative to IV therapy in all but the most severe cases of dehydration. Like IV therapy, ORT does not cure the diarrhea. Rather, it maintains or restores the body's critical fluid balance until the infection subsides.

Most episodes of diarrhea are self-limiting in 3 to 6 days. Maintaining sufficient fluid intake with ORT during these bouts can eliminate much of the mortality that results from dehydration. In contrast to IV therapy, ORT and ORS are easily administered, significantly cheaper, and easier to distribute and obtain. It can also be easily administered by lay people after only a few basic instructions, thus making it available for community distribution and home use.

Home available fluids (HAVs), sugar and salt solutions (SSS), and commercially prepared salts that include key electrolytes (ORS) each have advantages and disadvantages. HAVs such as rice water, young coconut water, and soup, can help maintain a child's fluids when diarrhea is mild. Like HAVs, SSS also has the advantage of being a therapy that can be prepared in the home, but is thought to be more effective than HAVs, when mixed correctly. It can also serve as a backup when ORS is not available, but SSS has its limitations too. Measuring correct proportions of salt and sugar is critical in order for it to be effective and safe. Sugar and salt may not be as widely available in homes as expected.

Commercially prepared oral rehydration salts (ORS) are widely thought to be the best formulation for rehydrating of dehydrated children. Good quality control during manufacture are required to ensure proper proportions of ingredients. Key electrolytes such as potassium and bicarbonate (or citrate) can prevent or correct potentially dangerous imbalances in the patient. ORS does have its drawbacks, one being its cost. Locally manufactured ORS averages about ten cents U.S. per liter sachet to manufacture. Some countries may lack the expertise necessary to manufacture ORS safely. Some countries may also have insufficient demand in the country to make production economically viable.

Unfortunately, access to and use of ORT/ORS remains quite limited. This is now the foremost problem and challenge for public diarrhea control programs today. Access to ORT and ORS, defined as the proportion of the population less than five years of age, with reasonable access to a trained supplier of ORS or informed mixer of ORT, is currently 58%. Estimated rates of use for ORT/ORS during diarrhea bouts remains at around 23% world-

wide. Usage figures for ORS alone are significantly lower.

Many factors account for these low rates of access. In most developing countries, ORS is still a comparatively new product with an as-of-yet unappreciated, unrecognized market. Firms that would typically respond to such a market simply have not yet done so.

In some countries, legal or regulatory statutes may hinder or discourage the production, distribution or sale of ORS. For example, classifying it as a prescription pharmaceutical would require mothers to visit a physician and pharmacy before gaining access to the product.

Shortage of product can also be a factor. The quantities UNICEF is able to provide any given country may not be enough. Purchasing additional supplies is out of the question for most countries, where foreign exchange is hard to come by. And local production, for a host of reasons, is not an option in all developing countries.

In many countries, ORS distribution is carried out only through public sector clinics. This poses obvious problems for those people not close to such facilities, or who need it after clinic hours. It also means that supplies of ORS will be dependent on public sector shipping and distribution systems which are often severely handicapped. This strain on public health facilities gets greater as populations grow and more people migrate into urban and periurban areas where they have access to such clinics.

Cost can serve as a major impediment to access. Surveying many developing countries' pharmacies will turn up a wide range of diarrheal therapeutics. These items are typically sold for very high prices, because there are few alternative products, and quantities are limited. Pharmacists have a clear financial interest in promoting these more profitable products over ORS.

2. ORT/ORS Program Implementation

Many developing countries and international assistance groups have begun programs that address various aspects of diarrheal diseases. Collectively these are often referred to as Control of Diarrheal Disease programs, or simply CDD. Some of these groups' strategies focus on preventive measures that target disease transmission, such as water and sanitation programs, and education on personal hygiene and food handling. Nutrition programs, promoting amongst other things continued feeding during bouts of diarrhea, breast feeding, and feeding with key nutrients like vitamin A, are also part of this preventive effort.

Other programs focus on changing behaviors and practices that contribute to prevention and/or treatment of diarrheal diseases. Considerable health systems development support is also provided to programs such as expanded immunization. Donors and international assistance groups also conduct or support research on new vaccines that target the leading diarrheal disease agents such as rotavirus and cholera.

Other components of CDD programs focus on treatment and therapy of diarrhea cases, (or case management as it is known in the field). Included here has been policy dialogue to encourage adoption of sound medical practices as well as training of professional and paraprofessional health workers and lay people, including mothers. Research is also being conducted on different formulas of ORS, some that contain flavoring and/or coloring, others that include nutritional supplements. Finally, other programs focus on making ORS commodities more readily available, through procurement or local production assistance.

Along with A.I.D., the World Health Organization (WHO), and the United Nations Children Fund (UNICEF), are providing leadership and major assistance to combat diarrheal diseases. The WHO CDD Program provides technical support and funding for countries implementing national CDD programs. Since 1980, CDD programs have been established in 96 countries, which comprise 98% of the total population of the developing world. One of WHO's major activities has been training, emphasizing skills for mid-level and senior program managers. Technical training has also been prioritized, as well as development of manuals and guidelines for general distribution. Since 1984, a considerably expanded program of biomedical and epidemiological research has been in operation.

UNICEF has assisted governments with ORS commodities and distribution and logistics technical support. They have also provided direct assistance to over half of the fifty-five countries that have or are attempting local production. In some cases this has taken the form of equipment and production set up, in others it has meant quality control and packet design. Almost all UNICEF field offices are involved in some way with promotion of ORT as the preferred treatment for diarrhea and dehydration.

3. Involving the Private Sector

Among the international donor community, A.I.D. has taken the lead in acknowledging the limitations which confront the public sector in providing services to the general public; and in identifying appropriate spheres of responsibility in which the private sector can have a beneficial effect. In the area of diarrheal disease control, there are a number of advan-

tages to be gained by involving private sector groups in ORS production and distribution. Private for-profit firms typically exhibit greater production efficiencies, which help keep product costs to a minimum. Private sector competition also serves to keep firms responsive to consumer preferences. Established private firms also have a greater amount of expertise in pharmaceutical production and quality control, as a result of their more extensive manufacturing experience.

Private sector advantages exist in the marketing area as well. Pharmaceutical firms employ teams of detail men to develop and maintain good contacts with private physicians and pharmacists. Both physicians and pharmacists hold a great deal of influence over consumers' drug purchasing choices. Private firms also pursue the most cost-effective channels for advertising their products. They have a considerable amount of experience accumulated from the promotion of other products that can be applied to ORS. Incorporated with this more effective marketing is the willingness to adapt products' labeling and packaging to satisfy local market and consumer preferences. Surveying consumers to determine the most desired type of packaging, sizes, and instructions on products is widely recognized as important to a complete market analysis.

For all these reasons, private firms offer considerable potential for increasing access to health commodities. This seems particularly true for a commodity like ORS, for which financial incentives could spur local, for-profit pharmaceutical firms to manufacture, distribute and promote ORS in their respective countries.

While the number of countries with local production efforts has been increasing, it still constitutes only a small proportion of all LDC countries. In any given country though, a variety of other factors, actual or perceived, may discourage private pharmaceutical firms from producing and marketing ORS. Some examples of these obstacles to local production include:

- o Demand for ORS may be considered insufficient in some developing countries to justify entry into the market. Unlike pain killers or cough syrups which consumers readily perceive the benefit of, ORS is still largely an under-recognized, under-appreciated form of therapy among the general population. The fact that ORS does not do what mothers want it to do--that is, it does not stop diarrhea--contributes to its lack of appreciation. The fact that antidiarrheal products falsely claim to stop diarrhea does not help either.
- o ORS tends to have a small profit margin. Marketing of ORS is directed towards poorer segments of the population among whom diarrheal rates are highest. These

populations could not consider a more expensive product. Compounding this situation are the greater profits companies may reap from production/sales of other types of anti-diarrheals, many of which are ineffective or contraindicated.

- o Foreign currency, sometimes needed to procure raw materials, can be difficult to obtain. In some cases firms cannot obtain the ingredients needed for ORS from local sources. This necessitates purchasing from overseas sources that require foreign exchange.
- o Firms may lack knowledge of production technologies and Good Manufacturing Practices (GMPs) required to manufacture this product efficiently and safely. Blending four dry powders of different particle size and specific gravity is a fairly exacting process. Quality control is critical because of the adverse consequences that can result from excessive amounts of potassium or sodium. While these technologies and training can be transferred to such firms, it involves a moderate amount of investment.
- o Public sector's free distribution of ORS can spill over and saturate the market that private firms would go after.
- o Government Officials may be resistance to private sector involvement in health activities. There may be suspicions, mistrust, and very fundamental ideological differences between public and private sector groups.

These factors, occurring individually or in combination, can discourage private firms from getting involved with ORS production and distribution.

B. Project Strategy

Both SUPPORT projects' I and II embody the same strategy. This strategy seeks to encourage local private pharmaceutical businesses to get involved with ORS production and promotion. To encourage this involvement, only the minimum assistance necessary is provided. By minimizing this assistance, it is thought that dependence and excessive involvement will be avoided. Private firms involved will remain subject to open market forces just as before. There will be no attempt to provide protection or shelter these ventures or firms once initiated.

This strategy does recognize the need to obtain the government's support for local production before attempting such an

undertaking. Usually this approval must be obtained from all the government parties involved (for example ministries of health and drug regulation), including any regulatory or legal agencies that are involved with private pharmaceutical regulation. There must also be sufficient existing or potential demand for ORS in a country before production start up would be considered. Coordinating private and public activities is critical for long term success. While such coordination may cause delays for the private firms, it is a prerequisite for long term success.

ORS products developed with this assistance are intended only for local consumption, or nearby intra-regional sales. They would not otherwise be exported internationally to compete in other markets. In fact, there is little or no U.S. export production of ORS.

Finally, this strategy includes limiting assistance to those pharmaceutical firms that are well-established, have demonstrated financial stability, and have demonstrated consistent concern for quality of production. Such firms have far more expertise to offer, and more reputation and business to lose if they cut corners and release an inferior product.

Not all countries are appropriate sites for local production. Insufficient demand, lack of an adequately experienced pharmaceutical firm, restrictive policies and regulations, or resistance by public officials can pose serious problems to attempting such work. Existence of any of these conditions could mean that it is most advisable not to initiate local production. In such cases, importation of ORS commodities may be the recommended alternative, until local circumstances change.

A.I.D. began putting this strategy into action in 1985 when it initiated a cooperative agreement with The Program for Appropriate Technologies in Health (PATH) of Seattle. In the beginning months of the project, oversight was shared between the S&T Office of Health and the Private Enterprise Bureau. The project was called "SUPPORT" (Supply, Production, and Promotion of ORS). This project's objective was to provide technical assistance and loans to help establish local production facilities in 4 countries, two of which would be producing by the end of the agreement. A cooperative agreement was used as the contractual mechanism in recognition of the exploratory nature of this enterprise. The three-year project was extended for a fourth year and now expires in October 1989.

Project SUPPORT sought to identify and select those countries with interest in, and the greatest potential for sustained local production. Guidelines for selecting countries included:

- o Existence of sufficient demand and need for ORS;

- o Degree of government support for ORS;
- o Level of technical feasibility; and
- o A.I.D. Child Survival priority country.

In places where a national ORT program was operating successfully, local ORS production would replace the international donor imports of ORS packets. In other places, where the national ORT program was not yet functioning successfully, project SUPPORT could serve as a catalyst for further expansion of the national ORT program. The project provided technical assistance and incentives to local private pharmaceutical firms that helped make ORS production feasible. Such assistance typically included:

- o Either direct loans or loan guarantees used for capital improvement and/or equipment procurement;
- o Guidance on production and quality assurance equipment, where to get it, and, in certain cases, actual equipment procurement;
- o Technical assistance and training of staff in all aspects of production and quality control;
- o Technical assistance and training of staff in marketing and distribution issues including, market analysis, product placement, labeling and packaging, pricing, storage and distribution.

Several project sites received all or most of these types of assistance. By the end of its fourth and final year, SUPPORT will have helped initiate ORS production in five countries:

Turkey	Ghana
Guatemala	Peru
Paraguay	Uganda

PATH has also provided short term assistance to a number of other countries in areas such as product use, consumer research, quality assurance, and marketing. Those countries were:

Philippines	Costa Rica
Ecuador	Mexico
Guinea	Honduras
Lesotho	Zaire
Somalia	Yemen
Cameroon	

Finally, the project also provided technical assistance to AID/W with the latter's efforts to plan a centralized procurement system for ORS, and to establish more appropriate quality

assurance measures for ORS manufacture.

C. Findings from Project SUPPORT Evaluation

A final evaluation of Project SUPPORT I was conducted in September and October 1988. This included field visits to ORS manufacturers participating in the project in Guatemala and Ghana. Important lessons concerning the viability and how to's of working with private pharmaceutical firms have been learned from almost four years of testing the SUPPORT strategy.

The evaluation findings are contained in the Annex to this paper. The design for Project SUPPORT II incorporates these evaluation findings and expands on the private sector initiatives begun in SUPPORT I. Over three years of experience gained from SUPPORT I has contributed significantly to A.I.D.'s knowledge of how to plan and implement ventures with private ORS manufacturers.

D. A.I.D. Policies

The strategy proposed for this project translates into practice many of the key aspects of A.I.D.'s policies and goals pertaining to Private Enterprise Development, Diarrheal Disease Control, and Women in Development.

1. Private Enterprise Development

A.I.D.'s private enterprise development (PED) policy objective in pursuing "the ultimate goal of growth, is the establishment of viable, competitive markets and the expansion of private enterprise in LDCs" (Policy, pg. 10). Project SUPPORT II will contribute to this objective through its provision of technical assistance to firms, resulting in upgrading of their business planning, operations, and products, thus making them more competitive.

The project's policy dialogue component addresses, in a very immediate and applied way, those government policies and regulations that impact on local private enterprise. Issues such as drug regulation and classification, import tariffs, and pricing can arise when SUPPORT II becomes involved with developing competitive local ORS products. These matters and others will be carefully assessed when considering assisting with a local production effort. Where potential impediments exist, the project will initiate dialogue with the appropriate government source to discuss revisions. There may be cases where the aggregate effect of such regulations makes local production inappropriate. In such cases, project staff would so advise all parties involved.

The A.I.D. policy "preference is to build up and rely on the indigenous private sector...rather than to assist continued reliance on parastatals" (Policy, pg. 10). SUPPORT II incorporates this into the selection process of appropriate firms, specifying that it works with private, for-profit firms in all but the most special of circumstances.

This project's use of loans also follows A.I.D.'s strategy. The PED Strategy specifies that providing financial capital is appropriate where resources are channeled to activities which (1) are consistent with A.I.D.'s country development strategy, and (2) are unable to attract the full amount of required financial capital from commercial sources (Policy, pg. 13). Further, loans are provided only where necessary. In some situations, A.I.D. project funds are used as collateral against a local financial institution's loan to the company in question. SUPPORT II assistance is provided only to those places where the mission has requested such assistance and has included local production as part of its development initiative.

2. Diarrheal Disease Control

A.I.D. has led the international community in directing attention to the role of the private sector in pursuing health objectives. Agency policies encourage harnessing of private sector efforts to further economic and social development.

The A.I.D. Control of Diarrheal Diseases Strategy states, "The private sector as well as the public sector should be included in planning and program activities Commercial manufacturers produce and distribute medications widely, often with much better coverage than possible from public sector drug distribution ORT programs must actively seek to include these private sector elements in all aspects of their program efforts Local private sector manufacturers should be encouraged and, if appropriate, supported in the local production and commercial sales of ORS (Policy, pgs. 13-14)."

Project SUPPORT is a well-integrated enactment of these directives. It harnesses private sector dynamics and resources in pursuit of health objectives. Close coordination between public and private sectors is maintained through the duration of in-country activities. Both reap the benefits of the increased availability and access provided by private production and distribution channels.

3. Women in Development

The A.I.D. policy concerning women in development aims to ensure that women have access to the opportunities and benefits of economic development. This project addresses two devel-

opment aims: improved health status through access to ORS products and private sector economic development through fostering of industrial production and employment. Women will benefit directly from both aims of the project.

ORS empowers mothers with a means to take direct action for their families' welfare by providing them with therapeutic to treat potentially life-threatening diarrhea. In addition, the project will seek the collaboration of women and women's groups in the design and implementation of promotional and educational efforts at each private sector firm. Women, specifically mothers, constitute the target group for communications and promotional campaigns. Educating them on the benefits and use of ORS makes them more effective care-givers.

The private sector economic development aims of the project will provide opportunities for employment of women in all phases of the commercial enterprise. SUPPORT I's experience reconfirmed that women play significant roles in all phases of these small and medium-sized firms, including managerial, marketing, and technical positions. The project will give special attention with training and development efforts to ensure that women are given opportunities for training and advancement. In addition, collaboration with women who have positions of responsibility within the host country health sector will be sought in the policy dialogue component of the project.

II. PROJECT DESCRIPTION

A. Goal

The overall goal of this project is to improve the health status of infants and children in developing countries. The program goal is to provide appropriate therapeutic agents--especially oral rehydration salts (ORS)--for diseases that contribute to high infant and child mortality.

B. Purpose and Specific Objectives

The purpose of the project is to promote and foster private sector production and marketing of low cost, high quality ORS, including the results of project-funded research on new or enhanced ORS products. In addition, the project will provide assistance in determining the feasibility of producing other health-related products in the private sector which support child survival goals and will help with further development of the A.I.D. central procurement system for ORS packets.

The project seeks to achieve several specific objectives

related to local production:

- (a) Sustain the availability, accessibility, and quality of locally produced oral rehydration salts which are being manufactured by Project SUPPORT I assisted firms;
- (b) Reach agreements with one or more companies in each of up to four developing countries for comprehensive technical and financial assistance leading to the manufacture and/or distribution of ORS. (The time-phased sequence of steps taken at each project site would be staggered over time to permit continued attention and follow-up by project staff of previously launched firms as well as new ones.) Technical assistance will be continued, including follow-up of quality control surveillance, at all Project SUPPORT I sites. Activities in all new sites will be initiated no later than the end of Year 3.
- (c) Provide short-term (up to two months) assistance in up to twelve (12) countries, working usually with local USAID missions and pharmaceutical firms in the areas of production, quality assurance, or marketing, or combinations of these areas.
- (d) Develop operations and pharmaceutical research studies in approximately twelve (12) issue areas, concerning, for instance, ORS packaging and production improvements, quality assurance procedures, ORS sales and distribution methods, and ORS formula and presentation enhancements.
- (e) Document, validate, and disseminate written instructional materials (audio or video materials, if deemed appropriate) concerning the ORS production, quality assurance, and marketing processes, including but not limited to: equipment maintenance procedures, Good Manufacturing Practices (GMP) for ORS, packaging and testing processes, marketing procedures, market forecasting, and methods for cost control.
- (f) Conduct up to three (3) feasibility studies for establishment of production for other health-related products.

With respect to assisting in the formation of an A.I.D. central procurement system, the project seeks to:

- (g) Provide technical assistance, as needed, to procure and distribute to country ports, U.S. produced ORS packets requested by USAID missions.

C. Project Components

The project will have four implementation components through which the work will be accomplished:

- o Country Programs. The country programs will consist of all technical assistance and financing provided to establish and sustain local producers of ORS, including short-term assistance in ORS production, quality control, or marketing, or combinations of these areas.
- o Health System Support. The programs in this component will include assistance provided to AID/Washington, USAID Missions, international organizations, and other A.I.D. projects related to private sector initiatives in health production and marketing.
- o Research and Evaluation. This component will focus on operations research, pharmaceutical product research, and impact evaluation of projects implemented in the country programs.
- o Information Collection and Dissemination. This component will focus on assembling and publishing technical and managerial information of use to policymakers, company managers, and health professionals related to local private sector production of pharmaceuticals and related topics.

It is expected that at least eighty percent (80%) of project resources will be used for technical assistance, training, and equipment financing for oral rehydration salts production. The remaining twenty percent (20%) will be applied to development of production in other health-related products and the ST/H central procurement system for oral rehydration salts.

The remainder of this section explains the project activities in each component and their approximate level of effort.

1. Country Programs

The country programs will be organized to provide technical and financial assistance for both the previous Project SUPPORT I projects as well as the country programs which will be launched during Project SUPPORT II. Three levels of involvement will be used for country programs, depending on the degree of assistance required and the previous involvement of the firm with the Project. The levels of involvement will be as follows:

- o Sustained--All technical assistance and financing pro-

vided to establish and sustain new local producers of ORS in a total of 7 countries. This assistance may include use of medium-term advisors. The project sites under Project SUPPORT I which have not had their product launch--Paraguay, Peru, and Uganda--are included in this category. In addition, up to four new sites will be added to this under SUPPORT II.

- o Intermittent--Technical assistance required to assist and follow-up the project sites launched under Project SUPPORT I are included in this category. These were: Turkey, Guatemala, and Ghana.
- o Ad Hoc Short-Term--Technical assistance will be provided to firms requiring consultations of up to two months during a given year for the purpose of solving production, quality assurance, or marketing problems.

Local producers of ORS products must overcome many barriers to entry and profitable operation in this segment of the drug market. The project addresses directly those obstacles and seeks to assure the profitability of the producers' efforts with the ORS product. The project services provided under Project SUPPORT I will be continued in this project. In addition, the project evaluation suggested the addition to SUPPORT II of policy dialogues and of designated demonstration and training centers, and these will be included in the new project.

The full range of services noted below will be provided in the Sustained Activity sites. Selected services, as required by each site's needs and interests, will be provided in the Intermittent Activity and Ad Hoc Short Term project sites:

- o Feasibility Study/Business Planning--Conduct field studies to determine the suitability of countries and firms to enter local ORS production and prepare integrated business plans for sites meeting project selection criteria.
- o Policy dialogue--The project will provide resources and a mechanism through which legal, political, and other policy constraints to successful private sector local production, distribution, and marketing of ORS can be identified and possibly addressed--by the project or by A.I.D. and other donors, or by appropriate interested parties with decision makers, through policy dialogue. The policy dialogue would seek to provide information (and potentially demonstrations at Training and Demonstration sites) of certain key issues: The benefits to public health of increasing the proportion of sales of ORS over competing, ineffective anti-diarrheal products; the value of increased public

sector support for private sector involvement in ORS; and the importance of effective host country and regional oversight of product quality.

- o Financing and Commodities.--Negotiate direct loans or loan guarantees to be funded from project core funds or buy-in sources to finance procurement and installation of equipment required by local firms participating in the project, covering production, quality assurance and quality control.
- o Production training and assistance.--Provide before product-launch and post-launch training and technical assistance in industrial pharmacy and production engineering methods, including preparation of a written production manual for each site and of written instructional materials meeting Good Manufacturing Practices (GMPs).
- o Quality assurance training and assistance.--Provide training and technical assistance for all aspects of quality assurance, including preparation of a written quality assurance manual for each site and written training and reference materials and validation of production processes and quality assurance procedures.
- o Marketing/distribution training and assistance.--Provide training and technical assistance for marketing services (including the "P's" of marketing: place, product, price, promotion, and packaging) and relations with host government ORT agencies), including a written marketing manual for each site and written instructional and reference materials on marketing.
- o Quality control follow-up and laboratory services.--Provide quality control monitoring and follow-up services for the products made by participating firms, including in-house or contract laboratory analysis services.
- o Training and demonstration centers.--Designate four (4) sites as Training and Demonstration Centers from among the group of project-assisted firms or others which uphold high standards of GMP and marketing. These Centers will be selected for geographic and cultural diversity and will be located so as that there is at least one site each which uses French, Spanish, and English as its working language. Impact studies, documentation of procedures, and training activities will be provided in or adjacent to the premises of the Centers.

2. Health System Support

The programs in this component will include assistance provided to AID/Washington, USAID Missions, international organizations, and other A.I.D. projects related to private sector initiatives in health production and marketing. The following two areas will receive specific attention during the project and others may be considered for inclusion with approval of the CTO:

- o ORS Procurement for ST/H.--Provide technical assistance to A.I.D. officials in formation of a central procurement process for ORS packets to serve USAID mission requirements. The purpose of the central procurement process for ORS packets is to ensure USAID mission access to high quality packets on a timely basis. Some missions need to provide packets on an interim basis while other aspects of local ORT programs take hold. Other missions will have a long-term role in providing their host countries with supplies of ORS packets. In addition to technical services under the project cooperative agreement, funding from the project may be provided outside the agreement to make ORS purchases on an interim basis in starting-up the central procurement process. The funding for commodity procurement is not being provided through the cooperative agreement but instead will be used, if needed, in furtherance of the procurement actions for ORS already started by S&T/H in 1988.
- o Surveys of feasibility for other health-related products.--Provide technical assistance to investigate the feasibility of local firms entering production or marketing (including distribution) of health-related products. Such products would be selected for their suitability in supporting Child Survival program objectives and their viability as business ventures. Examples of such products may include: out-of-patent over the counter therapeutic products which can be used without sophisticated medical care delivery systems, diagnostic products, and or other treatment devices.

3. Research and Evaluation

This component will focus on operations research, pharmaceutical product research, and impact evaluation of projects implemented in the country programs.

- o Pharmaceutical research.--The ingredients now used in the WHO formulation of ORS and the methods of packaging

have evolved over the past twenty years as new discoveries were made about the pharmacological and physiological aspects of oral rehydration. Also, newer technologies have aided the process of filling and packaging of ORS packets, based on work done in the field of industrial pharmacy. Specialists in these fields are focusing attention now on several problems related to: enrichment of the WHO formula for ORS to combat malnutrition often found among dehydrated infants (this area is generally termed, "super-ORS"); studies related to expanding the range of available presentations in addition to the simple dry powder product to include perhaps low-cost liquids and other ways of packaging electrolytes; tests of product stability; and arrangements for enhancing the aesthetics of the simple ORS formula through flavoring or coloring. Within this wide range of scientific activity, only a small amount of resources will be contributed by the project. The objective of the research will be to improve access to ORS products by low income populations through modifications or enhancements in the present product or its presentation. The pharmaceutical services research agenda will be set during the ninth month of the project, based on a technical symposium to be convened during the seventh or eighth month after start-up. Upon approval by the CTO of the research agenda, the project will announce a request for proposals for pharmaceutical services studies of ORS products based on the research agenda. Examples of study areas could include the following: Product research and quality control support; packaging studies; documentation and training materials.

- o Operations research.--Analytical methods will be applied to several areas of production, marketing, and quality assurance in an effort to solve certain operational problems. A review of operational problems will be made by the teams visiting existing project sites during the fourth and fifth month of project implementation. From this review, a operations research plan will be prepared by month six for approval by the CTO. Before beginning a given operations research study, the recipient will conduct a thorough problem analysis to define the operational problem and establish research priorities. Examples of research topics which could be included are the following: product presentation, demand elasticity, production methods, marketing and distribution arrangements, equipment selection and maintenance, and quality assurance systems.
- o Impact Evaluation.--The final evaluation Project SUPPORT I recommended that impact evaluation studies be

conducted during SUPPORT II to increase the understanding of how local ORS production is able to contribute to improved child health. An evaluation research agenda was prepared during SUPPORT I, which covered the epidemiological, promotional, and managerial elements of the project's work. During SUPPORT II, a modified version of that evaluation research agenda will be implemented. Examples of the evaluation research topics include: Examination of ORS product accessibility, business management decision-making, and marketing process impacts.

4. Information Collection and Dissemination

This component will focus on assembling and publishing technical and managerial information of use to policy-makers, company managers, production workers, and health professionals. The dissemination will include publications related to local private sector production of pharmaceuticals, especially ORS products, and related topics for use in policy dialogue and worker training aspects of the project. A key element in the dissemination program will be the documentation of lessons learned by the project, including issues of public health, business development, social marketing and promotion, and pharmaceutical production and quality assurance.

D. Expected Accomplishments and Achievements (Outputs)

This project will, through increasing involvement of the private sector in child survival activities, expand accessibility to oral rehydration salts and other health-related products.

Outputs are:

1. Sustained profitable production and marketing activities for ORS;
2. Increased numbers of private firms competing in ORS markets;
3. Application of reliable methodologies and staff training for quality assurance for locally produced ORS products, with consistently acceptable levels of quality for ORS manufactured by those firms;
4. Operations research, pharmaceutical research, and impact evaluation studies, including: product composition, quality control, marketing, production efficiency, and ORS product accessibility;

5. Feasibility studies for production of health-related products;

6. Effective application of technically sound procurement planning and quality assurance mechanisms in the ST/H ORS procurement system.

7. Development and dissemination of documents that contribute to the collective knowledge of local ORS and pharmaceutical production and promotion.

III. FINANCIAL PLAN

The project will extend over a five-year period with total funding of \$10 million. From this total, outside the project cooperative agreement, an amount of \$500,000 will be set aside for support of initial oral rehydration salts purchases under the A.I.D. Central Procurement System; and an amount of \$200,000 will be set aside for evaluations and audits. These funds will be set aside by line item in the project budget.

An amount of \$800,000 will be provided to fund loans to four (4) firms participating in the ORS production assistance. These loans would be administered by the contractor with approval of the CTO. Some or all of the loans may be negotiated with firms in countries having currency exchange restrictions. Following the practice established in Project SUPPORT I, loans may in some cases need to be repaid in local currencies which are then available for reuse in-country for purposes of expanding ORT program promotion or other purposes approved by the CTO and USAID Missions. The Financial Analysis section of the Project Paper provides a description of loan procedures and record keeping. Transition from the SUPPORT I Cooperating Agency, PATH, to a successor organization for SUPPORT II will be accomplished during the first and second months of the project. It is anticipated that fund balances in the SUPPORT I loan corpus will be transferred to the SUPPORT II recipient. An agreement for administration of any outstanding loan balances from SUPPORT I will be negotiated by A.I.D. during that period, and it is anticipated that the SUPPORT II recipient will take-over collection and follow-up needed under those agreements. Details of the loan agreements, terms, and procedures are provided below in the financial analysis.

During Project SUPPORT I, a limited number of USAID Missions provided funds through buy-ins for local ORS production activities. It is anticipated that a major portion of the funding for work under SUPPORT II would come from Regional and Mission funds. The core operations of the project would come from the

ST/H funding for assessments for Country Programs, Health Sector Support, Research and Evaluation, and Documentation and Dissemination. Regional Bureau and USAID Mission buy-ins must finance the following activities: implementation of the Country Programs Sustained Activities, regional training programs, and loan funds for ORS equipment. Core funds or buy-ins may finance: Country Programs Intermittent and Ad Hoc Short-Term Activities.

It is anticipated that Country Programs will be conducted in a total of 22 countries, including: 7 countries of Sustained Activity with 3 of the countries continuing from SUPPORT I initial technical assistance; 3 countries of Intermittent Activity (Ghana, Guatemala, and Turkey); and 12 sites of Ad Hoc Short Term Activity.

The Research and Evaluation effort, covering: pharmaceutical research, operations research, and impact evaluation, will be financed under the project and will consume approximately 50 person-months of staff and consultant resources. Project external evaluation activities will be set-aside and funded outside the cooperative agreement. The Collection and Dissemination activity will consume an additional 50 person-months of staff resources.

IV. IMPLEMENTATION PLAN

A. A.I.D. Management

The project will be managed by an S&T/H Cognizant Technical Officer (CTO), who will be principal A.I.D. contact for the cooperating organization. The CTO will be involved in all stages of the agreement and will monitor the cooperating organization's progress in fulfilling the objectives and intent of the agreement. The CTO will meet with other offices within A.I.D. as appropriate, including the Regional Bureaus, PPC, PRE, FVA/PVC, and USAID missions to discuss and review project activities and will arrange for appropriate clearances for project activities. The Regional Bureaus and USAID missions will contribute to this project through reviews and clearances of respective country activities, submissions of requests and cost-sharing (buy-ins) related to in-country operations and technical assistance.

The CTO will exercise a variety of functions, including:

(1) Approval of all technical staff proposed to participate as project staff by the cooperating organization;

(2) Approval of all activities carried out under this agreement including strategies; annual work plans; other work plans; budgets; sub-agreements; applied research protocols;

country technical assistance; study agreements; information dissemination and publication; consultancies; domestic and international travel; continuing education, training, or participation of project staff in symposia.

(3) Collaborative involvement and final approval of the selection of Sustained Activities and applied research sites and development of an annual work plan which describes the specific activities to be carried out under the agreement, by whom, when, how, and at what cost.

(4) Involvement in and approval of the selection, design, and implementation of applied research and Sustained Activities, as appropriate.

(5) Involvement in and approval of the publication and dissemination of project activities, findings, and results.

(6) Develop scopes of work for evaluations and audits; review of draft reports and substantive correspondence, participation in site visits, the Technical Advisory Group (TAG), and evaluations to review progress and future strategy.

(7) Responsibility for recommending, in coordination with other A.I.D. officials, the allocation of funds under this project for support of local production activities under other grants and contracts where deemed appropriate and essential to meet the objectives of this project. Such allocations will be approved by the Director of the Office of Health.

(8) Coordination with other A.I.D. S&T/H child survival initiative projects will be required in some instances. Experience in SUPPORT I showed that especially with respect to PRITECH and HEALTHCOM, there may be great deal of coordination required to ensure that a given country program operates effectively. Coordination will take the form of arranging exchange of information, convening of occasional joint planning meetings, and seeking advice from CTOs of related project. It is the responsibility of the CTO to initiate and oversee this coordination.

S&T/H anticipates that management of this project will be a part time job for a CTO with a strong background in the Child Survival Initiatives and private business organization.

B. Advisory and Support Services of a Cooperating Institution

A.I.D. is searching for an institution which has the skills, institutional mandate, and purpose to identify and enhance local private pharmaceutical production, marketing, and distribution capabilities in third world countries. Given the innovative and

exploratory nature of this donor supported, private sector development initiative, A.I.D. proposes to enter into a cooperative agreement with an organization which can meet this need.

The project design calls for considerable Agency collaboration with the recipient in the management of the project. This collaboration will include: (1) reviewing and approving of each work stage before work can proceed on a subsequent stage; (2) overseeing and adjusting the plans for production, quality assurance, and marketing arrangements; and (3) monitoring to permit redirection of work under SUPPORT II because of interrelationships with other projects managed by S&T/H. The principal purpose of the A.I.D. relationship with the recipient is the transfer of money, including funds for the equipment loans, to accomplish local production efforts in the participating countries.

The plan to use a cooperative agreement as the instrument to define and formalize arrangements is based on the A.I.D. Handbook criteria, which are as follows:

"a. The principal purpose of the relationship is the transfer of money, property, services, or anything of value to the recipient in order to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition, by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal Government, and

b. A grant would be appropriate except that substantial involvement is anticipated between the Agency and the recipient during the performance of the proposed activity."¹

It is anticipated that qualified groups, including private firms, not for profit organizations, and/or educational institutions may individually or jointly submit proposals to provide the required expertise in production, marketing, distribution, quality control, operational and pharmaceutical research, and financing. The agreement will be competitively bid.

Technical criteria for selection of the cooperating organization will cover general capabilities of the firm and staff expertise and experience as follows:

- (a) Organization and Management of the Firm
 - o Developing country experience
 - o Consulting experience with local profit-making pharmaceutical firms

¹A.I.D. Handbook 1, Supplement B, section 25E3, page 25-3.

- (b) Functional Capability
 - o Logistical support for overseas operations
 - o Procurement of technical equipment
 - o Equipment financing and loan negotiation
 - o Production of publications, training materials, and their dissemination

- (c) Staff Capabilities
 - o Project Director qualifications and experience
 - o Other Key Staff qualifications and experience
 - o Consultants qualifications and experience

The cooperating organization must present a core staff and roster of consultants who possess technical competence in the areas listed below. At least two members of the technical core staff must have a working knowledge of French and two in Spanish at the S-3 and R-3 levels. All language capabilities for proposed personnel shall be certified in the technical proposal as meeting F.S.I. levels required, or equal.

The Final Evaluation of Project SUPPORT I recommended that, based on experience under the project, many key elements in implementing local production be coordinated with the national ORT and national health-related communication development efforts. The project will be working in technical areas that are closely related to the following other A.I.D. Child Survival Initiative projects: PRITECH, REACH, HEALTHCOM. Also, the UNICEF and WHO Control of Diarrheal Diseases (CDD) programs are related but not overlapping program services. An especially close working relationship is planned between the project and two other A.I.D. projects: PRITECH and HEALTHCOM.

The SUPPORT II CTO together with the cooperating organization will hold meetings with the CTO and staff members of these related projects and programs. By exchange of work plans and country project plans, the CTO and cooperating organization will identify possible overlaps and gaps in the technical assistance. The cooperating organization is responsible will provide copies of telexes, facsimile transmissions, and letters to the CTO which are sent to USAID missions and host country firms. The cooperating organization will have two regional program specialists, whose duties will include the structuring of information exchanges and joint planning of field activities with the other projects.

1. Cooperating Organization Activities

In the Country Programs, the cooperating organization will be responsible for providing technical assistance, policy dialogue, action research, and equipment commodities under this project. The steps to be taken in implementing the project will differ among these several project elements. The field

elements will involve at least the following steps: identifying countries and firms for local production activities; assessing the epidemiological, market, and financial situation for local production, conducting policy dialogues with public and private sector officials; developing working agreements with specific firms; obtaining necessary clearances and approvals; implementing the financing, commodity procurement, and training arrangements; planning following-up and investigating production and marketing practices; and analyzing, writing-up, and disseminating results. The CTO must approve the stages in the Country Programs as specified above in Section IV.A. on A.I.D. management.

The Health System Support component focuses on: (a) ORS Procurement for S&T/H and (b) surveys of feasibility for other health-related products. The technical assistance for ST/H central procurement of ORS could involve the development of tracking arrangements for centrally-procured commodities; monitoring developments in the fields of product packaging, labeling, and quality assurance requirements and methods for ORS; and convening individuals or panels of experts, as needed, to advise A.I.D. officials on plans and problems in the ORS central procurement system.

The surveys of feasibility for other health-related products may involve market studies, business plan development, economic surveys, and engineering and product development studies. These surveys would be developed in response to requests from regional bureaus or from USAID Missions and through them from local firms.

The Research and Evaluation component for operations and pharmaceutical research is expected to provide guidance to the project staff, participating firms, A.I.D. and international organizations in dealing with certain technical issues relating to production and marketing of ORS and other pharmaceutical products. The Collection and Dissemination component will provide policy-oriented documentation and instructional materials on topics relevant to ORS local production, quality assurance, and marketing and on other topics pertinent to health-related production activities.

The CTO approvals for all stages of assistance specified above in Section IV.A will be requested before proceeding with implementation.

2. Gray Amendment Considerations

This project will be competitively bid, with all proposals to be considered on an equal basis. The request for technical proposals will encourage proposals from minority and women-owned enterprises.

3. Project Staffing

The cooperating organization will need to establish a core group of individuals that will be responsible for the planning and implementation of the project. A trade-off to assembling a strong core staff would be to increase the use of outside consultants. The project requires continuous attention and follow-up of problems to ensure high quality production and to permit cumulative improvements in procedures based on lessons-learned. The core staff can best ensure that those lessons are applied over the life of the project.

The members of this core staff should include representatives of the major participating organizations involved. These individuals will be expected to be available for work on this project on a full-time basis, except in the case of unusual circumstances, which must be approved by the CTO. The skills, experience, and technical capabilities for key staff are described below.

(a) Project Director. The Project Director will be a highly experienced and qualified professional in the field, having developing country experience and with ORT/ORS programs and objectives. It is also important that, at minimum, this individual be familiar with efforts to pursue development objectives through private sector ventures. Any additional experience in this area, particularly with pharmaceutical firms, will be highly advantageous. He or she will be the senior spokesperson and advisor for the project. This person will also exercise management responsibility and authority for all project activities. He or she shall provide management and technical guidance and be responsible for the completion of the project objectives. He or she will determine the program objectives, policies, and procedures in consultation with appropriate A.I.D. personnel. This position will serve as the principal liaison with the A.I.D. Project Manager and Contract Officer. This person will be expected to represent the project in the U.S. and overseas. Travel required 30% of the time.

(b) Deputy Director. The Deputy Director shall be expected to undertake a large portion of the day-to-day management responsibility of the project. He or she should have prior experience in managing or working in a large development project in a developing country and have extensive experience working with a U.S. government agency. Their skills should be complementary to the Project Director, and in the latter's absence, will exercise management responsibility and authority as delegated by the Project Director. This person shall be responsible for reporting on the project's financial status to A.I.D. He or she will be expected to represent the project in the U.S. and overseas in the absence of the Project Director. Travel required

0-10% of the time.

(c) Senior Marketing Expert. The Senior Marketing Expert will share some project management responsibilities with the Project Director and Deputy Director (either of who will be responsible for managing the project in the absence of the Project Director). This person will be the key technical advisor to the project for marketing issues. A.I.D. has learned that effective marketing of ORS is absolutely critical for an effective, sustainable project effort. This person will serve as the project's key resource on marketing issues as well as advising A.I.D. This person will provide liaison with HEALTHCOM and PRITECH. A significant amount of travel will be involved with this position in order to advise on marketing matters for both long and short term project sites. The person chosen for this position should have considerable prior experience and accomplishment with private sector pharmaceutical marketing in developing countries. Language skills (French and Spanish at the S-3 and R-3 levels) are considered very advantageous. A second choice for applicable experience would be involvement with social marketing programs, such as in contraceptive social marketing. Travel required 30%-40% of the time.

d. Senior Production and Quality Control Engineer. ORS has come to be appreciated as a more complex and difficult product to safely manufacture than was initially thought. Establishing practices for consistent safe manufacture of ORS in new settings often means establishing practices which currently are not followed. Doing this in a cost-effective manner makes it even more challenging. Expertise in pharmaceutical engineering and quality assurance and quality control are indispensable to this project's production start-ups. This person shall have the experience to be able to advise and direct production start-ups in developing country settings. They should be familiar with the complexities of attempting this kind of work. This person will travel to assist with feasibility studies, planning of manufacturing plans, advising on equipment procurement, helping with the training of pharmaceutical firms' staff, and also helping orient other project staff (especially the regional program specialists) to quality control and quality assurance procedures. Travel required 30%-40% of the time.

(e) Regional Program Specialist--2 to 3 people. Each of these program specialists will be responsible for backstopping of ongoing and new comprehensive project sites, and short term country activities. They should have knowledge of and experience with providing technical assistance and collaborating with host country counterparts. The number and deployment of these personnel shall be adjusted as the workload and level of effort for project staff changes. Each should have a geographic area of expertise and language skills (French at S-3 and R-3 level with African experience; Spanish at S-3 and R-3 level with Latin

American experience). Travel required 20%-25% of the time.

f. Editor/Information Manager. This person shall have demonstrated writing and editorial capability necessary to prepare and edit reports and publications. These materials will include trip reports drafted by other staff members, as well as technical reports developed by the project. This person will also be responsible for categorizing and managing all technical document resources collected by the project over its five-year life. He or she should have demonstrated interpersonal skills to work with professionals from various fields. Demonstrated language capabilities for translating and editing in French or Spanish are desirable. Travel required 0%-10% of the time.

(g) Management Systems Specialist. This person shall be responsible for tracking and reporting on key activities and resource flows of the project. He or she should have proven managerial and administrative skills, interpersonal skills, experience with management information systems and pertinent computer software, and familiarity with primary health care and development technical assistance. Travel required 0% of the time.

(h) Secretary/Administrative Assistant--2 persons. The project should include two to three administrative staff with clerical skills, including experience with word processing and microcomputers. The number and deployment of these personnel shall be adjusted as the workload and level of effort for project staff changes. Travel required 0% of the time.

(i) Financial Analyst/Loans Manager (1/4 time). This person will be responsible for developing, tracking, monitoring, and advising on loan mechanisms for the firms whom the consortium establishes pertinent agreements with. This will be required for setting up terms and conditions for long-term financial agreements. Such experience is rather specialized. People with experience complementary to this position are likely to be found in commercial banking and/or financial management or consulting. This position will require approximately one-fourth time, and this assistance will be needed in the early years of the project. Travel required 0%-10% of the time.

(j) Procurement Coordinator (1/4 time). Each new start-up involves choosing, locating, and ordering appropriate production machinery and equipment. Travel required 0% of the time.

(k) Short Term Consultants (2 or more people). Consultants will be recruited as needed to work with core staff members. They will be hired for their expertise in key technical areas, especially in marketing, production engineering, pharmaceutical quality control and quality assurance, and country project back-stopping. A roster of potential consultants shall be maintained

by the project.

4. Relationships with Host Countries and Firms

The initiation of local ORS production must be carefully coordinated with the host country efforts to develop oral rehydration therapy. This coordination among the host government, participating local firm(s), and USAID must be encouraged and sustained by the Cooperating Organization.

The practice of negotiating a working agreement between the Cooperating Organization and the participating ORS firm, which was used in Project SUPPORT I, will be continued in the new project. Neither A.I.D. nor the host government typically were parties to these working agreements, and they are not expected to be signatories of the agreements made in SUPPORT II. Concerns over the potential for product liability suits led in SUPPORT I to use of hold-harmless conditions within the agreements. Conditions holding A.I.D. harmless from liability for faulty ORS products will be made part of SUPPORT II agreements. The loan agreements entered into for purchase of equipment under the project will contain the standard provisions concerning A.I.D.'s rights under the project.

The cooperating organization will establish close working relationships with the participating firms. This relationships will be spelled-out in the working agreements. The firms will be required to provide monthly reports on their progress, production levels, quality control processes, marketing activities, and cost of operations. The practice under SUPPORT I related to production samples will be used in SUPPORT II. Under this arrangement, the firms are required to submit samples of production runs for testing by the cooperating organization of its designated laboratory. Submissions will be provided on the schedule contained in the Project Production Manual and the Project Quality Assurance Manual.

C. Project Monitoring

1. Cooperating Organization Reporting

The Cooperating Organization shall submit the following reports to the A.I.D. CTO:

(a) Annual work plan, the first received three months after project start. Preparation of subsequent Annual Work Plans will be scheduled to coincide with the TAG meetings so that the Annual Work Plans can serve as a review document for the TAG members. Subsequent Annual Work Plans should also include summaries--by country, by component of activities conducted in the previous

year, and as to their current status. The work plan shall detail technical activities by country and by technical component; level of effort, including involvement of staff and consultants; budget; collaborating host country institutions; timetable; and travel.

(b) Monthly Update Reports, submitted monthly after project start and received by the CTO with 7 days of the close of the month. The reports should include, but not be limited to a brief description of all activities and their status to date, accompanied by planned activities and responsible persons for each activity.

(c) Project strategy, to be submitted once at the end of the third month, with attention to four components of implementation, including: Country Programs, Health System Support, Research and Evaluation, and Collection and Dissemination.

(d) Proposal for each Sustained Activity, prior to initial site visit, to be followed by refined business plan and work plan, due 15 days after returning from initial site visit. The refined business plan shall include: detailed marketing plan and production and quality assurance plan, each of which have been developed collaboratively with participating firms who have also agreed to follow these plans.

(e) Proposal for each Ad Hoc Short Term Activity, prior to each short term assignment, containing proposed work plan.

(f) Proposal for each Applied Research Activity, providing methodology, collaborating institutions, staff and consultants, and budget.

(g) Final reports for all Country Report and Research and Evaluation activities, will be due within one month after completion and should include but not be limited to description of purpose, methodology, findings, and recommendations, and final cost.

(h) Trip reports, providing details of trip purpose, findings, recommendations, and persons contacted, to be provided within 15 days of the conclusion of each trip.

(i) Monthly budget summaries, with activities grouped by region (such as AFR), mode of implementation (such as SUSTAINED), technical area (such as MARKETING), and contractual expenditure category (such as salaries, travel, overhead, etc.). This is particularly important to ensure that project expenditures can be monitored by distinct categories of operation, including total expenditures by country on each specific buy-in. As the project evolves, the CTO may add other categories for characterizing project expenditures. The project will maintain expenditure

records, including, but not limited to, in-house training, participation in seminars and continuing education, and recruiting. The tracking of buy-ins must be organized such that detailed, timely information can be provided in routine reports and in answer to A.I.D. inquiries.

(j) Other financial reports and vouchers, including those for payment and reporting of project expenditures conforming to standard A.I.D. regulations and procedures. Advance copies of vouchers shall be sent to the CTO for review.

2. Technical Advisory Group

This project will have a Technical Advisory Group (TAG), whose major purpose will be to advise A.I.D., and particularly the CTO, on technical and strategic issues arising in the project. Project SUPPORT I did not have a TAG, and the project evaluation team recommended that due to the highly technical nature of the production, quality assurance, and marketing program that the new project include provision for appointment of a TAG. The TAG will be comprised of a select group of technical experts, chosen from international organizations, universities, donor organizations, PVO's, or relevant other A.I.D. projects. Five to seven persons will be identified by the CTO within the first three months of the project to participate in the TAG. It is anticipated that Projects SUPPORT and PRITECH will appoint some joint TAG members in an effort to cross-fertilize the technical advise required for project success.

The TAG will provide expert review of the project and make recommendations for improvement or modification. TAG members are expected to meet formally at least annually during the course of the five-year project, however, the CTO or the Project Director may consult with members of the TAG as frequently as need be. The formal TAG meetings will include the Project Director, Senior Marketing Expert, Senior Production and Quality Control Engineer, and will be chaired by the CTO. Other A.I.D. staff may be included.

Minutes will be kept at each TAG meeting. Within twenty days following each TAG meeting, there will be convened an Annual Management Review to respond to TAG recommendations. The meeting will be attended by the CTO, Project Director, project staff and Office of Health staff to review the Annual Work Plan, project activities to date, and to plan the next year's strategy. The Project Director shall be responsible for preparing the next year's strategy based on TAG recommendations. As the project evolves, the time and agenda of these TAG meetings may be changed by the CTO in order to maximize the contribution of all the technical experts. In the case of drop out, the CTO may choose another technical expert to participate in the TAG. They may

also assist the contractors and/or A.I.D. in developing research plans and protocols and reviewing technical proposals and reports.

D. Project Evaluation

The project will be subject to two external evaluations, an interim evaluation conducted at the end of the second year and a final evaluation near the end of the fourth year of the project. The mid-term and final evaluations will be looking especially at impact. Examples of issues to be examined will include the following:

- o How well will firms be doing in relationship to central marketing and production plans (sales figures, profitability)?
- o The role project will have played or not played in realizing project goals;
- o Process and input indicators will be important, but long-term commercial success has to take bottom lines in account;
- o Quality assurance results;
- o Test assumptions about economic fluctuations, multinational competitors, competition among products using non-WHO formula for ORS, etc.

The objective of the interim evaluation is to assess the effectiveness of the management structure of the project; project responsiveness to USAID missions and to AID/W; project direction and strategy; and any major issues which have arisen during the course of operation. Evaluators may include S&T/H or other AID/W staff members external to the project, and independent consultants. The evaluation should take approximately ten to fourteen working days and may require travel. The recommendations from the evaluation should be used to modify the project to make it more effective.

The objective of the final evaluation will be to assess the contractor's effectiveness and success in carrying out the mandate of the Cooperative Agreement. This shall include, but not be limited to, an assessment of: the quality, effectiveness and accomplishments of technical assistance, training, and information dissemination; financial management of the project; development and application of new tools to solve problems in production, quality assurance and quality control, and marketing of ORS; and the effectiveness of applied research to respond to critical questions in the field.

The evaluation team shall make recommendations to A.I.D. regarding the Cooperating Organization's ability and capacity to effectively carry-out the final year of the project, particularly regarding the culmination, syntheses, and presentation of lessons learned. The team shall also advise A.I.D. on appropriate direction, strategy, management, and operations of any follow-on work, reflecting the experiences of the first four years.

Funding for the evaluation will come from the project budget and will be held by S&T/H separately from the implementation agreement. The evaluation will take place over 30 working days and will require travel to field sites of major activities.

The criteria against which the project activities will be evaluated will differ from site to site, but will reflect the country strategy documents, business plans, and work plan. The TAG will have as one of its agenda items in the third and fourth meetings, the review and finalization of the evaluation framework. Among the most appropriate criteria with which to judge project success are improvements in ORS accessibility to users and increased sales and use of ORS.

E. Implementation Schedule

An implementation plan is included as Annex C to this project paper. The cooperating organization will submit a detailed annual work plan to the CTO. The first year's work plan will be submitted to the CTO within three months after the signing of the cooperative agreement, and will be reviewed and distributed to the TAG members one week prior to the first TAG meeting. This work plan will (1) describe the start-up activities, including the orientation, responsibilities and proposed travel of staff, and structure for project management; (2) potential countries for Sustained Activities and proposal for initiating activities; (3) potential topics and sites for research activities; (4) structure for handling short-term technical assistance requests; (5) strategy for information dissemination and training; (6) standardizing and reporting of project financial accounts; (7) the work plan will reflect the cooperating agency's understanding of the ORS/ORT situation in a proposed country and will describe how the SUPPORT II plan will articulate with other A.I.D. and other donor-supported activities and national programs. All of those areas mentioned above should be placed within the context of the project strategy, objectives, and technical areas of activity. The work plan will be modified to reflect the recommendations of the TAG, discussion with Regional Bureaus, and approved by the CTO.

V. PROJECT ANALYSES

A. Technical Analysis

1. Need for Project

Diarrheal diseases remain one of the largest causes of morbidity and mortality amongst third world children. ORS has become widely recognized as a most appropriate and effective therapy to reverse or prevent the dehydration resultant from these diseases that can kill. Availability of ORS is still significantly limited in most developing countries.

Importation of foreign manufactured ORS is usually a compromised alternative, providing benefits but at the expense of flexibility in tailoring products to local needs. UNICEF and other donors, including A.I.D., have provided this service in the past, but this is not a service that UNICEF intends or prefers to continue endlessly. Additionally, UNICEF packets are not specially adapted for each country's use. Their size and labeling must be standardized for worldwide use. Purchasing and importing ORS products from other commercial sources is usually prohibitively expensive for developing countries, especially with the shortage of foreign exchange most must contend with. Thus, locally produced and distributed ORS, developed specifically for the local market and culture, is often highly advantageous and greatly needed.

2. Interest in SUPPORT II

The types of services provided by SUPPORT I and the proposed SUPPORT II are also wanted by USAID Missions and private pharmaceutical firms. Six project sites in six different countries still require a minimal to moderate amount of T.A. follow-up in order to increase the likelihood of sustained production.

In addition to these six sites where SUPPORT I has already begun activities, three other countries have been consistently requesting SUPPORT production, QC and marketing assistance, that to date, SUPPORT has not had the resources or staff available to initiate.

Responses to cables of inquiry sent out by S&T/Health show additional countries interested in the types of technical assistance offered by SUPPORT. Two USAID Missions have responded stating certain interest in such assistance. Twelve other missions note tentative interest in some or all of the types of technical assistance that SUPPORT II could provide.

3. Technical Appropriateness and Feasibility

SUPPORT I has and SUPPORT II will continue to meet and respond to the needs of countries and pharmaceutical firms in the most technically appropriate manner. Such appropriateness of technical assistance is exactly what ensures greatest likelihood of sustainability and project success. Both training and production equipment provided are based on the firm's level of sophistication, the most appropriate technology to permit efficient production. Product packaging and marketing also varies in response to local needs and opportunities.

Packaging materials and sachet volume are good illustrations of this. In Guatemala and Ghana, each product was specially adapted to local needs. Ghana opted for a 600 ml size that could be used with a commonly available beverage bottle for mixing. The product was packaged in polyethylene double bags which was cheaper, locally available, and acceptable to consumers. In Guatemala, the 1000 ml sachet size was chosen to complement a public sector product and campaign that was being planned. The producer used a more expensive but more appealing aluminum laminate packaging material and overlapping package that allowed for attractive design and instructions on mixing and use of ORS.

4. Methodology

SUPPORT II will use the basic methodology begun under SUPPORT I, with refinements based on this project's experience and recommendations from the Evaluation Team. A greater level of attention and resources will be given to the production/quality control and marketing areas in order to enhance overall assistance.

5. Cost Effectiveness

The approach taken in SUPPORT I is very cost-effective. The project used limited technical assistance to private pharmaceutical firms to initiate and upgrade local production and marketing of ORS. ORS is first, a less expensive therapeutic than intravenous solutions, and can be substituted for IVs in all but the most extreme cases of dehydration. ORS can also be widely distributed through settings other than clinics. This has a two-fold impact. First, it puts more basic health care provision into the hands of parents so that more cases can be treated at home (thus relieving some of the burden on public sector clinics). Second, by being available for administration in homes, fewer cases of severe dehydration should be seen if treatment can be started in the homes.

Transferring this technology will also free countries from

the need to import ORS commodities. Scarce foreign exchange can be used for other medical supplies. The fact that these private sector products are sold at a price that covers the manufacturers' costs means that recurrent costs will be covered. It is often the burden of meeting recurrent costs that undermines and terminates development projects, after the outside assistance has ended.

B. Social Soundness Analysis

1. Participating Parties

This is a centrally funded project of S&T's Office of Health. Buy-ins will be used to finance approximately 50% of all field activities. Main players will include the Office of Health, the contracted implementing firm (or firms in the case of award to a consortium of groups), and the local pharmaceutical firms receiving the technical assistance.

USAID missions in project site countries are also involved. This involvement is more significant in those sites where the mission has bought in and a more comprehensive package of assistance is being provided (as opposed to short term assistance). Ministries of health responsible for CDD programming are always consulted when initial feasibility assessments are conducted. The extent of MOHs' involvement can vary from a minimum of their condoning such activity by the private pharmaceutical firm, to active participation and coordination in those cases where joint promotion campaigns and/or public purchasing of private sector product may occur.

Other groups which might play a minor role could include local marketing/survey groups that could be contracted for knowledge-attitudes-practices (KAP) surveys, marketing research, etc.

2. Beneficiaries

The immediate beneficiaries of this project will be pharmaceutical firms who receive the assistance, and consumers who will benefit from increased accessibility to ORS. The firms will benefit with improved knowledge and means to manufacture and market ORS safely and efficiently. Consumers benefit from having an ORS product that is more widely available, is of assured quality, is sold at affordable prices, and is packaged in a size with language labeling most appropriate for that country.

Other beneficiaries of this project include ministries of health and health sectors that will be able to plan their programming based on more dependable supplies of ORS. They also

stand to benefit from a reduced load on clinics as more mothers are able to effectively treat their children's diarrheal bouts at home.

3. Disciplines involved

This project employs a multidisciplinary approach, relying on expertise from four broad fields: medical/epidemiologic, social/anthropological, financial/business, and pharmaceutical production and quality control engineering. Each field plays a crucial part or parts at various stages of project assistance. Medical expertise is consulted when assessing the epidemiologic profile of diarrheal diseases in a given country, and current practices therewith.

Social/anthropologic experts are consulted or contracted to assess people's perceptions of diarrhea, to determine what containers are most widely available, and to help develop the most appropriate and effective label and instruction design for the product. Financial and business knowledge is important when assessing prospective pharmaceutical firms, developing the product line and marketing strategies, and developing loan mechanisms desirable to both parties involved.

Production and QC engineering is equally critical to be able to select appropriate equipment for improving an existing facility, for installing purchased equipment in the most efficient way, for training all staff involved, and for overseeing manufacture to ensure the product meets quality specifications and is being manufactured as efficiently as possible, given local situations.

4. Project Strategies

This project provides a range of technical expertise, or services. These can be provided individually on a short term basis, or as a comprehensive package as part of a longer term assistance effort. Only those needed or requested by the local firms and missions are applied.

5. Analysis of Community, Family, and Individual Care Giver

Part of the initial feasibility assessment visit involves collecting information available concerning local understanding and practices with diarrheal diseases. It is usually necessary to conduct more research on availability of local containers and sales points. This data collection typically relies on community and home survey tools. Information gathered is used

to develop draft packet labels and instructions. Focus groups are usually used to ascertain the publics' reactions to such product presentations. Thus, considerable sensitivity to community, home and individuals' knowledge, attitudes and practice is maintained by this project's approach.

6. Role of Women

Women as mothers and nurses, tend to be the near-exclusive care givers when infants and children become sick. ORS will provide women with a much more readily available treatment for their children's diarrhea that has the potential to save lives. Education and marketing efforts associated with this product readily acknowledge that women are their key targets. These efforts strive to inform care-givers of the most effective way to mix and administer ORS. Women usually constitute the majority of staff at the pharmaceutical firms involved with this project. Addition of a new product to such firms can mean steadier or greater employment opportunities for women. Finally, women are likely to participate in project implementation and will play important roles therewith.

C. Administrative Analysis

1. Management

Two critical dimensions of management for this project are delegation of authority, and level of experience of appointed managers. Given the frequency with which key staff will be traveling, it is important that the project be able to respond to requests, either from the field or AID/W, while key staff may be absent. To assist in this matter a deputy director position has been proposed, the person of whom would handle a considerable amount of the internal administrative duties and oversee a number of the administrative staff. This person's capabilities and familiarity with AID/W project administrative responsibilities will be important considerations. Likewise with the Project Director, familiarity with AID/W project management and effective administration are very important. When recruiting for these two positions, finding a complementary match of skills will be highly desirable.

2. Staffing

Expertise is required in a fairly diverse range of fields for this project, including private sector business ventures, pharmaceutical production, marketing, and public health. Experience with the first project has shown that thorough competency in two fields, marketing and production, is especially

critical to accomplishing the project's objectives. Availability of such experts for this type of government contract work is limited. Considerable attention will be given to the selection of staff and consultants that are proposed.

3. Implementation Plan

The plan proposed herein is considered realistic and workable. It is based on experience gained from the first project's implementation, and improvements in certain areas. The plan begins with a continuation of assistance to countries where SUPPORT I has already begun work. This assistance tapers off over the life of the five year SUPPORT II project. New starts are initiated in the first 18 months of this project, allowing sufficient time for completion prior to conclusion. Short term assistance and dissemination work is fairly evenly spread over the duration of the project. The moderate decline in field activities towards the end of the five years will be offset by the increased level of work needed for completion of dissemination materials and reports on the project's experience.

D. Financial Analysis

1. Project Funding
(In preparation)
2. Loan Fund Procedures
(In preparation)

ANNEX A. Findings from Project SUPPORT Evaluation

A final evaluation of Project SUPPORT I was conducted in September and October 1988. This included field visits to ORS manufacturers participating in the project in Guatemala and Ghana. This nearly four years spent testing the SUPPORT strategy has yielded important lessons concerning the viability and how to's of working with private pharmaceutical firms. Among the lessons learned are the following:

(1) While only a limited number of firms meet all project site selection criteria, many firms are genuinely interested in such ventures. Participation offers firms the chance to expand their product line, improve their facilities and equipment, and avail themselves of relevant staff training in production engineering, quality assurance, and marketing. The financing terms allowed some of the firms to consider ORS production when it would otherwise have been infeasible.

(2) Marketing is absolutely critical to the success of a local production effort, as well as to the larger national ORT program. Prior to this project's start, it was assumed that because these firms were successful with other products, they must have competent marketing staff. This has not usually been the case. The considerable demand and comparatively low level of competition for other pharmaceuticals meant marketing efforts could be fairly simple and unaggressive. ORS products though have smaller profit margins, require higher sales volumes, and lack the consumer recognition other products have. The lower income of targeted consumers further complicates marketing efforts. Without sufficient demand or an aggressive campaign, sales will never reach levels sufficient to ensure sustained participation by the firms.

(3) The amount of assistance firms want and/or need varies greatly. At the outset it was expected that the project would provide a similar comprehensive package of services to each of the firms it worked with. Over time though it has become apparent that some firms want or need more assistance than others. This is evidenced by the range of assistance requests received by SUPPORT I.

(4) Technologies crucial for the success of these ventures include: industrial pharmacy, quality assurance and control, and commercial marketing. Expertise contracted to provide technical assistance must be very experienced. Three years of implementation has shown the difficulty and complexity of production, quality assurance and quality control (QC/QA) and marketing activities included in this project. While general purpose advice and documentation about ORS production and marketing

practices are valuable, implementing contractors must also have access to highly experienced experts in these specialized fields.

(5) A broad range of expertise and services is required to successfully execute such a project. In addition to the areas noted earlier in marketing and production/QC, firms must also be familiar with production equipment, where it can be procured, financial assessments, developing business plans and commercial loans, etc.

In sum, the evaluation team concurred with the rationale for Project SUPPORT I and encouraged A.I.D. to plan a follow-on SUPPORT II. In light of lessons learned during SUPPORT I, the evaluation team recommended several modifications be made when designing the follow-on project. Key modifications include:

(a) Provide expertise for policy dialogue--either from Project SUPPORT alone or in concert with the PRITECH Project. The dialogues can help national leaders in government and the health professions to better understand the benefits of local private production of ORS, the feasible approaches to regulation of ORS product quality, and the critical importance of the separate roles to be played by both the public and private sectors in all aspects of ORS marketing.

(b) At the company selection stage of the project's assistance to a firm, expand the previous approach to include not only production and financial plans but also more thorough marketing, training, and quality assurance plans to ensure an integrated approach to implementation.

(c) At the ORS product launch stage of the project's assistance to a firm, assign more intensive technical assistance with senior specialists in production, quality assurance, and marketing areas; and continue with this intensive assistance through the process validation of production, documentation of Good Manufacturing Practices, and satisfactory operation of promotion and distribution activities.

(d) Expand the documentation and dissemination of the rationale for local ORS production for audiences of policymakers as well as know-how for training in ORS production, quality assurance, and marketing, using print and audio-visual media.

(e) Consider designating training and demonstration centers at a few participating firms that could receive visiting policymakers and ORS manufacturing trainees for short periods of orientation.

(f) Provide resources for feasibility studies leading to possible business ventures in production or distribution of other health-related products needed in the child survival initiative.

(g) Provide resources for operations research directed to problem solving in ORS packaging, composition, production, quality assurance, and marketing.

The design for Project SUPPORT II incorporates these evaluation findings and expands on the private sector initiatives begun in SUPPORT I. Over three years of experience gained from SUPPORT I has contributed significantly to A.I.D.'s knowledge of how to plan and implement ventures with private ORS manufacturers.

PROJECT DESIGN SUMMARY
LOGICAL FRAMEWORK

Life of Project
From FY 89 to FY 94
Total U.S. Funding \$10,000,000
Date Prepared: Mar. 9, 1989

Project Title & Number: Project SUPPORT II (936-5985)
Supply, Production, and Promotion of Oral Rehydration Salts

NARRATIVE SUMMARY	OBJECTIVELY VERIFIABLE INDICATORS	MEANS OF VERIFICATION	IMPORTANT ASSUMPTIONS														
<p>Sector Goal: To improve the health status of infants and children in developing countries.</p> <p>Program Goal: To provide appropriate therapeutic agents--especially oral rehydration salts (ORS)--for diseases that contribute to high infant and child mortality.</p>	<p>Measures of Goal Achievement: Reduction of infant and child morbidity and mortality.</p>	<p>--National vital statistics;</p> <p>--Epidemiological data from ministry of health records;</p> <p>--A.I.D. program data and special health surveys;</p> <p>--Contractor, host country, A.I.D., and evaluation reports.</p>	<p>1. Disease control technologies and strategies are effective and safe in reducing infant and child morbidity and mortality.</p> <p>2. Local production and marketing of disease control technologies will result in cost effective product accessibility in host country.</p>														
<p>Project Purpose: To promote and foster private sector production and marketing of low cost, high quality ORS, including the results of project-funded research on new or enhanced ORS products. In addition, the project will provide assistance in determining the feasibility of producing other health-related products in the private sector which support child survival goals and will help with further development of A.I.D. ORS procurements.</p>	<p>End of Project Status: --Improved rates of accessibility for locally produced oral rehydration salts and other health products; --Increased production sites and sales for locally produced ORS in project countries; --Upgraded capability in production and marketing by local ORS producers; --Increased proportion of ORS sales over antidiarrheal products --Adequate ORS quality regulation</p>	<p>--Sentinel and random sample surveys;</p> <p>--National CDD and EPI monitoring reports;</p> <p>--Commercial market survey reports for pharmaceutical products (where available);</p> <p>--Contractor, host country, A.I.D., and evaluation reports.</p>	<p>1. Existence of national government policy commitment to sustained CDD and EPI program;</p> <p>2. Private sector experiences a positive working relationship with government.</p>														
<p>Outputs:</p> <ol style="list-style-type: none"> 1. Sustained profitable production and marketing activities for ORS; 2. Increased numbers of private firms competing in ORS markets; 3. Reliable quality assurance at all project manufacturing sites; 4. Studies (Operations, Pharmaceutical, & Impact Evaluation) of ORS; 5. Feasibility studies of other products 6. Effective systems in ST/H ORS procure 7. Dissemination of ORS production info. 	<p>Magnitude of Outputs: 12 private firms, including 10 "comprehensive assistance" sites, in sustained local production; 4 of above firms performing as "Training and Demonstration" sites; 12 private firms assisted as "short term" efforts; (up to 12) operational and pharmaceutical research issues studied; 3 country assessment and feasibility studies for other health products.</p>	<p>--National ORT/CDD and EPI program reports and IEC reports;</p> <p>--Contractor reports;</p> <p>--USAID mission reports;</p> <p>--Mid-term and final evaluations.</p>	<p>1. Relevant skills and expertise required for technology transfer in pharmaceutical engineering and marketing will be available through contractor's services.</p>														
<p>Inputs:</p> <ol style="list-style-type: none"> 1. Commodity, technical, and managerial assistance to local drug firms; 2. Financial resources in the form of concessionary loans to local firms; 3. Technical assistance to ST/H, USAID missions, and local firms in product development and quality control; 4. Technical assistance, and potentially commodities, for ST/H central procurement of ORS; 5. Policy dialogue on private sector involvement and quality control; 6. ORS product quality follow-up. 	<p>Implementation Target:</p> <table border="0"> <tr> <td>Country Programs:</td> <td>\$</td> </tr> <tr> <td>Research & Development:</td> <td></td> </tr> <tr> <td>Management:</td> <td></td> </tr> <tr> <td>ORS Commodities for A.I.D.:</td> <td></td> </tr> <tr> <td>Evaluation:</td> <td></td> </tr> <tr> <td>Contingency:</td> <td></td> </tr> <tr> <td style="text-align: right;">TOTAL</td> <td><u>\$10,000,000</u></td> </tr> </table>	Country Programs:	\$	Research & Development:		Management:		ORS Commodities for A.I.D.:		Evaluation:		Contingency:		TOTAL	<u>\$10,000,000</u>	<p>--Contractor accounting records;</p> <p>--Annual project manager reviews;</p> <p>--Mid-term and final evaluations.</p>	<p>1. A.I.D. inputs available in a timely fashion;</p> <p>2. Contractor implementation mechanism can be provided to meet broad interdisciplinary needs.</p>
Country Programs:	\$																
Research & Development:																	
Management:																	
ORS Commodities for A.I.D.:																	
Evaluation:																	
Contingency:																	
TOTAL	<u>\$10,000,000</u>																

IMPLEMENTATION SCHEDULE

Project Title & Number: Project SUPPORT II (936-5985)
Supply, Production, and Promotion of Oral Rehydration Salts

Life of Project
From FY 89 to FY 94
Total U.S. Funding \$10,000,000
Date Prepared: Mar. 9, 1989

Activities and Products	Project Implementation				
	Year 1	Year 2	Year 3	Year 4	Year 5
1. Contractor's Start-Up Actions					
a. Final staff recruitment	█				
b. Site preparation and mobilization	█				
c. Equipment installation	█				
d. Project start-up workshop		█			
e. Preliminary work plans		█			
f. Preliminary documentation plans		█			
g. Work plans approved		█			
h. Documentation plans approved		█			
i. World-wide announcements, mtgs.		█			
2. Continued Assistance (SUPPORT)					
a. Assessment visits--Producing firms		█			
b. Turkey		█			
c. Ghana		█			
d. Guatemala		█			
e. Assessment visits--Nonprod. firms		█			
f. Paraguay		█			
g. Peru		█			
h. Uganda		█			
3. Comprehensive Assistance					
a. Site selections assessments		█			
b. Country 1		█			
c. Country 2		█			
d. Country 3		█			
e. Country 4		█			
4. Demo/Training/Q.C. Sites					
a. Regional center assessments		█			
b. LAC/Spanish-Portu. selection		█			
c. ANE/English center selection		█			
d. AFR/French center selection		█			
e. Other Center selection (optional)		█			
f. Headquarters center preparation		█			
g. Production training package dev.		█			
h. Policy dialogue package devel.		█			
i. Qual. assur. training package dev.		█			
j. Marketing training package devel.		█			
k. Training programs launched		█			
l. Training operations on-going			█		

IMPLEMENTATION SCHEDULE
(Continued--Page 2)

Life of Project
From FY 89 to FY 94
Total U.S. Funding \$10,000,000
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Project Title & Number: Project SUPPORT II (936-5985)
Supply, Production, and Promotion of Oral Rehydration Salts

Activities and Products	Project Implementation				
	Year 1	Year 2	Year 3	Year 4	Year 5
5. Short-Term Assistance					
a. Countries 1-2	██████████				
b. Countries 3-5		██████████			
c. Countries 6-8			██████████		
d. Countries 9-11				██████████	
e. Country 12					██████████
6. Health Product Feasibility Studies					
a. Country 1 assessment			██████████		
b. Country 2 assessment				██████████	
c. Country 3 assessment					██████████
7. Operations Research					
a. Proposal of OR & Pharm Topics 1-3		██████████			
b. Studies 1-3		██████████			
c. Proposal of OR & Pharm Topics 4-6			██████████		
d. Studies 4-6			██████████		
e. Proposal of OR & Pharm Topics 7-9				██████████	
f. Studies 7-9				██████████	
g. Proposal-OR & Pharm Topics 10-12					██████████
h. Studies 10-12					██████████
8. Dissemination					
a. Conference 1		██████████		██████████	██████████
b. Manual 1	██████████				
c. Manual 2		██████████			
d. Manual 3			██████████		
e. Policymaker Documentation 1		██████████			
f. Policymaker Documentation 2				██████████	██████████

PROJECT SUPPORT II Financial Analysis (13 March 1989)

PROJECT SUPPORT II Financial Analysis (13 March 1989)

Financial Plan Budget for All Components

Description	Rates (Per Month)	Project Costs (\$000)					TOTAL
		-----YEAR-----					
		1	2	3	4	5	
Staff--Technical	\$4,250	293	310	378	306	247	\$1,534
Staff--Support	\$2,025	105	109	109	105	105	535
Consultants	\$5,000	90	135	170	125	85	605
Tech. Assist Trips	\$1,550	84	132	197	141	73	626
Per-Diems	\$2,000	82	104	150	102	58	496
Training--Local	\$500	4	6	6	4	3	22
Training--Participant	\$1,500	6	15	21	12	6	60
Poli. Dial.--Inv Trav	\$1,500	6	9	9	6	6	36
Subtotal		670	820	1,040	801	583	\$3,914
Overhead (incl. Benefits)							
Staff (% of Salaries)	75%	372	392	460	385	325	1,935
Consultant (% of Fees)	50%	45	68	85	63	43	303
Loan Fund Corpus		0	400	400	0	0	800
Publication/Dissemination		50	50	50	50	50	250
Office Space Rental (3000 SF)		54	54	54	54	54	270
Equipment Purchases		70	0	0	0	0	70
Other Directs (Phones, Supplies, etc.)		50	50	50	50	50	250
Contract Subtotal		1,311	1,834	2,139	1,403	1,105	\$7,792
Inflation (% per year)	5%	0	92	214	210	221	737
Contract Total		1,311	1,926	2,353	1,613	1,326	\$8,529
Components NOT included in Contract but in Project:							
ST/H Commodity Purchases		200	200	0	0	0	400
Evaluation		0	0	75	0	75	150
Contingencies	10%	151	213	243	161	140	908
TOTAL		1,662	2,338	2,671	1,775	1,541	\$9,987

PROJECT SUPPORT II Financial Analysis (13 March 1989)

Component-Specific Costs	-----YEAR-----					Total Cost (\$000)
	1	2	3	4	5	
1. Previously Launched Sites	97	60	58	0	0	\$216
2. Ready-to-Launch Sites	159	146	116	0	0	421
3. New Sites	0	112	292	277	98	778
4. Short-Term Assistance	53	79	79	53	53	317
5. Feasibility Studies	0	33	104	111	72	319
6. Research & Dissemination	59	89	89	59	59	356
7. Home Office Support	301	301	301	301	301	1507
Total Component Costs:	670	820	1040	801	583	\$3,914
Average Monthly Rates	55.8	68.4	86.7	66.8	48.6	65.2

PROJECT SUPPORT II Financial Analysis (13 March 1989)

Summary of Level of Effort for all Components	Units	Implementation Level of Effort					TOTAL
		-----YEAR-----					
		1	2	3	4	5	
Staff--Technical	Person-Mo	69	73	89	72	58	361
Staff--Support	Person-Mo	52	54	54	52	52	264
Consultants	Person-Mo	18	27	34	25	17	121
Tech. Assist Trips	Rnd Trips	54	85	127	91	47	404
Per-Diems	Person-Mo	41	52	75	51	29	248
Training--Local	Person-Mo	7	12	11	8	6	44
Training--Participant	Person-Mo	4	10	14	8	4	40
Poli. Dial.--Inv Trav	Rnd Trips	4	6	6	4	4	24

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Summary of Staff and Consultant Person-Months	Implementation Level of Effort					Total Person- Months
	-----YEAR-----					
	1	2	3	4	5	
1. Previously Launched Sites	12	6	6	0	0	24
2. Ready-to-Launch Sites	18	15	12	0	0	45
3. New Sites	0	12	30	28	10	80
4. Short-Term Assistance	4	6	6	4	4	24
5. Feasibility Studies	0	4	12	12	8	36
6. Research & Dissemination	12	18	18	12	12	72
7. Home Office Support	93	93	93	93	93	465
Total Person-Months	139	154	177	149	127	746
Full-Time Equivalents	11.58	12.83	14.75	12.42	10.58	62.17

PROJECT SUPPORT II Financial Analysis (13 March 1989)

	Units	Model Intervention Package (Years 1,2,3)			Implementation Level of Effort					TOTAL
		A	B	C	-----YEAR-----					
					1	2	3	4	5	
Launched Sites (Ghana, Guatemala, Turkey)		--	--	-->	3	0	0	0	0	3
Per-Site Levels:										
Staff--Technical	Person-Mo	3	1	1	9	3	3	0	0	15
Staff--Support	Person-Mo				0	0	0	0	0	0
Consultants	Person-Mo	1	1	1	3	3	3	0	0	9
Tech. Assist Trips	Rnd Trips	4	4	4	12	12	12	0	0	36
Per Diems	Person-Mo	4	2	2	12	6	6	0	0	24
Training--Local	Person-Mo	1	1	0	3	3	0	0	0	6
Training--Participant	Person-Mo				0	0	0	0	0	0
Poli. Dial.--Inv Trav	Rnd Trips				0	0	0	0	0	0
Ready Sites (Paraguay, Peru, Uganda)		--	--	-->	3	0	0	0	0	3
Per-Site Levels:										
Staff--Technical	Person-Mo	4	3	3	12	9	9	0	0	30
Staff--Support	Person-Mo				0	0	0	0	0	0
Consultants	Person-Mo	2	2	1	6	6	3	0	0	15
Tech. Assist Trips	Rnd Trips	9	10	8	27	30	24	0	0	81
Per Diems	Person-Mo	6	5	4	18	15	12	0	0	45
Training--Local	Person-Mo	0	1	1	0	3	3	0	0	6
Training--Participant	Person-Mo				0	0	0	0	0	0
Poli. Dial.--Inv Trav	Rnd Trips				0	0	0	0	0	0
New Sites (4)	Start-ups	--	--	-->	0	2	2	0	0	4
Per-Site Levels:										
Staff--Technical	Person-Mo	4	6	3	0	8	20	18	6	52
Staff--Support	Person-Mo				0	0	0	0	0	0
Consultants	Person-Mo	2	3	2	0	4	10	10	4	28
Tech. Assist Trips	Rnd Trips	9	18	10	0	18	54	56	20	148
Per Diems	Person-Mo	6	9	5	0	12	30	28	10	80
Training--Local	Person-Mo	0	1	1	0	0	2	4	2	8
Training--Participant	Person-Mo	2	2	0	0	4	8	4	0	16
Poli. Dial.--Inv Trav	Rnd Trips				0	0	0	0	0	0
Short Term Assistance (12)	Start-ups	--	--	-->	2	3	3	2	2	12
Per-Site Levels:										
Staff--Technical	Person-Mo	1	0	0	2	3	3	2	2	12
Staff--Support	Person-Mo				0	0	0	0	0	0
Consultants	Person-Mo	1	0	0	2	3	3	2	2	12
Tech. Assist Trips	Rnd Trips	4	0	0	8	12	12	8	8	48
Per Diems	Person-Mo	2	0	0	4	6	6	4	4	24
Training--Local	Person-Mo	2	0	0	4	6	6	4	4	24
Training--Participant	Person-Mo	2	0	0	4	6	6	4	4	24
Poli. Dial.--Inv Trav	Rnd Trips	2	0	0	4	6	6	4	4	24

PROJECT SUPPORT II Financial Analysis (13 March 1989)

Staff Salary Expenses

Title	Rate/Year	Months	Total
Project Director	55,000	60	\$275
Deputy Director	47,000	60	\$235
Senior Marketing Expert	55,000	60	\$275
Senior Production Engineer	55,000	60	\$275
Regional Program Spec.	47,000	60	\$235
Regional Program Spec.	47,000	60	\$235
TOTAL			\$1,530
Editor/Information Spec.	33,000	60	\$165
Management Systems	25,000	60	\$125
Secretary/Admin Assist.	19,000	60	\$95
Secretary/Admin Assist.	19,000	48	\$76
Financial Analyst	25,000	15	\$31
Procurement Coord.	25,000	15	\$31
TOTAL			\$524

PROJECT SUPPORT II Financial Analysis (13 March 1989)

Non-Salary Direct Costs

Item	Rate/Year	Total
Space Rental	250 SF * 12 people * \$18	\$270,000
Equipment		
Telephones	12 people * \$300	\$3,600
FAX machine		2,000
Photocopy machine		3,000
Personal computers	12 people * \$1500	18,000
PC software	12 people * \$600	7,200
PC Printers/network		10,000
PC furniture	12 people * \$300	3,600
Office furniture	12 people * \$700	8,400
Central furniture		10,000
TOTAL		\$65,800
Other Direct Costs		
Communications	12 people * \$150	\$108,000
Travel-Related Costs	384 P-M * \$100	38,400
Office Supplies	12 people * \$25	18,000
Materials, Books	12 people * \$50	36,000
Photocopy Operations	\$300/month	18,000
FAX operations	\$100/month	6,000
PC Operations	\$150/month	9,000
Local Travel	\$300/month	18,000
		\$251,400