

CELIERO AMERICALIA DE PLASMARHERESIS, S. A. Km. 315 AUTORISTA KENNEDY APARTADO 4781 - TELEFONOS 40851-40852 MANAGUA, D. N.

CABLE: "CEPSA"

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## October 15, 1975

Director Bureau of Biologics DHEW/PHS, Food and Drug Administration \$800 Rockville Pike Bethesda, Maryland 20014

RE: Centro Americana de Plasmapheresis, S.A. License #626

Dear Miss Malta:

We hereby request authorization to ship 15,434 liters of Fresh Frozen (Human ) Plasma, collected from normal donors to, Cutter Laboratories, Fourth & Parker Streets, Berkeley, California 94710.

The use of this plasma will be for manufacturing purposes into Human Inyectable Materials. The tentative port of entry of this product shall be San Francisco, California (air freight).

We already have being authorized by you to make this SAME SHIP-MENT to Abbott Laboratories with tentative port of entry Los Angeles, California. (Kindly see attached copy of your letter of aythorization dated July 31, 1975). We wish to inform you that such shipment did not take place as Abbott Labaratories informed us at the time, they were overstock.

Your promt attention in this matter will be greatly appreciated.

GRO-C

Guillermo B. Castro, Responsible Head.

GEĆ/rb

CC: Mrs. Rita Conroy

- Mrs. Joan Roelands Mr. Oscar Polvis , Cutter Laboratories
  - Hr. Pedro M. Ramos, M.D.
  - Mr. Fausto Alvarez



DEPARTMENT OF HEALTH, EDIJCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BETHESDA, MARYLAND 20014 October 22, 1975

Mr. Pedro M. Ramos Centro Americaca De Plasmapheresis, S.A. Km 3/2 Autopista Kennedy Apartado 4781 Managua, D.N.

Dear Mr. Ramos:

Permission is hereby granted to Centro Americana De Plasmapheresis, S.A. Managua, N.A., to import into the United States a shipment of Source Plasma (Human) for further manufacturing by Cutter Laboratories, Inc., Berkeley, California. It is understood that 15,434 liters (1550 Cartons x 22,700 bags) of Source Plasma (Human) will be shipped by air to Cutter Labs., through the San Francisco, CA port of entry.

It is suggested that you send a copy of this permit letter with the shipment in order to expedite entry into the United States. We believe that such a letter will be accepted by the U.S. Customs as authorization for importation. Should there be further questions of Customs concerning the shipment, this office may be notified.

**GRO-C** Marry M. Meyer, Jr., M.L Director Bureau of Biologics

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