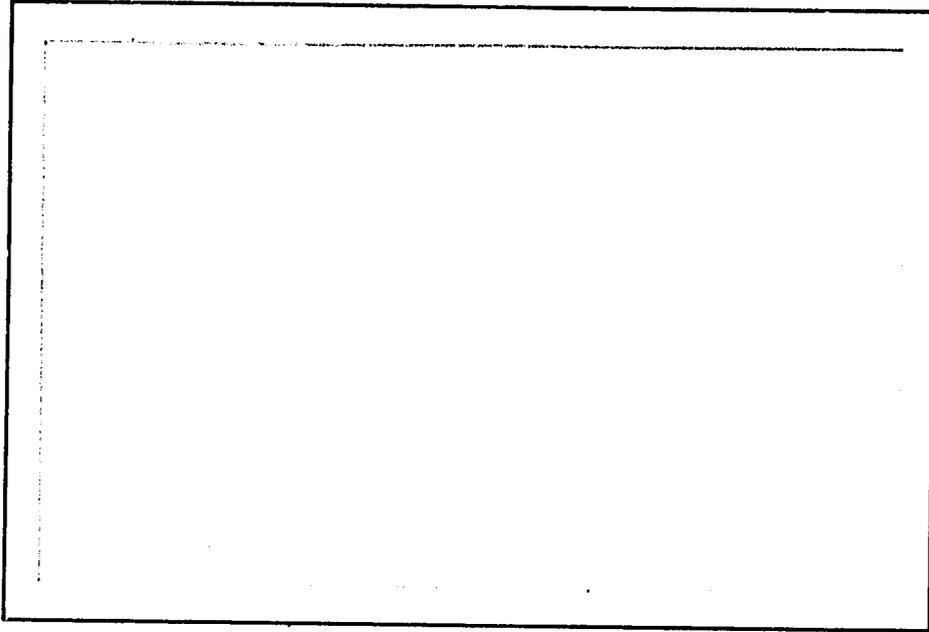


PN-ABN-904  
81974



**PRITECH**  
*Technologies for Primary Health Care*

**Management Sciences for Health**  
*1925 North Lynn Street*  
*Suite 400*  
*Arlington, Virginia 22209*

PN-HBIV-904

**REVIEW AND ASSESSMENT OF  
THE LAPROMED FACILITY**

**GUATEMALA CITY**

**A Report Prepared by:**

**HUMBERTO ZARDO, Assoc. Technical Director, PATH  
STEPHEN G. FAY (PATH Consultant)**

**During The Period:**

**APRIL 28 - MAY 29, 1991**

**TECHNOLOGIES FOR PRIMARY HEALTH CARE (PRITECH) PROJECT**

**Supported By The:**

**U.S. Agency for International Development  
CONTRACT NO: AID/DPE-5969-Z-00-7064-00  
PROJECT NO: 936-5969**

**AUTHORIZATION:**

**AID/S&T/HEA: 2/18/93  
ASSGN NO: HSS 114-GU &  
HSS 116-GU**

## INTRODUCTION

At the request of USAID/Guatemala, PATH conducted this assignment under the auspices of the PRITECH project for the purpose of assisting key parties in Guatemala in determining what is needed in order to finish Lapromed, the local production facility located at the University of San Carlos.

This assignment was carried out in two phases, the first of which entailed the development and preparation of a Master Plan for presentation to USAID/Guatemala and included meetings with key parties, assessment of the Lapromed facility, and data gathering in Guatemala. The second phase involved follow up in California and Seattle to prepare necessary flow sheets, specifications, and construction drawings for the remodeling recommendations, after which a meeting was held in Seattle to discuss the findings, recommendations, and action items, and prepare this report.

It is the objective of this report to provide recommendations to USAID/Guatemala regarding the Lapromed facility. For the purpose of planning future ORS production in Guatemala, these recommendations indicate the most:

- cost-effective,
- sustainable, and
- appropriate alternatives.

## OVERALL CONSIDERATIONS AND RECOMMENDATIONS

The recommendations provided in this report are based on the team's previous experience with the local manufacture of ORS. This experience includes the provision of technical assistance to a private sector company in Guatemala.

It should be noted that the assessment team provides these recommendations in part based on the observation of USAID/Guatemala's intention to provide the University of San Carlos with a model pharmaceutical facility that can be used to promote good manufacturing practices (GMPs) within the local and regional pharmaceutical industry. For this purpose, all the building and facilities aspects of the GMPs were observed to full compliance by the team.

Upon review of the facility, it is concluded that Lapromed's current premises can be efficiently converted into an ORS manufacturing site. After conversion, Lapromed will be capable of manufacturing an average of two million sachets per year on a single shift. The recommended improvements within the Lapromed facility are distinctively better suited to the ORS area than the other areas, e.g., Toxicology and Clinical Analysis labs, Pharmaceuticals, and Quality Control (QC) lab. The recommendations made herein are specifically limited to the ORS production area and a projected flat production rate of two million sachets per year.

The estimated cost to complete the engineering work; purchase additional equipment for ORS production; and train the ORS team in production, quality control, and plant management is \$375,000.

All costs considered, Lapromed can, at a production rate of two million sachets per year, produce sachets at Q.0.60—equivalent to US\$0.1251.

### Key Considerations:

In PATH's estimation, there are two key areas of considerations for USAID/Guatemala prior to undertaking the establishment of the Lapromed facility—one focused at overall policy issues, the other focused at Lapromed's sustainability.

#### ■ Policy:

PATH considers it essential and recommends that the Mission fully assess the level of demand in Guatemala and consider its implications on both the private and public sectors. Given that total country demand is limited in Guatemala, it is important to determine what portion (percentage) of the demand will be served by the public versus the private sector. This issue is key in that the interaction/proportion each sector has will have critical influence on their individual financial feasibility.

PATH further suggests that the Mission review Ministry of Health policy issues regarding promotion and education strategies for ORS. Is it a therapy for dehydration or a preventive for dehydration? What are the strategies/policies in regard to ORS education and usage instructions?

The Mission's review of these issues is of the essence in enabling the program, with its various components of private and public sector interaction, to go forth and succeed.

#### ■ Sustainability:

It is essential to Lapromed's success that the Mission, prior to or in conjunction with this activity, work with the University of San Carlos in establishing systems/procedures which will enable Lapromed to function in virtually a private sector mode. The sustainability of the ORS plant is solely dependent on the ability of Lapromed to perform as an organization.

Systems must be in place so that Lapromed will maintain the ability to manage direct personnel matters, procure raw materials and components in a timely manner, produce and control the quality of goods produced, store finished goods and components, and ensure maintenance and good personnel management. In order for Lapromed to achieve these requirements, the ORS manager must be granted a level of autonomy and authority to allow Lapromed to function as an efficient production operation.

Of specific concern is whether the ORS manager at Lapromed will be able to make timely decisions for ordering materials. If the manager is required to go through an elaborate/complicated approval process through the University prior to procuring, then the University must establish a system to maintain an increased level of spare parts and inventory to overcome these procedures. It is essential that the need for safety levels of inventory be recognized in order for Lapromed to function successfully. Potential situations that may occur if these systems are not established include:

- If raw materials are not procured in a timely manner, backorders will result and production will be interrupted. If there is no production, ORS labor resources must be absorbed into other areas of Lapromed. If labor resources are not absorbed and salaries must be paid by Lapromed, excess costs will result and will, in turn, increase the cost of the product.
- If backorders result in the stoppage of production, it is necessary to stop the plant. This interruption may result in severe damage to the air and water systems which will require revalidation before production may be started up again.
- If production stops, employees may leave. This will result in the need for retraining.
- Interruption longer than two to three weeks will require quality control procedures to revert back to the "validation phase." If the plant had previously progressed to the "normal" or "advanced" phases, this can increase quality control costs three-fold. Return to either of these phases from the "validation phase" will have to proceed gradually and is a time-management demanding and costly process.

Lapromed's QC procedures for other products is unknown at this time but are thought to be limited. Ideally, the QC procedures to be introduced and implemented by PATH in the ORS production area will filter into and be implemented by the other production areas. There is concern, however, that other less-than-adequate QC procedures might infiltrate the ORS production area and thereby jeopardize the ORS product.

Since Lapromed is producing for the public sector, there should be a long-term ordering agreement from the government specifying deliverables, detailing quantities to be purchased, and payment. The government should not hold payments to Lapromed or there will be insufficient funds to pay for costs such as salaries, materials, spare parts, etc.

It must be made clear to all parties that Lapromed can produce up to two million sachets per year. If it is determined that Lapromed should produce less than that amount, volume-related costs will increase in such areas as salaries, depreciation, electricity, etc.

Therefore, an agreement should be established with the government to procure at least two million sachets per year.

A system should be established so that Lapromed can maintain an account with funds available for purchasing equipment spare parts, inventory, etc., as well as for covering such costs as contracts for equipment and air conditioning system maintenance. Further, if there is equipment breakage, funds must be available so that Lapromed does not have production stoppage so as not to compromise its production level of two million sachets per year. These funds must stay available to Lapromed indefinitely so that it will continue to function as a normal industrial operation.

It should be noted that the completion of facility renovation, equipment installation, and training for Lapromed is technically feasible and is not considered to be a problematic undertaking.

#### WHAT IS NEEDED TO FINISH THE ORS AREA AT LAPROMED:

Using Lapromed's current facilities at the University of San Carlos, the following provides the requirements necessary to make the ORS plant functional. A floor plan showing equipment allocation is attached (see Attachment 1). All room/area numbers referred hereafter can be located in the drawing.

#### Electric System:

The total electric power demand for the current and suggested equipment/systems for the ORS plant is estimated to be:

Manufacturing equipment	82kWh
QC equipment	5kWh
Building	40kWh
HVAC	<u>30kWh</u>
Total electric demand	157kWh

The team proposes maintaining the transformer currently located on a pole outside the building on 7<sup>a</sup> Avenida. From that transformer, cables will be brought into a proposed switchboard to be located in Room 304. This proposed switchboard should have one switch for every piece of equipment using three-phase power and one separate switch for the air conditioning unit. Units demanding lower power can be combined per local regulations.

It is recommended that Lapromed obtain a 5kVA voltage stabilizer for quality control equipment.

#### Equipment Installation:

For the purpose of this assignment, the team considered installation of manufacturing (MFG) equipment only. Since Lapromed will be combining all of their current products, installation of QC equipment is left to Lapromed's discretion.

As previously noted, it recommended, however, that a 5kVA voltage stabilizer be installed to protect equipment such as the analytical scale, flame photometer, Ion Selective Electrode (ISE) unit, and polarimeter.

#### Enclosing Machinery, Dust Extract, and External Windows Protection:

It is proposed that airwalls be built to cover external windows on all walls of the MFG area. Airwalls will guarantee that all product powder will not rise above the floor level.

Airwalls will be constructed by (a) covering all internal faces of the external windows to prevent leakage and infiltrations and to alleviate the need for internal maintenance and (b) building a second wall facing the MFG area to provide a smooth surface to better facilitate washing. The air will circulate in between these two walls, maximizing the number of air changes per hour. In turn, turbulence will be reduced and will create air curtains that will prevent any cross-contamination.

Product powder will be removed through the airwalls and into the pre-filter and bag filter on the return ducts of the air conditioning system.

For further safety, supplied air will also have a bag filter and 95 percent (95%) retention for particles above 0.5 micron (a.k.a. HEPA filters). The air system is designed to permit a pressure gradient from the filling area to the exterior to facilitate cleanliness.

Equipment that can generate dust, e.g., mill and sifter, will be located in Room 200. This room will be connected to a separate air system. This system will also serve three additional rooms—Room 203 (drying and mixing area), Room 202 (corridor for compounding), and Room 201 (air lock to compounding area).

A main air system will operate independently for Room 100 (dosing/packing area) and Room 101 (production office).

A separate air system will provide air for the cleaning and service areas which includes Room 300 (equipment washing), Room 301 (air lock from the warehouse), Room 307 (employees' changing rooms), Room 306 (buffer zone), and Rooms 302 and 303 (rest rooms).

#### PROJECT MANAGEMENT

The team recommends that the project management company selected be a local (Guatemala City) engineering company highly experienced in industrial construction, specifically pharmaceutical construction, and most particularly, experienced in sterile or penicillin areas.

Further, it would be very beneficial if the same company preparing the designs also controls the quality and installation of selected materials.

The ORS plant requires a supply of air that permits good handling of the mixture throughout the production process to guarantee proper flow and shelf-life of the final product. Therefore, the experience required for this undertaking is comparable to that required for construction of an efficient sterile facility.

The ORS plant generates a large amount of dust during the compounding phase (milling, drying, and sifting) and requires a level of expertise similar to that required for penicillin areas.

#### LOCAL VENDORS

It is anticipated that the project management company contracted can control quality, cost, delivery dates and schedules for materials, services, installations, etc.

#### REVIEW OF THE ACTUAL PLANT SITUATION

The Lapromed site was inspected in August 1990 by the FDA-equivalent division of the Ministry of Health in Guatemala (División de Registro y Control de Medicamentos Y Alimentos - Dirección General de Servicios de Salud - Ministerio de Salud Pública y Asistencia Social). (See Attachment 2.) Recommendations from the assessment team are in line with the inspection findings and will satisfy all requirements made.

#### Air treatment:

The Lapromed facility does not satisfy the WHO/CDD/SER/85.8 recommendations that ORS should be prepared and filled in areas with a temperature below 24° and level of relative humidity below 60%.

Without appropriate air treatment, the ORS produced by Lapromed:

- may not satisfy the expected shelf-life of 36 months due to high moisture;
- may be cross-contaminated by other pharmaceuticals made in adjacent areas;
- will be exposed to street fumes, particulates, airborne particles, and other contaminants; and
- will be exposed to microorganisms present in the nontreated air.

High moisture content in the air, resulting from water and dust infiltrations through the current windows, reduces the expected life of equipment due to corrosion.

#### Exposed windows:

The presence of windows which connect directly to the exterior makes the Lapromed facility unsuitable for the production of pharmaceuticals. Windows are a source of contamination for particulate materials,

micro-organisms, rainwater, and other contaminants. Windows can also contribute to the temperature increase making the ORS mixture unsuitable for proper dosing and filling.

Further, exposed windows can be easily broken and offers the opportunity for vandalism.

#### Wood doors and window frames:

Wood fixtures are improper for pharmaceutical plants because:

- microorganism growth is allowed on the surface and interior, and
- it is easily broken and permits the introduction of particulates into the manufacturing area.

#### Layout:

The final quality of ORS, as with other products, is highly dependent on the efficient flow of raw materials, staff, and final product. The current layout at Lapromed will expose raw materials to the exterior environment when the materials are moved from the existing warehouse to the compounding area.

The rest rooms are currently directly connected to and compromises the quality of the environment of the compounding area.

Material handling, particularly receiving and shipping, is cumbersome at best. Moving drums and boxes upstairs and downstairs is tremendously tedious and may cause damage to walls and floors each time material is moved.

There is no segregate area for lockers, which may also increase the particulate, microorganisms, and airborne material.

There is no segregate area for a production office within the ORS area, which is necessary to keep records, prepare reports, and conduct training and other managerial activities. An off-site office creates an intensive transit in and out of the ORS plant which will contribute to an increase of particulate, microorganisms, and airborne material.

#### Other building limitations:

The team determined that the building lends itself for renovation for a suitable pharmaceutical facility.

- The existing ceiling height allows for installation of duct work and a modern air conditioning system.
- The walls can be covered to provide smooth sanitary finishes.
- There is enough space to build walls for the segregation of unitary processes.

- The existing floor in the MFG areas is of terrazzo and needs only to be regrinded and polished.
- The floors for the raw material storage area (Room 309) and quarantine area for finished products (Room 304) are of poor ceramic tiles and must be removed and replaced with a smooth concrete floor.

Further, the team suggests that:

- The internal patio be used to create an office for the plant manager, an air lock, and dressing rooms. This will increase utilization of the internal space for manufacturing exclusively and, at the same time, increase the zoning of the individually identified areas.
- The raw material warehouse be relocated to an adjacent room (Room 309) to create a natural materials flow, reduce external contamination during transfer, and provide environmental pharmaceutical conditions without increasing the cost of air conditioning and material handling.

Relocation of the raw material storage area to Room 309 will also permit the building of an unloading dock at the street level, thereby alleviating the currently cumbersome process of moving raw material upstairs through the main building entrance.

- A pallet lift be built in the finished product quarantine area (Room 304) to facilitate product removal.
- Doors be enlarged to permit easy flow of pallets, the pallet hand-lift, drums, and carts carrying finished goods.
- ORS equipment and ancillary must be rinsed with purified water to avoid presence of heavy metals, particulate, and microorganisms. It is possible to move Lapromed's existing water still to the floor above and provide piping to feed ORS and pharmaceuticals by a gravity, no-return system.

## COST ESTIMATE

The cost estimation is divided into two sections—one in U.S. dollars and one in Quetzales. All imported equipment and the engineering fees are calculated in dollars. All locally provided material and sub-contracted services are estimated in local currency.

Design Fees		\$ 26,000
Construction	Q.452,460	
Air conditioning (imported)		60,000
Stainless steel piping for WFI (imported)		2,000
Roof reinforcement (contingency)	Q. 75,000	
Contingencies for civil and electric work		90,500
Additional equipment for MFG		50,000
Training and support by PATH		<u>113,000</u>
	Q.617,960	\$251,000

Total cost estimation is US\$374,592 (using Q.5.00 per US\$1.00).

Note: Amounts indicated, excluding additional equipment for MFG and training and support by PATH, are based on a budget prepared by Pelayo Llarena y Colaboradores for estimation purposes (see Attachment 3).

## ADDITIONAL EQUIPMENT REQUIRED BY LAPROMED

The following items are necessary for Lapromed to properly conduct ORS manufacturing activities:

### 1. Manufacturing

Mill	\$12,000
Checkweigher	1,300
Vacuum cleaner	1,200
In-feeder	12,500
Pallet handlift	2,500
Carts	1,000
Coding device	3,000
Packing conveyors	2,800
Miscellaneous	<u>3,000</u>
ESTIMATED TOTAL	\$39,300

## 2. Quality Control

Moisture scale	\$ 3,500
pH meter	1,700
Glassware	2,000
Vacuum testing apparatus	1,500
Miscellaneous	<u>2,000</u>
<b>ESTIMATED TOTAL</b>	<b>\$10,700</b>

3. ESTIMATED TOTAL COST \$50,000

### Justifications:

- Mill: Chemicals currently stored at Lapromed require milling to render particles within the 1-2 mm range for proper mixing and dosing.
- Checkweigher: Lapromed intends to deliver sachet in bulk in boxes of 100. A mechanical checkweigher can reduce cumbersome manual counting.
- Vacuum cleaner: To reduce the moisture content in the ORS area, most of the cleaning can be done by means of an efficient industrial vacuum cleaner.
- Pallet handlift: To move pallets from trucks, up and down shelves, and within the ORS area.
- In-feeder: The height of the UPI form-fill-seal machine requires automated bulk transfer to the hopper to avoid excessive labor and reduce risk of constant moving up and down a ladder or platform.
- Coding device: Necessary to overprint "Lot No." and "Exp. Date" on each sachet. The UPI machine does not currently have this device.
- Packing conveyor: The conveyors currently at Lapromed are not suitable for packing. They can be relocated to the warehouse to help in loading/unloading trucks.
- Carts: To move goods to quarantine area.
- Moisture scale: Lapromed has only one oven which is used for a myriad of other activities. A moisture scale will expedite QC results.
- pH meter: Lapromed received one ISE that can also work as a pH meter. However, the switching of electrodes for a level of two million sachets per year requires a dedicated device for pH.
- Vacuum testing apparatus: Lapromed does not have this device.

- Glassware: Lapromed has a limited number of volumetric flasks, pipettes, burettes, and beakers.
- Miscellaneous: To cover additional items of low unit cost.

PROPOSED SUPPORT FROM PATH

For the purpose of expediting this report, the budgets provided below are estimations. Actual budgets will be prepared by the PATH Finance Department and will be sent to the Mission at a later date.

1. Prepare a proposal detailing the steps for plant remodeling, production, QC, and materials management plans for the next 5-year period.

Estimated time: 31.5 days  
Estimated cost: \$10,000

2. Assist with equipment procurement and coordinate delivery dates, payment terms, insurance, etc.

Estimated time: 48.5 days  
Estimated cost: \$17,000

3. Develop specific manuals for QC, MFG, and materials management. Prepare and adapt methods, policies, and procedures to support local production of ORS within the current GMPs and good laboratory practices (GLPs).

Estimated time: 29.5 days  
Estimated cost: \$9,000

4. Training of supervisors in QC, MFG, and materials. PATH will prepare a training manual tailored to Lapromed's actual needs. Training will be conducted in Guatemala.

Estimated time: 48.5 days  
Estimated cost: \$21,000

5. Approval of local Standard Operating Procedures (SOPs). PATH will instruct, review, and offer recommendations to Lapromed's SOPs.

Estimated time: 14 days  
Estimated cost: \$4,000

6. QC lab validation. PATH will design and monitor a validation process for raw materials, packaging components, in-process, and final products.

Estimated time: 7.5 days  
Estimated cost: \$2,000

7. Assist equipment installation. PATH will contract technical people through vendors and monitor the final installation of all MFG equipment.

Estimated time: 20.5 days  
Estimated cost: \$18,000

8. Plant validation. PATH will design a tailored validation protocol for Lapromed to validate all equipment, the ORS MFG process, and test the initial three batches through a Project SUPPORT-certified QC lab. A technical assistance visit will be conducted for plant validation/production start-up.

Estimated time: 7.5 days  
Estimated cost: \$4,000

9. Troubleshooting. PATH recommends a technical visit three months after the production start-up to identify and solve potential problems with equipment, systems, or methodology. Results and recommendations will be presented together with an action plan.

Estimated time: 29.5 days  
Estimated cost: \$14,000

10. QA audit and QC sampling phase progression. PATH will audit Lapromed from receiving to shipping and make recommendations and action plans to conform to the current GMPs and GLPs. PATH will also make suggestions to a reduced sampling plan based on statistical analysis of Lapromed's QC data.

Estimated time: 16 days  
Estimated cost: \$12,000

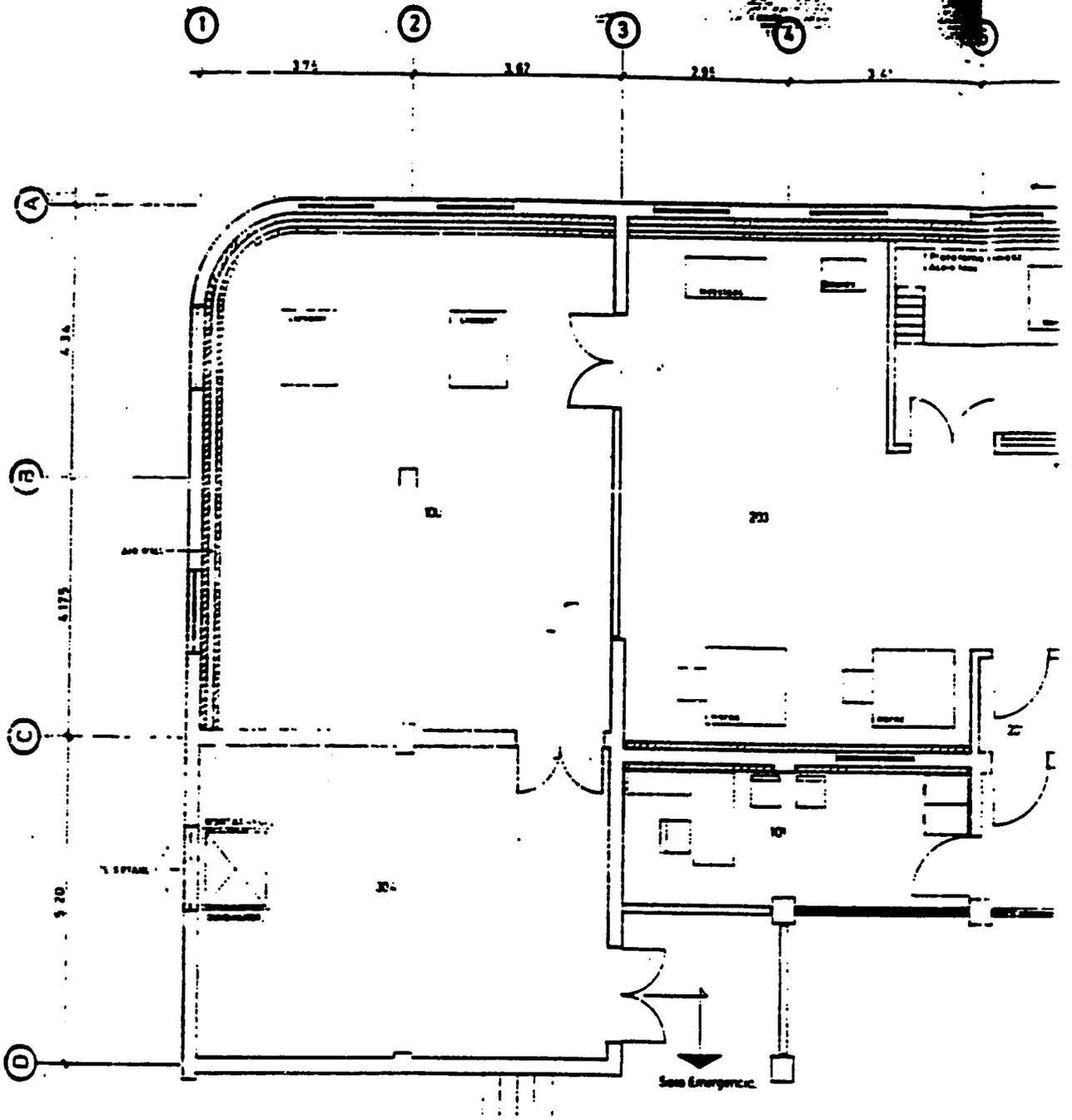
Total amount of estimated time: 253 days  
Total estimated cost: \$113,000

RSUP0079

**ATTACHMENT 1**

3<sup>a</sup> Calle Zona I

7<sup>a</sup> Avenida Zona I



# DIRECCION GENERAL DE SERVICIOS DE SALUD

## DEPARTAMENTO DE REGISTRO Y CONTROL DE MEDICAMENTOS

### SECCION DE SUPERVISION

Empresa:	Fecha:
Responsable de Inspección:	Establecimiento:
Título:	Dirección:
Cargo en la Empresa:	Teléfono:

#### DURANTE LA INSPECCION DE SU EMPRESA SE OBSERVO:

Las puertas deberán recubrirse de material plástico y pintadas con pintura epóxica que facilite su limpieza y las proteja.

La tubería, debido a que está expuesta, debe pintarse con pintura epóxica y los colores deben ser de acuerdo a la codificación internacional.

Las ventanas deben sellarse y cubrirse de tal manera que quede una superficie completamente lisa.

Se debe dar un informe a usted para informarle que adjunto a la presente AREA DE LLENADORAS el informe efectuado en base a la inspección realizada.

- Debe colocarse extractores de polvo, por arriba de las tolvas alimentadoras de la llenadora. Se debe de atender sus vibras.

- Las lámparas deben tener cajas y difusores y estar colocadas dentro del cielo falso.

- Colocar un cielo falso, similar al del área de producción para que los sistemas de conducción y extracción de aire queden dentro del mismo.

- El aire inyectado debe ser de un 95-30% de eficiencia.

- Las puertas y ventanas deben seguir las observaciones hechas al área de producción.

#### BANOS Y VESTIDORES:

- Deben existir 2 baños dentro del área uno para hombres y otro para mujeres y cada uno debe contar con vestidor.

- Los baños deben contar con un sistema eficiente de extracción.

- Los vestidores debido al número de personas con que va a contar la planta, son muy pequeños.

#### COMEDOR:

- Este debe estar delimitado y no debe servir de área de paso.

FIRMAR

JEFE DE LA DIVISION:

JEFE DE LA SECCION:

JEFE DEL DEPARTAMENTO:

SELLO:

# DIRECCION GENERAL DE SERVICIOS DE SALUD

## DEPARTAMENTO DE REGISTRO Y CONTROL DE MEDICAMENTOS

### SECCION DE SUPERVISION

Empresa:	Fecha:
Responsable de Empresa:	Establecimiento:
Título:	Circuito:
Cargo en la Empresa:	Teléfono:

DURANTE LA INSPECCION DE SU EMPRESA SE OBSERVO:

#### RECOMENDACIONES:

##### Instalaciones:

Es necesario identificar adecuadamente las tuberías (de ser posible que no estén expuestas y pintadas con pintura epóxica de acuerdo a la clasificación internacional que para ello existe.)

##### BODEGAS:

- **MATERIAS PRIMAS:** debe existir un control de humedad riguroso que garantice el correcto almacenamiento del material.

El material de empaque deberá colocarse en un área separada.

Esta Bodega debe tener un área de pesado, que sea independiente del resto de la bodega, debe contar con un sistema de inyección de aire 85-90% de eficiencia y de extracción de polvo.

Las Materias primas deben estar debidamente identificadas.

- **PRODUCTO TERMINADO:** Esta debe contar con áreas delimitadas para: Producto terminado, cuarentena, producto aprobado y rechazado.

Además debe existir un área de material para destrucción

##### - AREA DE PRODUCCION:

Debe existir áreas delimitadas para llevar a cabo los diferentes procesos (molienda, mezclado, granulado, secado, ect).

El sistema de inyección de aire de 85-90% de eficiencia, deberá estar colocado arriba del cielo falso, y el de extracción en la parte inferior de la pared.

En el área destinada al mezclado y molienda debe haber un extractor de polvos.

Sobre los hornos debe haber un sistema eficiente de extracción de humedad.

La iluminación debe ser suficiente, las lámparas de gas neón deberán estar empotradas en el cielo falso y contar con difusor.

FIRMAR

JEFE DE LA DIVISION:

JEFE DE LA SECCION:

JEFE DEL DEPARTAMENTO:

SELLO:



*[Handwritten signature]*





Dirección General de Servicios de Salud  
División de Registro y Control de Medicamentos y Alimentos  
10a. Avenida 14-00 Zona 1 Tel. 27303  
Guatemala, C. A.

NUM. \_\_\_\_\_  
REF. \_\_\_\_\_

Al contestar sírvase mencionar el  
Número de referencia de esta nota.

Guatemala  
13 de agosto de 1990

Lic.(a) Alba Nory de Barrera  
Regente de Proyecto de Sales de Rehidratación Oral  
Antigua Escuela de Farmacia  
LAPROMED.

Estimado Lic.(a) de Barrera:

Atentamente me dirijo a usted para informarle que adjunto a la presente  
estoy entregando el informe efectuado en base a la inspección realizada  
al establecimiento farmacéutico denominado Proyecto de Sales de Rehidra-  
tación Oral. ADSCRITO A LAPROMED.

Sin otro particular, me suscribo como su atenta servidora,

Licda. Silvia Martínez de Sanchineli  
Jefe del Depto. de Registro y Control  
de Medicamentos



**ATTACHMENT 2**

**ATTACHMENT 3**

arquitectos pelayo llarena  
& colaboradores  
arquitectos e ingenieros  
2a. avenida nº 9-76 zona 1. guatemala. c.a. tel 20647

Guatemala, May 9, 1,991.

Mr. Stephen G. Fay,  
Vice-President,  
Director of Engineering and  
Construction Services,  
COX & FAY, Inc.,  
Pharmaceutical Industry Specialists.  
69 Marbella,  
San Clemente, California. 92672.  
U.S.A.

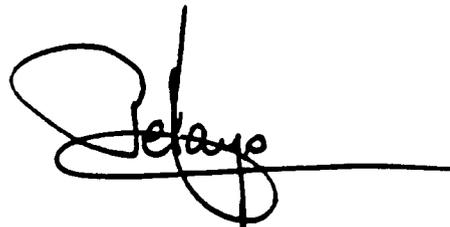
Dear Steve:

We have developed a construction cost estimate for the LAPROMED Project, here in Guatemala, following Mr. Humberto Zardo's, and your indications. We feel that at this preliminary stage of the Project, this estimate will be within 20% accuracy of what will be the final construction cost.

In order to give you an idea of the main considerations of the cost estimate we will make a brief description of each work aspect which merits some detail. In some cases we feel that there is no need for a description since the work is rather straight forward.

We hope that everything is going well for you, and that we have given you the information you need to proceed with your proposal to AID. We will gladly furnish additional details if you consider that you are in need of it.

Sincerely,



Arq. Pelayo Llarena

Enclosed: Cost Estimate.  
PLL/hp

PRELIMINARY COST ESTIMATE  
FOR LAPROMED PROJECT.

Quetzales

A.- Room finishes:

1.- FLOORS:

a.- Bodegas (New concrete):	24,500.00
b.- Production: (Regrind and Repolish)	3,400.00
c.- Restrooms (New tile):	3,000.00
d.- Wash Area (New concrete):	1,000.00

2.- WALLS:

a.- Air Walls, made with pressure treated Pine Wood, and Fiber Cement Sheets of 8 mm. thickness, painted with epoxy paint:	31,300.00
b.- New Walls made of the same materials of the Air Walls:	51,500.00
c.- New walls made out masonry for the Restrooms, including finishes:	13,000.00
d.- Relocation of doors:	3,500.00
e.- New walls for outdoor exposure which will be enclosing the corridor:	20,900.00
f.- Epoxy paint for existing walls:	7,500.00

3.- CEILINGS:

a.- New over Production Areas	51,000.00
b.- Resurfacing and finishing	3,300.00

4.- WINDOWS:

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a.- New over exterior walls: 3,750.00  
(Towards existing patio)

5.- DOORS:

a.- New, made of Plywood and painted with epoxy paint: 55,000.00

B.- PROBABLE REPAIRS TO EXISTING BUILDING:

a.- The existing roof cover is in very poor condition and it will have to be changed. We suggest changing the corrugated steel sheets for new ones. This would be a low cost solution which would be adequate for the five year usage projected for the LAPROMED production.

10,360.00

b.- We have not inspected the wood truss structure which is part of the roof system. The approximate area which is covering the Production space is 207 square meters. If this roof structure is in as bad a situation as the roofing sheet metal, we would recomend changing it, or renovating it. This could cost as much as 75,000 quetzales.

C.- SERVICES:

1.- STORM DRAINS:	2,100.00
2.- SEWAGE:	4,500.00
3.- COLD WATER: (Including Restroom fixtures)	21,400.00
4.- HOT WATER:	5,400.00
5.- COMPRESSED AIR: (Without Compresor)	3,600.00
6.- DISTILLED WATER: (Just labor)	750.00
7.- ELECTRICITY:	90,500.00
8.- AIR CONDITIONING DUCTS:	36,700.00

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(Including equip. vents)

D.- OTHER ITEMS:

1.- ROOF FOR AIR CONDITIONING  
AND COMPRESSED AIR EQUIPMENT:

4,500.00

2.- CONTINGENCIES:

90,492.00

TOTAL PROJECT COST (Excluding our fees  
and the items which are to be priced by  
Mr. Stephen G. Fay)

542,952.00

ITEMS TO BE PRICED BY  
MR. STEPHEN G. FAY.

1.- AIR CONDITIONING EQUIPMENT.

2.- AIR COMPRESSOR.

3.- STAINLESS STEEL PIPES AND FITTINGS FOR  
DISTILLED WATER:

a.- 5 Tees 3/4" diameter.

b.- 16, 90 degree elbows, 3/4" diameters.

c.- 4 valve outlets.

d.- 120 feet of 3/4" pipe.

4.- DUMBWAITER TO STORAGE IN BASEMENT.

The above cost estimate does not include the  
Architect's fees for the design documents and construction  
management of the job.

Mr. Stephen G. Fay mentioned a fee for these two  
activities equivalent to 10% of the total construction cost.  
Our standard fee for this type of work is 14% of the total  
construction cost. We would appreciate it very much if our  
fee was 14 percent. If Mr. Fay has already committed our work  
for the 10% fee we would honor his commitment.

Exchange rate: Q. 5.00 Quetzales to \$ 1.00 Dollar.

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