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International Consultants, Inc., 1032 Chuck Danley Blvd., Suite E, Mt. Pleasant, SC 29464. Officer: Paul A. Flaherty, President.

Horizon Trading Company, Inc., 1510 H Street, N.W., Suite 500, Washington, D.C. 20005. Officer: J. Browning Rockwell, Pres./Dir./Stockh.

Hilldrup Transfer and Storage, Inc., d/b/a Hilldrup Moving & Storage, 4022 Jefferson Davis Highway, Stafford, VA 22555. Officers: Charles G. McDaniel, President, Hilton G. Marshall, Vice President of Finance.

Ultimate Media Express Inc., d/b/a Ultimate Express, 144-25, 155th Street, Jamaica, NY 11434. Officers: Diane M. Correll, President, James W. Correll, Sr., Sec. Treasurer.

Dated: December 30, 1996.

[FR Doc. 97-112 Filed 1-3-97; 8:45 am]

BILLING CODE 6730-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Privacy Act of 1974: Altered System of Records

**AGENCY:** Office of the Assistant Secretary for Management and Budget, Office of the Secretary, HHS.

**ACTION:** Notice of an altered system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act, the U.S. Department of Health and Human Services (HHS) is publishing a notice of a proposed altered system of records, 09-90-0024, "Financial Transactions of HHS Accounting and Finance Offices." The principal purpose for the changes is in order to comply with the requirements of the Debt Collection Improvement Act of 1996 (Pub. L. 104-134, Sec. 31001). The proposal includes new and modified routine uses described below for this system.

**DATES:** HHS submitted a report of an altered system to the Office of Management and Budget and to the Congress on December 24, 1996. The new routine uses and the amendments to existing routine uses will take effect without further notice 40 days after the date of publication, unless HHS receives comments which would result in a contrary determination. Other changes

incorporated in the notice below will take effect upon publication.

**ADDRESSES:** Please address comments to: Deputy Assistant Secretary, Finance Room 739-H, Hubert H. Humphrey Building, 200 Independence Ave., SW, Washington, D.C. 20201. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m. Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Ms. Sue Mundstok Privacy Act Coordinator, Office of Financial Policy, DAS/ASMB, Room 705-D, Hubert H. Humphrey Building, 200 Independence Ave, SW, Washington, D.C. 20201, Telephone: (202) 690-6228.

**SUPPLEMENTARY INFORMATION:** The system notice was last published in full at 59 FR 7675 (1994). It was subsequently amended at 59 FR 55845 (1994).

On April 26, 1996, the Congress passed Pub. L. 104-134, Sec. 31001 known as the "Debt Collection Improvement Act of 1996" (DCIA). The purposes of this Act are to: (1) maximize collections of delinquent debts owed to the Government, (2) minimize the costs of debt collection, (3) reduce losses arising from debt management activities, (4) ensure that the public is fully informed of the Federal Government's debt collection policies, (5) ensure debtors are cognizant of their financial obligations to repay amounts owed to the Government, (6) ensure that debtors have all appropriate due process rights, including the ability to verify, challenge, and compromise claims, and access to administrative appeals procedures, and (7) encourage agencies, when appropriate to sell delinquent debts, particularly debts with underlying collateral, and rely on the experience and expertise of private sector professionals to provide debt collection services to Federal agencies.

The DCIA authorizes and requires several new techniques for collecting debts and claims, and we have modified existing routine uses and added ones to implement this statute. In particular, we have modified use 1 to provide for payment by methods other than checks.

We have amended use 11(b) to allow disclosure to the Treasury Department for purposes of administrative offset even when Treasury will not be the agency that effects the offset. We have amended use 11(e) to conform with the provision for using debt collection agents or contractors in the statute as amended by the DCIA. We have added uses 18-21 to provide for new techniques authorized by the DCIA. Use 18 allows the computer matching of debtors and federal employees. Use 19

allows disclosures to commercial reporting agencies.

Use 20 allows disclosure to Treasury or a Debt Collection Center to collect the debt. Use 21 allows disclosures in connection with selling the debt. Because all of these are for purposes of recovering or liquidating debts, they are compatible with the purposes for which HHS maintains this system.

Other revisions were made (1) to eliminate areas where the Social Security Administration (SSA) is referenced since SSA is no longer a part of HHS; (2) to improve the quality of the document by making minor editorial changes; and (3) to combine the two Appendices into one Appendix, including the updating of system records locations.

The complete system notice is republished below.

Dated: December 23, 1996.

John J. Callahan,

*Assistant Secretary for Management and Budget.*

**SYSTEM NAME:**

Financial Transactions of HHS Accounting and Finance Offices, HHS/OS/ASMB.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

See Appendix 1.

Memoranda copies of claims submitted for reimbursement of travel and other expenditures while on official business may also be maintained at the administrative office of the HHS employee. Records concerning outstanding debts may also be maintained at the program office or by the designated claims officer apart from the finance office.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All persons who receive a payment from the Operating Divisions (OPDIV) Headquarters, Area and District offices and all persons owing monies to these HHS components. Persons receiving payments include, but are not limited to, travelers on official business, grantees, contractors, consultants, and recipients of loans and scholarships. Persons owing monies include, but are not limited to, persons who have been overpaid and who owe HHS a refund and persons who have received from HHS goods or services for which there is a charge or fee (e.g., Freedom of Information Act requesters).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, identification number, address, purpose of payment, accounting

classification and amount paid. Also, in the event of an overpayment and for outstanding loans, grants or scholarships, the amount of the indebtedness, the repayment status and the amount to be collected.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Budget and Accounting Act of 1950 (Pub. L. 81-784); Debt Collection Act of 1982 (Pub. L. 97-365); Debt Collection Improvement Act of 1996 (Pub. L. 104-134, Sec. 31001).

**PURPOSE(S):**

These records are an integral part of the accounting systems at OPDIVs Headquarters and specific Area and District locations. The records are used to keep track of all payments to individuals, exclusive of salaries and wages, based upon prior entry into the systems of the official commitment and obligation of government funds. When a person is to repay funds advanced as a loan or scholarship, etc., the records will be used to establish a receivable record and to track repayment status. In the event of an overpayment to a person, the record is used to establish a receivable record for recovery of the amount claimed. The records are also used internally to develop reports to the Internal Revenue Service (IRS) and applicable State and local taxing officials of taxable income. This is a Department-wide notice of payment and collection activities at all locations listed in Appendix 1.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Records will be routinely disclosed to the Treasury Department in order to effect payment.

2. Records may be disclosed to members of Congress concerning a Federal financial assistance program in order for members to make informed opinions on programs and/or activities impacting on legislative decisions. Also, disclosure may be made to a congressional office from an individual's record in response to an inquiry from the congressional office made at the request of the individual in order to be responsive to the constituency.

3. In the event HHS deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

4. A record from this system may be disclosed as a "routine use" to a Federal, State or local agency

maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract or the issuance of a license, grant or other benefit.

5. A record from this system may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to its decision on the matter.

6. Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service (IRS) or the Civil Rights Commission, issue a subpoena to HHS for records in this system of records, HHS will make such records available, provided however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

7. Where a contract between a component of HHS and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in the system of records may be disclosed to such organization.

8. A record may be disclosed to the Department of Justice, to a court, or other tribunal, or to another party before such tribunal, when: (1) HHS, or any component thereof; (2) Any HHS employee in his/her official capacity; (3) Any HHS employee in his/her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (4) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

9. A record about a loan applicant or potential contractor or grantee may be disclosed from the system of records to credit reporting agencies to obtain a credit report in order to determine the person's credit worthiness.

10. When a person applies for a loan under a loan program as to which the OMB has made a determination under I.R.C. 6103(a)(3), a record about his/her application may be disclosed to the Treasury Department to find out whether he/she has a delinquent tax account, for the sole purpose of determining the person's creditworthiness.

11. A record from this system may be disclosed to the following entities in order to help collect a debt owed the United States:

a. To another Federal agency so that agency can effect a salary offset;

b. To the Treasury Department or another Federal agency in order to effect an administrative offset under common law or under 31 U.S.C. 3716 (withholding from money payable to, or held on behalf of, the individual);

c. To the Treasury Department to request the person's mailing address under I.R.C. 6103(m)(2) in order to help locate the person or to have a credit report prepared;

d. To agents of HHS and to other third parties, including credit reporting agencies, to help locate the person or to obtain a credit report on him/her, in order to help collect or compromise a debt;

e. To debt collection agents or contractors under 31 U.S.C. 3718 or under common law to help collect a past due amount or locate or recover debtors' assets;

f. To the Justice Department for litigation or for further administrative action; and

g. To the public, as provided by 31 U.S.C. 3720E, in order to publish or otherwise publicly disseminate information regarding the identity of the person and the existence of a nontax debt.

Disclosure under part (d) and (g) of this routine use is limited to the individual's name, address, social security number, and other information necessary to identify the person. Disclosure under parts (a)-(c) and (e) is limited to those items; the amount, status, and history of the claim; and the agency or program under which the claim arose. An address obtained from IRS may be disclosed to a credit reporting agency under part (d) only for purposes of preparing a credit report on the individual.

12. A record from this system may be disclosed to another Federal agency that

has asked HHS to effect an administrative offset under common law or under 31 U.S.C. 3716 to help collect a debt owed the United States.

Disclosure under this routine use is limited to: name and address, Social Security number, and other information necessary to identify the individual; information about the money payable to or held for the individual; and other information concerning the administrative offset.

13. Disclosure with regard to claims or debts arising under or payable under the Social Security Act may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. § 1681a(f)) or the Federal Claims Collection Act of 1986 (31 U.S.C. § 3701(a)(3)). The purpose of this disclosure is to aid in the collection of outstanding debts owed the Federal Government. Disclosure of records is limited to the individual's name, address, Social Security number, and other information necessary to establish the individual's identity; the amount, status and history of the claim; and the agency or program under which the claim arose.

14. Information in this system of records is used to prepare W-2s and 1099 Forms to submit to the Internal Revenue Service and applicable State and local governments items considered to be included as income to a person: certain travel related payments to employees, all payments made to persons not treated as employees (e.g., fees to consultants and experts), and amounts written-off as legally or administratively uncollectible, in whole or in part.

15. A record may be disclosed to banks enrolled in the Treasury Credit Card Network to collect a payment or debt when the person has given his/her credit card number for this purpose.

16. Records may be disclosed to a contractor (and/or to its subcontractor) who has been engaged to perform services on an automated data processing (ADP) system used in processing financial transactions. The contractor may have been engaged to develop, modify and test a new ADP system, including both software and hardware upgrades or enhancements to such a system; perform periodic or major maintenance on an existing ADP system; audit or otherwise evaluate the performance of such an ADP system; and/or operate such a system.

17. Records may be disclosed to student volunteers, individuals working under a personal services contract, and other individuals performing functions for the Department but technically not having the status of agency employees,

if they need access to the records in order to perform their assigned agency functions.

18. A record from this system may be disclosed to any Federal agency or its agents in order to participate in a computer matching of a list of debtors against a list of Federal employees. Disclosure of records is limited to debtors' names, names of employers, taxpayers identifying numbers, addresses (including addresses of employers), and dates of birth, and other information necessary to establish the person's identity.

19. A record may be disclosed to a commercial reporting agency that a person is responsible for a current claim, in order to aid in the collection of claims, typically by providing an incentive to the person to repay the claim or a debt timely. Disclosure of records is limited to information about a person as is relevant and necessary to meet the principal purpose(s) for which it is intended to be used under the law.

20. A record from this system may be disclosed to the Treasury Department or to an agency operating a Debt Collection Center designated by the Treasury in order to effect a collection of past due amounts.

21. If HHS decides to sell a debt pursuant to 31 U.S.C. § 3711(i), a record from the system may be disclosed to purchasers, potential purchasers, and contractors engaged to assist in the sale or to obtain information necessary for potential purchasers to formulate bids and information necessary for purchasers to pursue collection remedies.

#### Disclosure to Consumer Reporting Agencies

Disclosure pursuant to 5 U.S.C. § 552a(b)(12): Disclosure may be made from this system to "consumer reporting agencies," as defined in 31 U.S.C. § 3701(a)(3). The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal Government, typically, to provide an incentive for debtors to repay their debts timely, by making these debts part of their credit records.

Disclosure of records is limited to the individual's name, address, social security number, and other information necessary to establish the individual's identity; the amount, status and history of the claim; and the agency or program under which the claim arose. The disclosure will be made only after the procedural requirements of 31 U.S.C. § 3711(e) have been followed.

Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records in the System

#### STORAGE:

Hard copy documents are maintained in file folders at agency headquarters and area/district office sites; and on computer disc pack and magnetic tape at central computer sites.

#### RETRIEVABILITY:

This varies according to the particular accounting system within the HHS Operating Divisions, Area and District Offices. Usually the hard copy document is filed by name within accounting classification. Computer records may be indexed by social security number and voucher number. Intra-departmental uses and transfers concern the validation and certification for payment, and for HHS internal audits.

#### SAFEGUARDS:

1. Authorized Users: Employees and officials directly responsible for programmatic or fiscal activity, including administrative and staff personnel, financial management personnel, computer personnel, and managers who have responsibilities for implementing HHS funded programs.

2. Physical Safeguards: File folders, reports and other forms of personnel data, and electronic diskettes are stored in areas where fire and life safety codes are strictly enforced. All documents and diskettes are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas. Magnetic tapes and computer matching tapes are locked in a computer room and tape vault.

3. Procedural Safeguards: Password protection of automated records is provided. All authorized users protect information from public view and from unauthorized personnel entering an office. The safeguards described above were established in accordance with HHS Chapter 45-13 of the General Administration Manual; and the HHS ADP System Manual Part 6, "ADP Systems Security."

#### RETENTION AND DISPOSAL:

Records are purged from automated files once the accounting purpose has been served; printed copy and manual documents are retained and disposed of in accordance with General Accounting Office principles and standards as authorized by the National Archives and Records Service.

**SYSTEM MANAGER(S) AND ADDRESS:**

Department of Health and Human Services, DHHS, Assistant Secretary for Management and Budget, Office of the Secretary, Room 510A, Hubert H. Humphrey Building, Washington, DC 20201.

**NOTIFICATION PROCEDURE:**

Inquiries should be made, either in writing or in person, to the organizations listed under "Location" in Appendix 1, with the exception of Food and Drug Administration records. For those records, contact:

FDA Privacy Act Coordinator (HFW-30)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

The individual making the inquiry must show proof of identity before information is released. Give name and social security number, purpose of payment or collection (travel, grant, etc.) and, if possible, the agency accounting classification.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also clearly specify the record contents being sought, and may include a request for an accounting of disclosures that have been made of their records, if any. (These access procedures are in accordance with HHS regulations (45 CFR 5b.5(a)(2)).)

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedure above, and reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

Travel vouchers submitted by the individual; grant, contract and loan award document; delinquent loan, grant and scholarship record; consultant invoice of services rendered; and application for travel advance.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

Appendix 1

Location

**Indian Health Service Area Offices (IHS)**

Aberdeen Area, IHS  
Federal Building  
115 Fourth Ave., SE  
Aberdeen, SD 57401  
Alaska Area, IHS

250 Gambell Street  
Anchorage, AK 99501  
Albuquerque Area, IHS  
505 Marquette NW  
Suite 1502  
Albuquerque, NM 57102-2163  
Albuquerque Headquarters West, IHS  
300 San Mateo, NE  
Suite 500  
Albuquerque, NM 87108  
Bemidji Area, IHS  
203 Federal Building  
Bemidji, MN 56601  
Billings Area, IHS  
711 Central Avenue  
Billings, MT 59103  
California Area, IHS  
1825 Bell Street  
Sacramento, CA 95825-1097  
Nashville Area, IHS  
3310 Perimeter Hill Drive  
Nashville, TN 37211  
Navajo Area, IHS  
P.O. Box "G"  
Window Rock, AZ 86515-5004

Oklahoma Area IHS  
3625 NW 56th Street  
Five Corporation Plaza  
Oklahoma City, OK 73112  
Phoenix Area, IHS  
3738 North 16th Street  
Suite "A"  
Phoenix, AZ 85016-5981  
Portland Area, IHS  
1220 SW Third Avenue  
Room 476  
Portland, OR 97204-2892  
Office of Health Program Research and Development, IHS  
7900 South "J" Stock Road  
Tucson, AZ 85746-9352

**Food and Drug Administration District Offices (FDA)**

Food and Drug Administration, FDA  
60 Eighth Street, NE  
Atlanta, GA 30309  
Food and Drug Administration, FDA  
Boston District Office  
One Montvale Avenue  
Stoneham, MA 62180  
Food and Drug Administration, FDA  
599 Delaware Avenue  
Buffalo, NY 14202  
Food and Drug Administration, FDA  
Room 700  
Federal Office Building  
850 3rd Avenue (at 30th Street)  
Brooklyn, NY 11232  
Food and Drug Administration, FDA  
61 Main Street  
West Orange, NJ 07052  
Food and Drug Administration, FDA  
Room 1204  
US Customhouse

2nd and Chestnut Streets  
Philadelphia, PA 19106  
Food and Drug Administration, FDA  
900 Madison Avenue  
Baltimore, MD 21201  
Food and Drug Administration, FDA  
San Juan District Office  
PO Box 5719 PTA  
De Tierra Station  
San Juan, PR 00906-5719  
Food and Drug Administration, FDA  
Room 1222  
Main Post Office Building  
433 West Van Buren Street  
Chicago, IL 60607  
Food and Drug Administration, FDA  
1560 East Jefferson Avenue  
Detroit, MI 48207  
Food and Drug Administration, FDA  
1141 Central Parkway  
Cincinnati, OH 45202  
Food and Drug Administration, FDA  
240 Hennepin Avenue  
Minneapolis, MN 55401  
Food and Drug Administration, FDA  
3032 Bryan Street  
Dallas, TX 75204  
Food and Drug Administration, FDA  
4298 Elysian Fields  
New Orleans, LA 70122  
Food and Drug Administration, FDA  
National Center for Toxicological  
Research  
Jefferson, AR 72079  
Food and Drug Administration, FDA  
1009 Cherry Street  
Kansas City, MO 64106  
Food and Drug Administration, FDA  
US Courthouse and Courthouse  
Building  
1114 Market Street, Room 1002  
St. Louis, MO 63101  
Food and Drug Administration, FDA  
Building 20  
Denver Federal Center  
PO Box 25087  
Denver, CO 80255-0087  
Food and Drug Administration, FDA  
Federal Office Building  
Room 506  
50 United National Plaza  
San Francisco, CA 94102  
Food and Drug Administration, FDA  
1521 West Pico Boulevard  
Los Angeles, CA 90015  
Food and Drug Administration, FDA  
22201 23rd Avenue, SE  
Bothell, WA 98021-4421  
Food and Drug Administration, FDA  
Headquarters Office  
5600 Fishers Lane  
Room 11-83  
Parklawn Building  
Rockville, MD 20857  
*Centers for Disease Control and Prevention (CDC)*  
Centers for Disease Control and  
Prevention, CDC

Accounting Section (CO-5)  
Robert A. Taft Laboratories  
4676 Columbia Parkway  
Cincinnati, OH 45226  
Centers for Disease Control and  
Prevention, CDC  
and

Agency for Toxic Substances and  
Disease Registry (ATSDR)  
Financial Management Office  
1600 Clifton Road NE, (M/S D-04)  
Atlanta, GA 30333

*Health Care Financing Administration  
(HCFA)*

Health Care Financing Administration,  
HCFA  
Room C3-0927  
7500 Security Boulevard  
Baltimore, MD 21244

*National Institutes of Health (NIH)*

National Institutes of Health, NIH  
Building 1, Room 222  
Rocky Mountain Laboratory  
Hilton, MT 59840

National Institutes of Health, NIH  
National Institute of Mental Health  
WAW Building, Room 562  
St. Elizabeth's Hospital  
Washington, DC 20032

National Institutes of Health, NIH  
Frederick Cancer Research Facility  
Fort Detrick Building, Room 427  
Frederick, MD 21702-1201

National Institutes of Health, NIH  
National Institutes of  
Environmental Health Sciences  
Room B2-03, Building 101  
Research Triangle Park, NC 27709

National Institutes for Health, NIH  
National Institute on Drug Abuse  
Addiction Research Center  
Building C, Room 248  
4940 Eastern Avenue  
Baltimore, MD 21224

National Institutes for Health, NIH  
Headquarters Office  
Operations Accounting Branch  
Building 31, Room B1-B63  
9000 Rockville Pike  
Bethesda, MD 20892-0134

Individual records of the following  
HHS Operating Divisions may be  
obtained from the Program Support  
Center (PSC):

*Administration for Children and  
Families (ACF)*

*Administration on Aging (AoA)*

*Agency for Health Care Policy and  
Research (AHCPR)*

*Indian Health Service (IHS)*

*Substance Abuse and Mental Health  
Services Administration (SAMHSA)*

*Office of the Secretary (OS)*

*Program Support Center (PSC)*

Program Support Center, PSC

Division of Fiscal Services  
5600 Fishers Lane  
Room 16-05  
Rockville, MD 20857

[FR Doc. 97-16 Filed 1-3-97; 8:45 am]

BILLING CODE 4150-04-P

**Food and Drug Administration**

[Docket No. 96N-0290]

**AM-Rho Laboratories, Inc.; Revocation  
of U.S. License No. 991-001**

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug  
Administration (FDA) is announcing the  
revocation of the establishment license  
(U.S. License No. 991-001) and the  
product license issued to AM-Rho  
Laboratories, Inc., Jacksonville, FL, for  
the manufacture of Source Plasma. In a  
letter to FDA dated April 11, 1996, AM-  
Rho Laboratories, Inc., voluntarily  
requested revocation of its  
establishment and product licenses. In a  
letter dated July 3, 1996, FDA informed  
the firm that the establishment and  
product licenses for its Jacksonville  
location were revoked.

**DATES:** The revocation of the  
establishment license (U.S. License No.  
991-001) and the product license  
became effective July 3, 1996.

**FOR FURTHER INFORMATION CONTACT:**  
Dano B. Murphy, Center for Biologics  
Evaluation and Research (HFM-630),  
Food and Drug Administration, 1401  
Rockville Pike, Rockville, MD 20852-  
1448, 301-594-3074.

**SUPPLEMENTARY INFORMATION:** FDA has  
revoked the establishment license (U.S.  
License No. 991-001) and product  
license for the manufacture of Source  
Plasma of AM-Rho Laboratories, Inc.,  
4130 Salisbury Rd., suite 2100,  
Jacksonville, FL 32216.

FDA inspected AM-Rho Laboratories,  
Inc., from October 16, 1995, through  
November 9, 1995. The inspection also  
involved a concurrent investigation that  
included interviews with individuals  
knowledgeable in the daily operations  
of the firm. The inspection of the facility  
and concurrent investigation revealed  
serious deviations from applicable  
Federal regulations. The deficiencies  
noted included, but were not limited to,  
the following: (1) Failure to properly  
immunize donors (21 CFR 640.66) by:  
(a) Permitting nonphysicians, working  
without a physician present, to inject at  
least 37 donors with red blood cell  
antigen; (b) immunizing at least one  
donor during plasmapheresis; and (c)

permitting nonphysicians to select  
antigens and schedule immunizations;  
(2) failure to adequately determine  
donor suitability by: (a) Not excluding  
for the required 8-week period at least  
21 donors who lost whole blood (21  
CFR 640.63(e)); (b) routinely  
reevaluating donor hematocrit without  
recording the initial hematocrit values;  
and (c) routinely not complying with  
established standard operating  
procedures that required the cross  
checking of donors against deferral logs;  
(3) failure to maintain complete,  
accurate, and concurrent donor records  
(21 CFR 606.160) by: (a) Routinely  
forging physician's signatures on  
numerous records; (b) not completing  
maintenance and calibration records  
concurrently with work done; (c)  
inaccurate documentation of red blood  
cells not returned to the donor; (d)  
documenting as destroyed red blood  
cells that were returned to the donor;  
and (e) not providing a unit number for  
certain plasmapheresis products; (4)  
failure to maintain and follow standard  
operating procedures (21 CFR  
606.100(b)) by: (a) Inadequately  
preparing phlebotomy sites on at least  
25 donors; (b) not following the  
procedure for verifying correct  
reinfusion of red blood cells; and (c)  
permitting donors to leave the premises  
before the minimum time for  
postimmunization observation.

FDA concluded that the serious  
nature of the deficiencies identified  
during the inspection and during the  
concurrent investigation of AM-Rho  
Laboratories, Inc., were the direct  
consequence of the establishment's  
disregard for the applicable regulations  
and standards in the license application.  
FDA determined that these deficiencies  
constitute a danger to the public health  
that warranted suspension under 21  
CFR 601.5(b) and 601.6(a). Additionally,  
the deficiencies noted demonstrated  
management's failure to exercise control  
over the facility relating to compliance  
and to assure adequate training and  
supervision of personnel as required by  
21 CFR 600.10(a) and (b) and 606.20(a)  
and (b).

In a November 27, 1995, letter to the  
firm, FDA suspended the establishment  
license (U.S. License No. 991-001) and  
product license for Source Plasma. In a  
February 14, 1996, letter to FDA, the  
firm stated it would not seek  
reinstatement of the suspended license  
(U.S. License No. 991-001) and would  
destroy all plasma products in  
inventory. In a letter to FDA dated April  
11, 1996, AM-Rho Laboratories, Inc.,  
requested voluntary revocation of U.S.  
License No. 991-001.