

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20503

AUG 30 1985

Dr. Gordon W. Perkin
PATH/PIACT
Canal Place
130 Sickerson Street
Seattle, Washington 98109

Subject: Cooperative Agreement No.
DPE-0060-A-00-5050-00

Dear Dr. Perkin:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development (hereinafter referred to as "AID") hereby provides to the Program for Appropriate Technology in Health (hereinafter referred to as "PATH" or "Recipient"), the sum of one million nine hundred seventy three thousand dollars (\$1,973,000) to provide support for a program directed towards increasing the availability and accessibility of Oral Rehydration Salt in order to reduce the mortality and morbidity due to diarrheal dehydration, as described in the Schedule (Attachment 1) of this Cooperative Agreement and Attachment 2, entitled, "Program Description."

This Cooperative Agreement is effective August 30, 1985. Obligation is made as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives during the period August 30, 1985 through August 29, 1988.

The total estimated cost of this Agreement is \$1,973,000 for the period August 30, 1985 through August 30, 1988.

PATH
DPE-0009-A-00-5050-00

This Cooperative Agreement is made to PATH on the condition that funds will be administered in accordance with the terms and conditions as set forth in Attachment 1, Schedule; Attachment 2, Program Description; and Attachment 3, Standard Provisions; which have been agreed to by your organization.

Please sign the original and seven (7) copies of this letter to acknowledge your acceptance of the conditions herein. Thereafter, please return the original and six (6) copies to the Office of Contract Management.

Sincerely



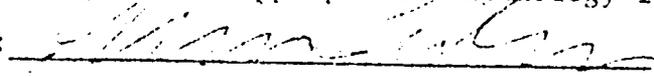
Judith D. Johnson
Agreement Officer
Chief, PE Branch
Central Operations Division
Office of Contract Management

Attachments:

1. Schedule
2. Program Description
3. Standard Provisions

ACKNOWLEDGEMENT:

The Program for Appropriate Technology in Health

BY: 

TYPED NAME: Gordon W. Perkin, M.D.

TITLE: President

DATE: September 18, 1985

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PATH
DFE-0009-A-00-5050-00

Fiscal Data

Appropriation No.:	72-1151021.8
Allocation No.:	548-34-099-00-69-51
Budget Plan Code:	PDAA-85-13480-CG-11
PIO/F No.:	534-2519
Project No.:	940-0009
Total Estimated Amount:	\$1,973,000
Amount Obligated:	\$1,973,000
Duns No.:	09-527-9224
Funding Source:	AID/W

FUNDS AVAILABLE
PROGRAM ACCTS. & FIN DIVISION
DATE 8/3/88
OFFICE OF FINANCIAL MANAGEMENT

SCHEDULE

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STANDARD PROVISIONS

The Standard Provisions applicable to this Cooperative Agreement are AID 1420-52 entitled, "U.S. Grantees and U.S. Subgrantees NonProfit Organizations - Other Than Educational Institutions," dated February, 1982.

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Article I - Purpose and Program Description

A. Purpose

The primary purpose of this agreement is for the Recipient to increase the availability and accessibility of ORS in order to reduce the mortality and morbidity due to diarrheal dehydration. A secondary purpose is to test the feasibility of the proposed collaboration between the commercial sectors, the PVO sector and the public sector, and its ability to meet public health needs.

B. Program Description

The Program Description is attached hereto as Attachment 2

Article II - Funds Obligated, Payment, and Total Estimated Cost

A. Funds Obligated

The amount obligated by this Agreement is \$1,973,000. It is anticipated that this amount will support Recipient performance of the Program Description through August 29, 1983.

B. Total Estimated Cost

The total estimated cost of this agreement is \$1,973,000. Costs are subject to Standard Provision No. 1 entitled, "Allowable Costs and Contributions," and No. 6 entitled, "Revision of Financial Plans."

C. Payment

The payment mechanism applicable to this agreement is the Letter of Credit/Treasury Financial Communications Systems (LOC/TFCS).

Article III - Substantial Involvement Understandings

It is anticipated that performance of the workscope requires substantial involvement by AID. Specific areas of involvement include, but are not limited to, the following:

- A. Prior review of all country selections, country assistance plans, technical assistance requests, initial and exceptional loan agreements. USAID procurement proposals, key personnel and consultant appointments, Technology Reviews, and review of all program reporting.
- B. Redirect work, if required, in the event of A.I.D. determination that such action is necessary to ensure optional use of A.I.D. funds and success of the undertaking.

Article IV - Reports and Implementation Reviews

1. Periodic Reporting will be in three forms: quarterly financial reports accompanied by a brief narrative report, semi-annual detailed narrative reports as a basis for semi-annual Progress Review meetings, and an annual report responding to the reporting requirements of the Child Survival Action Program. The quarterly and semi-annual reports will follow an agreed format which will be outlined in an implementation letter from A.I.D. to the Recipient within 60 days of the signing of the Cooperative Agreement. They will

include a review of major activities carried out during the period, of any major issues which will have developed during this time, and of performance against timetable.

a. Quarterly Reports will show expenses by program/activities/functions, in addition to line items. Any loan delinquencies will be reported. The financial reports will explain any significant variances compared to budget. They will include estimates of expenditures for the ensuing three-month period, as well as travel plans for that period. These reports will be provided within thirty days following the end of the three-month period covered by the report.

b. Semi-Annual Reports will require the following:

i. Progress Review Meeting: This meeting, attended by S&T, PRE and the Recipient, will serve to supplement the written report. The meeting will assess the implementation of the project to date, will identify any problem areas to be addressed, and will provide data for subsequent evaluation of the program.

ii. Written Report: This report will be submitted by the Recipient fifteen days in advance of the scheduled progress review meeting. It will report on the status of the following:

For the overall project:

Needs Assessment/Opportunity Identification Studies.

- Country Reports (and review of Country Detailed Plans).
- Technical Assistance Activities.
- USAID Commodity Procurement Program.
- Production, Distribution and Marketing Plans and Operations.
- Results in comparison with Timetable.
- Additional information as agreed upon between A.I.D. and the Recipient.

For Sub-Projects:

- Status of sub-projects for which assistance has been agreed to but investment is not yet made.
- Status of sub-projects for which loan agreements have been signed (or investment made), with regard to:
 - Capitalization of sub-project.
 - Projected Sales (value, and unit volume).
 - Loan terms.
 - Reimbursement of assistance, if any
 - License and/or technical assistance agreements.
 - Projected timetable for distribution of product.
 - Copy of completed feasibility study (which will contain valuable baseline data).
 - Names of key bank, and company decision makers.
 - Technical Assistance for Sub Projects.
 - Additional data as agreed upon by A.I.D. and Recipient.

Status of sub-projects in "post-investment" phase, with regard to:

- Implementation progress.
- Sales (value and unit volume).
- Loan performance. In the case of delinquencies, to include submission of balance sheets and income statements, as well as an outline of a recovery plan.
- Any reflows (including any royalty payments to the Recipient, whether or not credited to the program).
- Impact on target population.

Annual Progress Report on the indicators which respond to the reporting requirements of the Child Survival Action Program to be submitted, no later than 31 October in a given year. Format for this report will be outlined in an implementation letter from A.I.D. to the Recipient during the first quarter of the Cooperative Agreement.

2. Other Reports: At the appropriate time the Recipient shall submit to A.I.D. reports on the following:

Guidelines and Criteria for Country Selection (during the first quarter of the project, to be reviewed over the life of the project).

Timetable for major events/accomplishments during the life of the project: quarterly for the coming year, annually for subsequent years (submit during the first quarter of the project).

- List of countries for implementation activities (in stages, as outlined in Article II, 1. & 2., with selection of the first two countries prior to the end of the third quarter of the first year).
- Needs Assessment/Opportunity Identification Studies/Country Reports (within three months of final selection of country).
- Country Detailed Plan (within six months of final selection of country).
- Conditions and Agreements for Negotiations (within nine months of final selection of country).
- Assessment of Two Country Interventions (within fifteen months of final selection of countries).
- Country Protocol for Monitoring and Evaluation (within nine months of final selection of country).
- Mechanism for USAID Procurement of ORS Packets (eight months from start of project).
- Five Technology Reviews (in the first two years).
- LOP Evaluation Report, including substantive field notes (end of project).

All reports shall be submitted in quadruplicate (two copies to A.I.D./S&T and two copies to A.I.D./PRE). Periodic reporting, including Progress Review meetings, will be scheduled to coincide with reporting for the Health Link project.

3. Implementation Reviews: These will be conducted at the end of the first and second year after commencement of the project. The first review will be performed by S&T and PRE. The purpose of the review will be to determine the success of the ORS project in meeting certain established objectives. The review will entail three components:

- i. An implementation report prepared by the Recipient for review by S&T and PRE.
- ii. An implementation review meeting attended by the Recipient, S&T and PRE, and
- iii. A summary memorandum prepared by S&T and PRE.

The implementation report, to be prepared by the Recipient, will focus on providing objective data concerning implementation of the ORS project in terms of the objectives outlined in Article II, and particularly with respect to II.6. (Monitoring and Evaluation). In its report, the Recipient will provide a detailed summary of progress toward the achievement of these objectives. In addition, the report will discuss any unexpected problems or opportunities, and any recommendations for modification of the project design for future projects. The second implementation review will be more extensive, and will include limited field research. Included in the reviewing team, in addition to representatives of S&T and PRE, will be a representative of PPC as well as an outside evaluator agreed upon by A.I.D. and the Recipient. In addition to the three work components listed above, the second year review will

include field research conducted by a local consultant under the direction of an outside evaluator. The outside evaluator will design an interview format to be used by local consultants in interviews with selected company representatives who have been identified by the Recipient as the key decision makers involved in the companies' decisions to undertake the health product ventures. This field review will focus on:

- The specific incentives affecting the companies' decisions;
- The role of the Recipient in the transaction with the companies;
- The effect of the ORS program in enhancing the Recipient's interest in, and institutional capabilities for dealing with loans for low-income health ventures;
- Whether the local companies' participation in the ORS project has resulted in their consideration of other (non-ORS) primary health care product lines.

ARTICLE V: Key Personnel

1. The key personnel which the Recipient shall furnish for the performance of this work are as follows:

The Cooperative Agreement shall receive overall management supervision from Dr. Gordon W. Perkin. Program management shall be the responsibility of Dr. John Tomaro, Director of PATH. Dr. Richard Mahoney, Director of Health Link, would assure successful integration of the new project with the

Health Link program. Mr. Carl McEvoy shall supervise the placement and structuring of the loan component. The technology reviews shall be prepared under the direction of Ms. Vivien Tsu. The Procurement Study would be carried out by Ms. Margaret Morrow.

2. The personnel specified above are considered to be essential to the work being performed hereunder. Prior to diverting any of the specific individuals to other programs, the Recipient shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Recipient without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The listing of key personnel may, with the consent of the contracting parties, be amended from time to time during the course of the cooperative agreement to either add or delete personnel as appropriate.
3. The Recipient shall obtain A.I.D.'s approval to change key personnel, or to continue the work hereunder during a continuous period in excess of three months without the participation of the above approved personnel.

4. In addition to these, a full-time program officer shall be recruited to assist in program implementation. This individual should have a background in public health with experience in diarrheal disease control programs and be approved by AID. Consultants with expertise in diarrheal disease control program management, ORS production, and market development will be utilized as necessary. The Recipient will make an effort to bring in "junior" consultants and professionals from developing countries to increase the pool of expertise in this area. Possible consultants include Mr. Stephen Fabricant, Mr. Rodrigo Arce Montiel, Ms. Pamela Greene, Ms. Carole Kazi, and Ms. Cecilia Verzosa.

Article VI - Financial Plan

Funds in the amount of \$1,973,000 have been obligated to fully fund this Agreement. The budget indicated below sets limitations for reimbursement of dollar costs for individual items. The Recipient agrees to furnish data which the Agreement Officer may request on costs expended or accrued under the Cooperative Agreement in support of the budget information provided herein.

Budget Summary by Component

	<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>	<u>Total</u>
A. Program Marketing and Management	\$100,830	\$97,305	\$103,910	\$302,045
B. ICORT Workshop	93,900	-0-	-0-	93,900
C. Project Initiation Trips	60,970	27,095	-0-	88,065
D. New Opportunity Identification	27,090	28,710	-0-	55,800
E. Market Development	-0-	344,960	239,930	584,890
F. Production Technical Assistance	-0-	124,120	63,695	187,815
G. Loans	-0-	465,785	48,575	514,360
H. Procurement Mechanism Development	46,125	-0-	-0-	46,125
I. Evaluation	<u>-0-</u>	<u>-0-</u>	<u>100,000</u>	<u>100,000</u>
TOTAL	<u>\$328,915</u>	<u>\$1,087,975</u>	<u>\$556,110</u>	<u>\$1,973,000</u>

The Agency for International Development agrees to reimburse the Recipient for all reasonable, allowable and allocable costs incurred under this Agreement for the period August 1, 1985 through August 30, 1985, provided such costs do not exceed \$5,000. These anticipatory costs are included in the funds obligated by the budget.

With prior written approval of AID project managers, the Recipient may adjust line item amounts as reasonably necessary for the performance of work hereunder.

Article VII - Negotiated Indirect Cost Rates

a. Rates

Pursuant to the Standard Provision of the Agreement entitled,

"Negotiated Overhead Rates," a rate shall be established for each of the Recipient's accounts during the term of the Agreement. Payments on account of identifiable indirect costs shall be made on the basis of the following negotiated provisional rates applied to the base which is set below:

<u>Type of Rate</u>	<u>Rate</u>	<u>Period</u>
(G&A) provisional	26%	10/30/85-until amended

Base of Application

Modified total Direct Costs including the first \$10,000 of each account.

b. It is understood that ninety days after award of this Agreement, the Recipient will submit a new overhead rate proposal for formal establishment of a provisional rate to be applied to this Agreement. Failure to submit the proper documentation within this timeframe will result in suspension of all overhead costs paid under this Agreement.

Article VIII - Special Provisions

A. The Recipient shall put the following information of each voucher submitted under this Agreement:

Cooperative Agreement No.: A-00-5050-00

Project No.

Project Officer: /PPR

Obligation No.

B. The use of consultants is authorized under this Agreement subject to the technical concurrence of the CTO that the proposed individual is suitable for the task assigned. Fees paid to consultants and reimbursed hereunder shall be reasonable in accordance with the applicable cost principles, OMB Circular A-122, Paragraph 34, Professional Service Costs, and shall not exceed, without specific approval of the Agreement Officer, the maximum daily rate of a Foreign Service 1 (FS-1).

C. Management and Technical Direction

The Cooperative Agreement will be jointly managed by S&T/H PRE/PPR and, each of whom will designate a project manager. The S&T/H project manager will have authority for all technical matters, and will be the principal A.I.D. contact for the Recipient on such matters. The Recipient will be expected to work closely in all significant technical matters with S&T/H as well as with other A.I.D. personnel from time to time as designated by this office. The PRE/PPR project manager will serve as the principal A.I.D. contact for the Recipient on non-technical matters. His responsibilities will include private enterprise involvement on sub-projects, organization and financing of sub-projects, loan policy and terms, and relationships to the Health Link project. PRE's involvement as co-manager may be most beneficial in the early, organizational stages of the project. The Recipient is expected to coordinate activities closely with other A.I.D. projects such as Health Link, as well as with other organizations such as PRITECH, MM&P, and WHO.

D. Program Income

As with the Health Link project, the Recipient may recover some portion of its direct costs associated with the production of feasibility studies, or it may negotiate with U.S. technology source for a share of royalties or fees. All such fees and royalties will be treated as program income.

In the event that a PATH proprietary technology is utilized in this project, royalties and fees earned on the PATH technology shall be treated as program income and reimbursed to AID in an amount equivalent to the costs incurred by the sub-project which employed technology. Unless otherwise approved by the AID Contracting Office income in excess of sub-project costs shall be treated as program income.

- a. Program income represents gross income earned by the Recipient from A.I.D. supported activities. Such earnings exclude interest earned on advances and include, but will not be limited to, income from service fees, sale of commodities, usage or rental fees, and royalties on patents and copyrights. The standards forth in this special provision apply to Recipient accounting program income under this Cooperative Agreement.
- b. Interest earned at any time on advances of Agency funds shall be remitted to A.I.D. except for interest earned on advances to States or instrumentalities of a State as provided by the Intergovernmental Cooperation Act of 1968 (Public Law 90-577).
- c. Proceeds from the sale of real and personal property either provided by A.I.D. or purchased in whole or in part with A.I.D. funds, shall be handled in accordance with paragraph 1T of Handbook 13, Chapter

- d. Unless the agreement provides otherwise, the Recipient shall have no obligation to A.I.D. with respect to royalties received as a result of copyrights or patents produced under the agreement.
- e. All program income earned prior to the earlier of the expiration date of this agreement or the date upon which no further funds remain undisbursed shall be retained by the Recipient and used to reduce the total amount of A.I.D. funds required to support the ORS project.
- f. All program income as described in this paragraph, which is earned after the earlier of the expiration date of this agreement or the date upon which no further funds remain undisbursed, shall be refunded to A.I.D.

E. Source and Origin of Goods and Services.

"Goods and services procured under this grant must have their source and origin in the United States or an AID Geographic Code 941 country."

F. USAID Mission Relationships.

The Recipient agrees that it will consult regularly with the USAID Missions located in the country where each

proposed product is to be marketed regarding the relationship between the product, the basic health needs of the residents of that country, and the health strategy of the Mission.

G. Emergency Locator Information

The Recipient agrees to provide the following information to the Mission Administrative Officer on or before the arrival in the host country of every agreement employee or dependent:

1. The individual's full name, address, and telephone number;
2. The name and number of the Agreement, and whether the individual is an employee or dependent;
3. The Recipient's name, home office address, and telephone number, including any after-hours emergency number(s), and the name of the Recipient's home office staff member having administrative responsibility for the Agreement;
4. The name, address, and telephone number(s) of each individual's next of kin; and,
5. Any special instructions pertaining to emergency situations such as power of attorney designees or alternate contact persons.

Article IX - Standard Provisions

The Standard Provisions, contained in Attachment 3, are applicable to this Agreement with the exceptions of the modifications made hereunder.

A. Delete the following provisions in their entirety:

1. 5A. Negotiated Overhead Rates - Predetermined;
2. 7B. Payment - Periodic Advance;
3. 7C. Payment - Reimbursement;
4. 10B. Procurement of Goods and Services Over \$250,000;
5. 11. Local Cost Financing with U.S. Dollars;
6. 13B. Title to and Care of Property (U.S. Government Title); and,
7. 13C. Title to and Care of Property (Cooperating Country Title).
8. 16. Voluntary Participation
9. 17. Prohibition on Abortion-Related Activities
10. 18. Voluntary Participation Requirements for Sterilization Programs

B. Standard Provision No. 7A entitled, "Payment - Federal Reserve Letter of Credit (FRLC) Advance," is hereby amended to delete all references to "Federal Reserve Letter of Credit (FRLC)" wherever it appears and insert in lieu thereof "Letter of Credit/Treasury Financial Communications System (LOC/TFCS)".

C. Standard Provision No. 15 entitled, "Termination," is hereby amended to read, "Termination and Suspension," and to incorporate the following paragraph therein:

"(d) Suspension: Termination for Changed Circumstances.
If at any time AID determines (1) that disbursement by AID would be in violation of applicable law, or (2) that continuation of funding for a program should be suspended

or terminated because such assistance is not in the national interest of the United States, then AID may, following notice to the Grantee, suspend this Grant and prohibit the Grantee from incurring additional obligations chargeable to this Grant other than necessary and proper costs in accordance with the terms of this Grant during the period of suspension. If the situation causing the suspension continues to pertain for 60 days or more, then AID may terminate this Grant on written notice to the Grantee and cancel that portion of this Grant which has not been disbursed or irrevocably committed to third parties. Financial settlement of this Grant shall be governed by the termination procedures specified in paragraph (c) above."

D. Standard Provision No. 20 entitled, "Patents," is hereby deleted in its entirety and a new Standard Provision No. 20 entitled, "Patent Rights (Small Business Firms and Nonprofit Organizations)(March 1982)," is incorporated herein and attached hereto.

PROGRAM DESCRIPTION

A. Purpose and Objectives:

The primary goal of this Cooperative Agreement is to increase the availability and accessibility of ORS in order to reduce the mortality and morbidity due to diarrheal dehydration. A secondary goal is to test the feasibility of the proposed collaboration between the commercial sector, the PVO sector and the public sector, and its ability to meet public health needs.

The specific objectives of the agreement are:

1. Through discussions with A.I.D staff, existing A.I.D. contractors, and other organizations, identify at least six developing countries in which production of ORS could be initiated, expanded, or significantly improved in quality.
2. To reach agreements with companies in at least four developing countries to undertake activities leading to the manufacture and/or distribution of ORS. (This would be a phased process so that the last two countries would start only after an assessment had been conducted on the initial sites.)
3. To develop a series of guidelines for the local production of salts through private sector companies and revise them over the life of the project.

4. To provide technical assistance and other support so that new or expanded production facilities are operating in at least two countries and in at least the final stages of preparation in two others.
5. To develop an efficient mechanism to procure and distribute to country port U.S. produced ORS packets to meet USAID requests.
6. To conduct a series of Technology Reviews on key primary health care issues to help identify new opportunities for future commodity support interventions.

B. Statement of Work:

The Recipient shall provide necessary technical and administrative support to expand the production and distribution of ORS using private sector resources in developing countries. This Cooperative Agreement will involve a set of components which will be applied in individual combinations as appropriate to each country situation. These periods of activities would overlap to a certain extent as different country projects progress at different rates.

In general, the first year would involve extensive needs assessment activities, identification of specific project opportunities, the development of guidelines, initial start up in at least one country and development and implementation of a procurement mechanism for ORS. The second year would involve further implementation of activities begun in the first year, launching additional activities, assessment of progress to

date, and identification of new activities. In the final year, at least two projects would be completed and, if so determined, the other two country activities would also be initiated.

In the early stage, the program would provide assistance in assessing the feasibility of individual projects (making use of the existing reports and feedback from current projects in the field), in developing production plans (including facility design and equipment procurement), and in arranging loan financing as needed. In later stages, the program would provide assistance in establishing actual production and in developing appropriate marketing and distribution systems (working closely with select groups with projects and expertise in this area).

Specifically, the Recipient shall do the following:

1. Identification of Project Opportunities and Needs

Assessment:

a. The Recipient shall develop criteria and guidelines for the selection of appropriate countries for assistance in production and distribution of ORS using private sector resources. (The Recipient should utilize information contained in the A.I.D. ORS Data Base and existing consultant reports on this subject.)

Possible criteria include:

- Companies

1. Previous experience with the manufacture and/or distribution of pharmaceutical-quality products.

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2. Established capability for quality assurance of pharmaceuticals and powders. Adequate market for private sector ORS supply.
3. Sufficient financial resources to assure follow-through on the project.
4. Good management skills.
5. Excellent reputation in the private sector and with the Ministry of Public Health.

Countries

6. A.I.D. child survival priority country.
 7. Country to be targeted for other A.I.D. activities (MM&HP, PRITECH, SOMARC, etc.)
 8. High prevalence of Diarrheal Disease.
 9. Established private pharmaceutical sector.
- b. The Recipient shall organize a Coordination Meeting, soon after the Cooperative Agreement begins, of the various contractors and organizations currently involved in ORS. These agencies could include PRITECH, AED, NCIH, CCCD, WHO, and UNICEF. This meeting should be in Washington, D.C. and should cover the current status of ORS production, ways to increase ORS supplies (with a focus on the private sector), and means to coordinate such activities together.
- Necessary background material, to be determined by A.I.D., will be provided by PATH. Participants at the meeting would identify up to six countries in which private sector production of ORS appears to be desirable and feasible.

c. The Recipient shall organize a day-long international meeting to be held immediately following ICORT II which will be held in Washington, D.C. in December 1985. This meeting would bring together staff of A.I.D., WHO/UNICEF, key PVOs, S&T contractors engaged in ORT, private sector firms, especially from potential countries for assistance. The Recipient shall be responsible for the invitation, travel, and follow-up of approximately 16 participants (an estimated four people from each of the four selected countries). If feasible, two shall be the senior executive of the company and the head of manufacturing. The other two shall consist of one key government official and one person knowledgeable about marketing of pharmaceutical products in that country. The objective of the meeting would be to generate a consensus on what is needed to expand private sector involvement in ORS. The discussions at the meeting would be used to generate materials, including a series of guidelines, for the local production of salts through private sector companies.

Some of the topics to be addressed would be:

1. Options for machinery to be used for filling ORS sachets.
2. Cost implications of various size packets (150 cc, 500 cc, 1 liter).

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3. Pricing strategies.
 4. Marketing approaches, including placement of the product in conjunction with government-supplied products.
 5. Advertising and mass media campaigns.
 6. Storage, logistics, shelf-life, and quality assurance.
 7. Financing requirements for various levels of production and distribution channels.
 8. The involvement of pharmacies and other distribution sources.
 9. Likely future developments in ORS formulation, e.g., requirement for anhydrous glucose, cereal-based ORS.
- d. The Recipient shall conduct needs assessment/opportunity identification studies in selected developing countries. These visits would be made only after a full review of existing consultant reports in the proposed country and a determination by A.I.D. that additional information will be necessary to determine needs and opportunities. If appropriate, the teams shall generally consist of two-persons and shall meet with appropriate USAID and host country personnel. The contractor is encouraged to make a special effort to incorporate "junior" consultants in such visits to increase the pool of expertise in ORS.

Areas to be looked at during the needs assessment/opportunity identification stage include:

1. Sources of supply and current use of ORS.
2. Distribution channels-public sector/private sector.
3. Nature and quality of in-country production.
4. Trends in use and plans by the government for expansion of coverage.
5. Assessments of climate for establishment and/or expansion of private sector manufacture and distribution. This would include identification of constraints to licensing, pricing, registration, etc., for implementation of the program.
6. Identification of private sector entities that could undertake manufacture.
7. Identification of private sector organizations with the capability to distribute ORS.

The results of this assessment would be presented to A.I.D. as a report on each country reviewed. This information should be reviewed in terms of the guidelines and criteria for selection previously developed. Companies with partial government ownership shall be eligible, but preference shall be given to fully private companies in order to demonstrate that the private sector can make contribution to the availability of ORS in developing countries.

2. Country Selection and Proposed Plan

- a. From the discussion at the Coordination Meeting and the identification of project opportunities and needs

assessment, the Recipient shall present to A.I.D. a list of at least six developing countries in which production of ORS could be initiated, expanded, or significantly improved in quality. A.I.D. shall review this list and background material and with the Recipient determine two sites for initial start up activities. Two additional sites shall be identified for possible start up in years 2 and 3. These additional sites will be funded after a review of program performance of the existing sites. A.I.D. will seek to have regional representation in the countries selected.

- b. The Recipient shall develop a detailed plan for providing assistance in ORS to each country chosen. This plan shall include a timetable for events, types of technical assistance required, possible financial conditions to be provided, outside resources to be utilized, etc. A.I.D. shall review these plans and approval is necessary before further activities are undertaken. It is anticipated that country visits will be necessary during this stage by the Recipient.

3. Country Negotiations

- a. After countries have been selected and the plans approved, the Recipient shall negotiate agreements as necessary. Two types of implementation agreements will most likely be needed. One agreement shall be between the Recipient and the manufacturer. This agreement shall specify the nature of the technical assistance to be provided and other

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assistance which the Recipient shall provide such as loan financing. Another agreement shall be between the Recipient and the distributor, if different from the manufacturer. This agreement shall lay out the terms under which the Recipient or other contractor shall provide assistance in developing the marketing plan and supporting materials such as posters, packet instruction leaflets, advertising copy, etc.; it shall also lay out the obligations of the distributor to undertake the sales of the product throughout the country. In many cases the manufacturer will have its own distribution mechanism, either in-house or through a separate company with which it has an established relationship. In the case of an in-house distribution capability, the two agreements would be combined into one agreement.

- b. Before any final commitments are made by the Recipient, A.I.D. shall review conditions and agreements as to their appropriateness for the given country specifications. This would include a review of financial conditions, including annual interest rate proposed. A general statement of these conditions should be presented in the previous country plan.
- c. Visits by Recipient to the various countries will be necessary during this stage.

4. Production Technical Assistance

- a. The Recipient shall provide technical assistance as necessary to support the goals of this Cooperative Agreement. Areas of assistance could include the following:
- The exact formula, including the option of using bicarbonate or citrate, and the characteristics of the formulation in terms, for example, of its flow characteristics in packaging;
 - Specifications for quality assurance procedures and equipment;
 - Desirable factory layout plans, assistance in upgrading existing facilities, and specifications for air conditioning and humidity control;
 - Options for procurement of raw materials not available locally;
 - Packaging requirements; and
 - Information on sources, prices, and availability of machinery and quality assurance equipment.
- b. Once production has begun, the Recipient shall provide technical assistance, as appropriate, to any problem areas that would need outside expertise. A.I.D. approval is required on all technical assistance requests.
- c. For all technical assistance, the Recipient is encouraged to make a special effort to incorporate "junior" consultants and developing country personnel to increase the pool of expertise in ORS. Specifically, by the end of

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the three-year grant period, at least two individuals will have been trained who could provide assistance in ORS local production.

5. Distribution and Marketing

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

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

6. Monitoring and Evaluation

The Recipient shall develop and maintain a sufficient monitoring and evaluation system, consistent with the requirements, of the Child Survival Action Program, to be approved by A.I.D., to identify areas of difficulties and successes and to measure the overall progress and impact of the project. As this is a new activity in the area of ORT, we feel that sufficient time and effort should be spent in monitoring and evaluation to ensure a learning process approach. Through regular monitoring, the Recipient is expected to identify areas where corrections should be made

in the initial country plans and areas that have been successfully implemented. This is especially critical in the first two countries as new approaches will be field tested for the first time.

The Recipient shall conduct assessments on the two countries after the first year to determine lessons learned and areas of improvement. Based on this analysis, A.I.D. will determine the scheduling of further site implementation.

Over the life of the project, the Recipient shall seek to determine the extent to which availability of ORS and people's knowledge about using ORS for diarrheal disease treatment has increased. Some possible means to measure this include the following: Availability could be measured according to units of packets manufactured and sold and purchaser follow-up surveys to determine actual use. Knowledge about ORS could be evaluated by surveys conducted before and after launching of any of the communication activities. (Such studies would be done either by existing A.I.D. contractors or in close cooperation with them.) Success would be indicated by increased understanding of the use of ORS and of its correct preparation and administration. Another element of success could be increases in levels of positive attitudes towards ORS.

Data on availability could be collected from the manufacturers with confirming studies using interviews with pharmacists and other retailers. Knowledge and attitude of consumers could be measured by house-to-house surveys.

In each country, a specific protocol shall be developed after the countries have been selected and the country plan developed. A.I.D. shall review each country's protocol for monitoring, and evaluation by an A.I.D. - approved contractor based on an A.I.D. - approved Scope of Work, before it is used in the field.

The Recipient will submit annual progress reports on the indicators which respond to the reporting requirements of The Child Survival Action Program (see Article V, 1.)

7. Loans

- a. Loans shall be negotiated from the Recipient to the manufacturer, either directly or as a guarantee, to finance the procurement of machinery, quality assurance equipment, and working capital for initial supplies of salts and packaging materials. It is anticipated that four countries will be covered for a total of \$400,000. The loans would be made at terms to be determined on a country-by-country

- basis after a thorough review of the particular conditions in the country and the financial standing of the participating company.
- b. The structure of all loan agreements will be reviewed by A.I.D. before execution.
 - c. The loans may be denominated in local currency, since it is anticipated that the products will be sold almost exclusively in the local market and thus will not generate foreign exchange. Exchange risk should be evaluated on a case-by-case basis, taking into account the probability of devaluation, the credit worthiness of the borrower, and other factors.
 - d. A.I.D.'s prior approval shall be required for all U.S. dollar loans at interest rates more than 1% below that of U.S. Treasury Notes of corresponding maturity, for all local currency loans at interest rates more than 2% below what is typically available to a commercial lender in the host country, and for all loans which are judged by the Recipient to involve a higher degree of risk than would be acceptable for a typical sub-project of the Health Link Program.
 - e. Any repayments of principal, interest, or fees from the loans will not be used by the Recipient, without A.I.D.'s approval, for any other purpose than additional similar loans or guarantees.
 - f. Reporting procedure for outstanding loans is outlined in Article V.

8. Mechanism for the Procurement of ORS Packets

From previous consultant reports, field cables, and discussions with A.I.D. staff, the Recipient shall, over the initial eight-month period, develop a proposed mechanism to quickly and efficiently procure and distribute US-produced ORS packets to USAID missions. Once approved by A.I.D., this mechanism would provide a means for USAIDs to procure salts to meet their ongoing program needs. The Recipient will request additional funding, via the Child Survival Action Program, to implement this mechanism. Such a mechanism could involve a subcontract with a US-based firm for production of packets and/or stockpiling of supplies. The Recipient shall seek to reduce the price of the packets through competition and bulk ordering. Also, the current length of time to procure for the field (currently up to six months) should be reduced. Some of the issues to be examined include: a) uniform packaging and labeling, b) bidding, c) package size, d) formula, e) response time, f) financing. The Recipient shall be responsible for any correspondence to the field concerning this procurement mechanism. In addition, over the course of the project a system for estimating ORS demand for future years shall be developed.

9. New Opportunity Identification

The Recipient shall prepare five Technology Reviews during the first two years of the project on key primary health care issues related to the Child Survival Action Program as mandated by The Congress (issues such as Vaccines, Weaning Foods, Growth Monitoring, Maternal Education, Water Supply Sanitation, and others related to health of children). The purpose of these reviews will be to identify other opportunities, in addition to ORS, for which commodity support interventions in support of the Child Survival Action Program might be useful.

The Recipient shall submit to A.I.D. suggested topics for these reviews. The topics shall be chosen according to the following criteria:

- relevance to primary health care and child survival;
- relevance to several regions of the world;
- substantial number of people affected by the problem;
- significant technology choices available;
- relevance to private health providers in LDCs.

The Recipient shall conduct an extensive literature review of journals, bibliographic data bases, published or unpublished material, and shall contact experts by phone or

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mail to discuss the latest advances in a given field and gather descriptions of relevant field programs.

Information should be gathered on the best available technologies in select areas, how these technologies are used, prices and sources of supply (whenever available), and implications for program management.

The Recipient shall have this material reviewed by three or four experts with a mix of academic and practical experience in the topic area. These reviews shall be typescript, bound studies. The Recipient shall be acknowledged as the author of the studies and would retain full rights to use the information developed for other programmatic purposes. A.I.D. shall be acknowledged as the funder of the studies.