DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 24, 1983

FROM: Director, Office of Biologics,
National Center for Drugs and Biologics

SUBJECT: Source Material Used to Manufacture Certain Plasma Derivatives

TO: All Licensed Manufacturers of Plasma Derivatives

Extensive discussions among licensed manufacturers, the Office of Biologics and concerned groups such as the National Hemophilia Foundation, have led to a consensus concerning an appropriate approach to decreasing the potential risk of transmitting Acquired Immune Deficiency Syndrome (AIDS) by certain plasma derivatives.

Plasma collected from donors suspected of being at increased risk of transmitting AIDS (as presently defined: persons with symptoms and signs suggestive of AIDS, sexually active homosexual or bisexual men with multiple partners, Haitian entrants to the United States, present or past abusers of intravenous drugs* and sexual partners of persons at increased risk of AIDS) should not be fractionated into derivatives already known to have a risk of transmitting infectious diseases. Plasma from donors in any of the groups identified above may be collected for use in manufacturing only albumin, plasma protein fraction (PPF), globulin or in vitro diagnostic products. To prevent the possible misuse of such plasma, all licensed establishments collecting Source Plasma (Human) are being advised that in accordance with 21 CFR 606.120(b)(6) each unit must be conspicuously labeled either with the statement "CAUTION: For Use in Manufacturing Albumin, PPF, or Globulin Only," or "CAUTION: For Use in Manufacturing Noninjectable Products Only". HBsAg positive plasma for use in manufacturing vaccine or in vitro diagnostic products is already subject to additional special labeling and shipping precautions.

We request that you immediately institute procedures with your plasma suppliers to assure that they have adopted appropriate donor screening practices and procedures. Copies of notices that are being sent to all establishments collecting blood or source plasma concerning measures which should be taken, are enclosed for your information along with the recent Public Health Service Interagency Recommendations.

Please advise the Office of Biologics, in writing, of the procedures you have instituted to comply with this notice. The restrictions applied by your establishment on source plasma received for manufacturing high risk plasma derivatives should be effective immediately.

GRO-C , M.D.

John C. Petricciani, M.D.

Enclosures
RETURN - RECEIPT REQUESTED

*Such intravenous drug abusers are already excluded by existing regulations.