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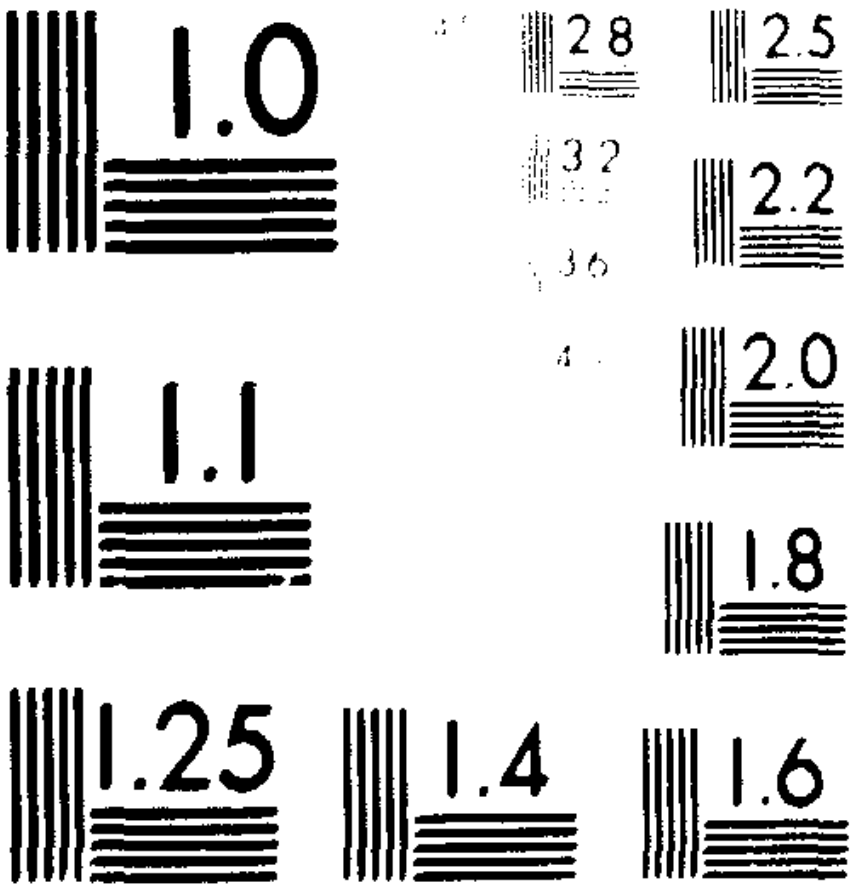
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UNITED NATIONS INDUSTRIAL
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PRODUCTION OF ORAL REHYDRATION SALTS

RP/HAI/80/001

HAITI

Terminal Report *

Prepared for the Government of Haiti
by the United Nations Industrial Development Organization

Based on the work of J.D.Amiran,
pharmaceutical expert

* This document has been reproduced without formal editing.

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CONTENTS

S U M M A R Y

A one month fact finding assignment for the future production of oral rehydration salts (ORS) in Haiti is reported on.

The urgency of creating a unit for the production of ORS, another for the production of intravenous fluids, and the third for the quality control of these two units, is stressed.

It is recommended that all three units be installed in the same building, and placed under the responsibility of the Haitian Blood Transfusion Bank.

P R E F A C E

Haiti has a population of nearly 6,000,000 inhabitants.

The Department of Public Health and Population operates two thirds of the country's 24 hospitals and about the same proportion of the 3900 hospital beds.

Sources concerning the actual consumption of intravenous fluids and oral rehydration salts (ORS) vary considerably, but there is a general agreement that the needs far exceed present day consumption. All of the ORS and intravenous fluids are imported.

Following a decision by the Government of Haiti to initiate the production of ORS for the treatment of diarrheal diseases, and its delivery on a national scale, UNIDO was requested to send a short-term consultant on a fact-finding assignment destined to evaluate the needs of the country in ORS, and to propose the necessary measures for its local production [1].

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[1] See Annex I for job description.

A C K N O W L E D G E M E N T S

This assignment would not have been possible without the full cooperation and constant help of the UNDP at Port au Prince.

I am deeply indebted to all the senior officials at the Secrétairerie d'État du Plan, at the Department of Health and Population, and at the Department of Commerce and Industry, for agreeing to see me at such short notice, notwithstanding their heavy schedules.

I would also like to thank Mrs. A. Tcheknavorian for her constant help and guidance, and Mr. M. Polievktov for very fruitful discussions.

1. FINDINGS

1.1. THE LOCAL PHARMACEUTICAL INDUSTRY

1.1.1. Pharval Laboratories

The company is run by a physician and his son. The factory premises visited were neat, and the production units air-conditioned by single units. The production equipment is satisfactory and maintenance adequate. The production personnel appears to be well qualified.

Production, according to the price list supplied to us, consists of about 70 different products in the form of tablets, capsules, and liquids. The product mix is satisfactory, and covers a wide range of therapeutic indications. The majority of the drugs appear in their generic names.

There is no quality control department, and it is assumed that the products answer the label claims.

ORS production: The new machine for the automatic forming, filling and closing of pouches has been given several trial runs during the current year, with different laminates. The company is trying to locate a supplier in the U.S. for the foil laminate recommended for ORS: polyethylene, aluminum, polyester foil of specific gauge.

Other constraints:

a. Once the company enters into mass production of ORS, there shall be a need for additional drying and granulating equipment to serve the unit.

b. There is no appropriate technical person to perform quality control on the product, although the company has installed new equipment in a suitable air-conditioned room for this purpose.

The equipment seen was:

- 1 pH meter
- 1 moisture balance
- 1 flame photometer
- 1 analytical balance
- 1 water still
- 1 polarimeter
- 1 drying oven

1.1.2. 4C: Caribbean Canadian Chemical Co.

The product mix, as seen in the current price list, is modest and consists of tablets and syrups.

ORS production: The company had at one time produced 'rehydration tablets' composed of electrolytes, but had stopped the production. The management agreed, on principle, to look into the production of ORS, should they receive the assurance that the product would be purchased by the Government.

1.2. THE FACULTY OF MEDICINE AND PHARMACY

1.2.1. The Dean and the Vice Dean reported that too often diarrheal diseases in infants went beyond the oral rehydration stage, reaching severe dehydration with acidosis. A system of re-education was urgently needed, which would on the long run bring those infants to treatment on time.

1.2.2. The Director of the School of Pharmacy talked about the re-organization of the School of Pharmacy, which has just started. From 1981, a 4th year will be added, which will include Applied Chemistry and, hopefully, Chemistry of Natural Substances.

Subjects discussed were:

a. Possible funding for a demonstration unit for pharmaceutical production.

b. Possible funding for a small unit for the study in depth of medicinal plants in Haiti.

1.2.3. The Chemistry Department - School of Pharmacy

The Head of the Department is serving for the past two years under the terms of the technical cooperation of the French Foreign Ministry.

Under a personal grant, the Head of the Department initiated a 2-year study, from 1973-1975, of the antifertility plants of Haiti. The pharmacological screenings were made by Prof. N. Farnsworth in the U.S., and by Roussel and Fournier Laboratories in France.

The future plans of the Department, should the necessary funding be obtained, are to broaden the research on traditional medicine in Haiti and form the necessary technical manpower.

According to the Head of the Department, some 600-1000 species of endemic plants are found in Haiti on which no chemical work has been performed. In addition, the lists of medicinal plants that have been compiled up till now may not exactly correspond to the traditional medicine practiced in the country. It appears that an intensive and long range program of ethnobotanical work has still to be done, involving a direct approach with people talking Creole.

The acute problem facing the Department is a lack of funds to acquire essential equipment, reagents, solvents.

1.3. THE DEPARTMENT OF PUBLIC HEALTH AND POPULATION

1.3.1. The Director General and the Under Secretary of State would welcome the creation of an intravenous fluids production unit

that would answer the needs of the Department. They felt that the production and distribution of ORS on a national scale was an urgent necessity.

The Head of the Department of Family Hygiene received 200,000 pouches of ORS from UNICEF, but this quantity was inadequate for their needs.

The Department of Public Health and Population cooperates with all the international organizations and would welcome all help for the availability, at a reasonable cost, of ORS pouches manufactured locally, either by a private firm or by a Government institution.

1.3.2. The Haitian Red Cross and the Blood Transfusion Bank

The Blood Transfusion Bank, which is an auxiliary of the Department of Public Health and Population, is located in a recently built modern building.

It uses the latest equipment for the collection and analysis of blood. The blood is either stored as such or separated into red blood corpuscles and plasma, for which a proper refrigeration unit exists.

The Bank seems to be fully equipped with quality control apparatus in a suitable air-conditioned room. They have a mobile unit, which is fully autonomous.

The overall impression is excellent.

1.4. THE STATE UNIVERSITY HOSPITAL

1.4.1. The Pediatric Services

According to Dr. Mondestin, Head of the Service, about 50% of infant mortality in Haiti is due to diarrheal diseases. Most of the infants are brought to the Service at a stage of severe

dehydration and acidosis, and the Department is unable to cope with the cases, especially in the summer months, where on an average, 500 infants are treated every 24 hours. Most cases receive intravenous fluids for the first 12-24 hours, and then ORS.

a. The Cornell Project

A demonstration of the efficacy of ORS will start shortly in a ward of the Pediatric Service. In collaboration with Dr. Mondestin, Dr. Jean Pape, a Haitian physician, now at Cornell University, will initiate a clinical trial in infants, where half the number of infants will receive ORS, and the other half will receive intravenous fluids.

2. CONCLUSIONS AND RECOMMENDATIONS

The principal conclusions and recommendations on the findings of this assignment are presented below.

2.1. PRODUCTION OF ORAL REHYDRATION SALTS (ORS) ON A NATIONAL SCALE

2.1.1. Requirements

The country's needs for a target within 5 years is estimated to be over 2 million pouches of ORS for a 1 liter solution. This figure is an extrapolation of present ORS consumption figures and estimates of the proportion of infants actually treated. Moreover, intravenous fluids are still extensively used.

2.1.2. Private or Public Operation

There are advantages and disadvantages in the production of drugs by either exclusively private or government means. It would therefore be advantageous if both could be encouraged, so as to ensure delivery schedules, competitive prices, proper quality, etc. This implies that the total production be shared between the private industry and a government controlled organization. The latter should be the same as that which would assume responsibility for the production of intravenous fluids (see paragraph 2.2), both production units being housed in the same building.

2.1.3. Size of the Unit - for the Government Controlled Operation [2]

The production should first reach the figure of 300,000 pouches, corresponding approximately to present day consumption. Fully automatic equipment for the production of ORS entails the solution of numerous technical problems.

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[2] See Annex II for list of equipment.

In order to acquire the necessary experience related to the product, while answering to the progressively increasing demand, it is recommended to start with relatively simple procedures, which could later be replaced by more elaborate systems, depending on the production of the private sector.

2.1.4. Semiautomatic Equipment

This method calls for a machine which automatically releases accurate doses of the mix, contained in a hopper, into hand held, preformed pouches. The sealing is performed manually. This type of equipment can produce about 400,000 pouches per year, with a 5-person team, on a basis of 40 hours per week.

2.1.5. Fully Automatic Equipment

Based on the form, fill, and seal principle, the film is fed into the machine from a roll in a V form. The pouches are sealed on 4 sides, and are severed by a cutoff knife. The use of this type of automatic packaging equipment allows the production of over 4 million pouches per year.

2.1.6. Assistance to the Private Producers of ORS

The possibility of long-term assistance by an international organization to the local producers, through the Department of Public Health and Population, should be looked into seriously. Such an assistance will enable the private industry to acquire the necessary know-how, and allow it to rapidly produce competitively priced ORS pouches.

A long-term assistance over a period of 5 years could be formulated with the Department of Public Health and Population. This help, to the private industry, could consist in the delivery of raw materials or equipment under advantageous conditions.

2.7.7. Promotion and Delivery of ORS

The consumption of ORS can only increase if there exists an efficient delivery system. An aggressive publicity and educational campaign will then accelerate the process.

a. Commercial Channels

- The local manufacturers must try to effect as great a coverage as possible through existing commercial channels.

- From 2-4 persons should be trained, with the help of an international organization, to work with the local drug manufacturers. Their responsibilities would include:

  - Meet and educate local influentials about treatment and prevention of diarrheal diseases: health workers, teachers, civil servants, traditional medicine men, etc.

  - Distribute promotional materials and samples to priority groups.

b. National Promotional Campaign

The Department of Public Health and Population has drafted a comprehensive national program for the fight against diarrheal diseases. This program will start when contributions from the Government and international organizations will make this possible.

c. Presentation of ORS Pouches

The Department of Public Health and Population, the international organizations, and the local manufacturers should agree on the final presentation of ORS pouches:

- A suitable name, simple to remember.

- Clear cut indications on how to use the product.

As the name and presentation of the ORS pouches will be used extensively in its promotion, no change in name or presentation should be allowed unless a decision to do so be taken at government level.

d. Packaging of ORS

The standard pouch for a 1 liter solution should initially be exclusively used for at least 2 years. The possibility of later producing either:

- pouches for 500 ml solution sold alone or as twin detachable pouches,

or

- 4 pouches for 250 ml solution, made into a joint strip, should also be looked into.

Although the above packaging would raise production costs, it may be more practical for the user, depending on the kind of container available at the village level.

2.2. PRODUCTION OF INTRAVENOUS FLUIDS

2.2.1. Requirements

The estimated amount of intravenous fluids necessary is of the order of:

a. University State Hospital: 100,000 liters per year.

b. All Government hospitals, including the University State Hospital: 450,000 liters per year.

2.2.2. Location of the Production Unit

The production unit could be administered by either the Blood Transfusion Bank, or by the State University Hospital. However, since the Blood Transfusion Bank is already respon-

sible for the production of quantities of transfusion fluids, and considering the high proficiency of the staff, it is recommended that the proposed intravenous fluids production be placed under their administrative responsibility. The actual location could be close to the Blood Transfusion Bank, and the unit should comprise its own technical staff.

2.2.3. Size of the Unit [3]

It is recommended to directly install the equipment to cover the overall Government hospitals requirements, amounting to about 450,000 liters per year.

One possible alternative could be the creation of a preliminary unit producing 100,000 liters per year required by the State University Hospital. This latter solution would allow the experience gained with a smaller unit to be used to advantage, when the system would be extended or replaced.

On the other hand:

a. The country's needs would not be covered, and the difference would still have to be imported.

b. The initial outlay would not be considerably lower than that of a unit capable of producing the full requirements, as building costs, personnel training, etc. would be practically identical.

It is recommended that polypropylene or PVC bags be used rather than bottles (which are fragile, heavy, and have to be washed carefully).

2.3. QUALITY CONTROL OF ORS AND INTRAVENOUS FLUIDS

It is not necessary to elaborate here on the strict procedures required under good manufacturing practice (GMP) and good laboratory practice (GLP). These are well known. It is therefore strongly recommended

[3] See Annex II for list of equipment.

to plan the implementation of proper quality control procedures so as to ensure that they be perfectly operational when production starts.

Since the quality control of intravenous fluids and ORS call for essentially analogous techniques - though some may be specific to one or to the other - it is recommended that a quality control unit be installed in the same building that houses both the Government ORS and intravenous fluids production facilities [4].

It is further recommended that quality control personnel be made competent to advise private producers of ORS and intravenous fluids on proper quality control procedures, and, in case of need, to perform the appropriate tests themselves.

2.4. EXPERTS

The following experts are recommended for the ORS and intravenous fluids units, and for the quality control unit:

2.4.1. Production Expert: 12 m/m

Industrial pharmacist or engineer with sound experience in the industrial production of sterile fluids. A knowledge in drug packaging equipment will also be required. The expert will have to initiate the production of ORS by semiautomatic methods, and his appointment should be planned so as to enable him to initiate also the semi-industrial pilot unit for intravenous fluids. A suitable counterpart shall be attached to the expert.

2.4.2. Quality Control Expert: 12 m/m

Industrial pharmacist with practical experience in modern quality control equipment and procedures. In order to allow the quality control unit to be operational at production start, the appointment of the expert must be planned so as to give him time to review and order the equipment, train personnel, etc. A suitable counterpart shall be attached to the expert.

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[4] See Annex II for list of equipment.

2.4.3. Plant Engineer: 12 m/m

Engineer with experience in planning, supervising, and installing production equipment. His assignment will call for:

a. Planning the installation.

b. Supervising installation and start-up.

c. Training technicians and supervisors on proper operation and maintenance procedures.

2.5. TRAINING PROGRAMS

The following training programs are recommended for the ORS and intravenous fluids units, and for the quality control unit.

2.5.1. Fellowships

a. Quality Control: 12 m/m

To a suitable pharmacist, to study modern quality control procedures for pharmaceuticals. At a university, hospital, or pharmaceutical company.

b. Production of Sterile Fluids: 6 m/m

To a suitable pharmacist, to study modern production of sterile fluids on a large scale. At a hospital or pharmaceutical company.

2.5.2. Study Tours

It is recommended that UNIDO arranges a study tour for a number of Haitian pharmacists to UNIDO pharmaceutical projects, where units for intravenous fluids production have been installed.

2.5.3. Training Courses

It is recommended that UNIDO includes candidates from Haiti in future training courses in pharmaceutical production and quality control.

A N N E X I

JOB DESCRIPTION

Post title	Pharmaceutical expert (production of oral rehydration salts).
Duration	One month.
Date required	As soon as possible.
Duty station	Haiti.
Purpose of project	Evaluation mission to up-date findings of Mr. Tawfik and to collect all necessary data for starting local production of oral rehydration salts.
Duties	The expert will specifically be expected to: 1. Assess the country's needs in oral rehydration salts for the forthcoming 5 years and conduct a marketing survey. 2. Investigate and advise on distribution arrangements within the country for the sale of oral rehydration salts packs. 3. Suggest the most suitable location of the unit and evaluate existing facilities. 4. Prepare a list of required equipment and spares with specification. 5. Suggest a training programme for local personnel both in the field of production and quality control.

Qualifications	University degree in pharmacy or chemistry with experience in the formulation of pharmaceutical products.
Language	French/English (French preferable).

A N N E X II

LIST OF EQUIPMENT

1. ORAL REHYDRATION SALTS (ORS)

1.1. SEMI-AUTOMATIC OPERATION

Production: 400,000 pouches/year.

1.1.1. Drying Oven (80 trays)

Electrically heated, with temperature control, recording graph, inlet air filter, and timer. Stainless steel trays.

1.1.2. Granulator

Dual blade type: hammer and sharp edge. Complete set of stainless steel sieves.

1.1.3. Mixer

Ploughshare, 160 liters, with chopper.

1.1.4. Dosing Machine

Stainless steel, volumetric type.

1.1.5. Containers

Stainless steel drums with tight lids. 20 units of 50 and 100 liters.

1.1.6. Heat-Sealing Machines

2 units. Foot operated.

1.1.7. Dehumidifiers

To lower the relative humidity to 55%.

1.1.8. Air Condition Units

For maximum temperature, 24°C.

1.1.9. Scales

Top loading: 1500 gr. X 0.1 gr.
Heavy duty: 20 kg. X 1.0 gr.
Platform: 50 kg. X 1.0 gr.

TOTAL ESTIMATED COST: U.S.$ 80,000

1.2. FULLY AUTOMATIC PACKAGING

Production: 4 million pouches/year.

1.2.1. Automatic Forming, Filling and Sealing Machine

Volumetric dosing. Output, 90 pouches/minute. Four-side sealing device.

1.2.2. Drying Oven (80 trays)

2 units. Stainless steel trays, temperature recording graph, timer, etc.

1.2.3. Mixer

Ploughshare, 320 liters, with chopper.

1.2.4. Granulator

Dual blade type: hammer and sharp edge. Complete set of stainless steel sieves.

1.2.5. Dehumidifiers

To lower relative humidity to 55%.

1.2.6. Air Condition Units

For maximum temperature, 24°C.

1.2.7. Containers

Stainless steel drums with tight lids. 30 units of 50 and 100 liters.

1.2.8. Scales

Top loading: 1500 gr. X 0.1 gr. Platform and floor scales of 50 and 200 kg., respectively.

TOTAL ESTIMATED COST: U.S.$ 150,000

2. INTRAVENOUS FLUIDS

2.1. UNIT FOR THE PRODUCTION OF 100,000 LITERS/YEAR

2.1.1. Thermocompressor Distillation Plant

Output, 100 liters/hour. Complete, with automatic puromatic diverter. Accessories and spare parts for 2 years.

2.1.2. Mixing Tanks (250 liters)

4 units. Stainless steel, jacketted, with agitator. Specifically for sterile fluids.

2.1.3. Storage Tanks (250 liters)

4 units. Stainless steel, jacketted. Maintained at 85°C-90°C. Specifically for sterile fluids.

2.1.4. Transfer Pumps

2 units. Stainless steel.

2.1.5. Sterilizers (21 cu.ft.)

2 units. Including a steam generator unit.

2.1.6. Filters

Sintered glass and millipore types.

2.1.7. Filling Machine

For polypropylene or PVC bags. All stainless steel. For bags of 1 liter, 500 ml., 250 ml.

2.1.8. Sealing Machine

For polypropylene or PVC bags.

2.1.9. Inspection Units

4 units.

2.1.10. Scales

Top loading: 1500 gr. X 0.1 gr.
Platform: 50 kg. X 1.0 gr.

2.1.11. Air Condition Units

TOTAL ESTIMATED COST: U.S.$ 120,000

2.2. SEMI-INDUSTRIAL PILOT UNIT

For the production of 450,000 liters/year.

2.2.1. Demineralizing Plant

Complete.

2.2.2. Thermocompressor Distillation Plant

Output, 225 liters/hour. Complete, with automatic puromatic diverter. Accessories and spare parts for 2 years.

2.2.3. Mixing Tanks (500 liters)

3 units. Stainless steel, jacketted, with agitator. Specifically for sterile fluids.

2.2.4. Storage Tanks (500 liters)

3 units. Jacketted, stainless steel. Maintained at 85°C-90°C. Specifically for sterile fluids.

2.2.5. Transfer Pumps

3 units. Stainless steel.

2.2.6. Sterilizers (28 cu.ft.)

2 units. Double door type, including a steam generator unit.

2.2.7. Filters

Sintered glass and millipore types.

2.2.8. Filling Machines

2 units. For polypropylene or PVC bags. All stainless steel. For bags of 1 liter, 500 ml., 250 ml.

2.2.9. Sealing Machines

2 units. For polypropylene or PVC bags.

2.2.10. Inspection Units

6 units.

2.2.11. Scales

Top-pan: 1500 gr. X 0.1 gr.
Platform: 50 kg. X 1.0 gr.
Floor: 200 kg. X 1.0 gr.

2.2.12. Air Condition Units

2.2.13. Laminar Flow

Console type.

TOTAL ESTIMATED COST: U.S.$ 250,000

2.3. QUALITY CONTROL UNIT

2.3.1. Flame Photometer

Complete set, with sodium, potassium, and calcium filter, with spare parts.

2.3.2. Ultraviolet Spectrophotometer

Range, 200-800 mm. Manual scanning. Automatic start-stop. With voltage stabilizer and accessories.

2.3.3. Infrared Spectrophotometer

Complete with accessories.

2.3.4. pH Meter

2 units. Range, 0-14 pH. Accuracy, ± 0.01 pH. Complete, with combination electrodes and 6 pairs of spare electrodes.

2.3.5. Polarimeter

For tubes to 400 mm. long, reading by double vernier to 0.01.

2.3.6. Scales

- Analytical
  Weighing range, 160 gr. Precision, ± 0.05 mg.

- Top-loading balance
  Capacity, 160 gr. Precision, ± 1 mg.

- Precision balance
  Weighing range, 1200 gr. Precision, ± 5 mg.

2.3.7. Incubator

Temperature range, 5°C-100°C. Fan/gravity convection.

2.3.8. Vacuum Oven

Temperature range, 5°C-150°C.

2.3.9. Pyrogen Test Equipment

Complete. "ELLAB" type, using rabbits.

2.3.10. Rabbit Cages

Stainless steel, with racks.

2.3.11. Laminar Flow

Console type.

2.3.12. Water Still

2.3.13. Karl Fischer Moisture Determination Apparatus

TOTAL ESTIMATED COST:	U.S.$ 60,000

A N N E X III

PEOPLE VISITED

1. UNDP

   Mr. F. Thomas, Resident Representative
   Ms. F. de Baquero, Assistant Resident Representative
   Ms. H. Morita, Junior Professional Officer

2. WHO

   Dr. C. Vallinoto, Representative
   Dr. A. Roisin

3. UNICEF

   Mr. A.K. Joppa, Resident Administrator of Programs

4. SECRETAIRERIE D'ÉTAT DU PLAN

   Mr. Yves Blanchard, Director of Foreign Aid

5. DEPARTMENT OF PUBLIC HEALTH AND POPULATION

   Dr. Volvik Remi Joseph, Director General
   Dr. Jeannot Cadet, Under Secretary of State
   Dr. Ary Bordes, Department of Family Hygiene

6. HAITIAN RED CROSS AND BLOOD TRANSFUSION BANK

   Dr. Laroche, President
   Dr. A. Westerban, Director of the Bank

7. DEPARTMENT OF COMMERCE AND INDUSTRY

   Ms. Maud Dupiton, Directrice de l'Industrie

8. STATE UNIVERSITY HOSPITAL

Dr. Mirville, Director
Dr. Mondestin, Head, Pediatric Service

9. FACULTY OF MEDICINE AND PHARMACY

Dr. G. Jean Louis, Dean
Dr. Sévère, Vice Dean
Dr. Jean Foucault, Director of the School of Pharmacy
Dr. B. Weniger, Head, Chemistry Department

10. CENTRAL GOVERNMENT LABORATORIES

Dr. Joseph V. Lacombe, Director

11. U.S. A.I.D.

Dr. Gerald Russel, Director
Ms. Sue Gibson, Assistant

12. MANAGEMENT SERVICES FOR HEALTH
(Contracted by A.I.D. and staying at the Department of Public Health)

Dr. John Rhode, On leave from the Rockefeller Foundation, Indonesia
Dr. Jean Pape, Cornell University

13. THE PHARMACEUTICAL INDUSTRY

13.1. PHARVAL - SOCIÉTÉ VALLIÈRE

Dr. Boulos, Sr., Director
Dr. Boulos, Jr., Vice Director

13.2. 4C: CARIBBEAN CANADIAN CHEMICAL CO., S.A.

Mr. Maurice Acra, Director
Ms. Mona Desrouleaux, Manager

13.3. LABORATOIRE DAY

Mr. Martial Day, Jr., Pharmacist

14. THE CATHOLIC RELIEF FUND

Mr. Raymond Etienne, Pharmacist