for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine use in this system meets the compatibility requirement of the Privacy Act. This SOR contains Protected Health Information as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, 65 FR 82462 (12–28–00), as amended by 66 FR 12434 (2–26–01)). Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information''.

In addition, our policy will be to prohibit release even of non-identifiable data, except pursuant to one of the routine uses, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary). We are proposing to establish the following routine use disclosures of information that will be maintained in the system:

1. To Agency contractors, or consultants who have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

2. To a Member of Congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

3. To the Department of Justice (DOJ), court or adjudicatory body when:

a. the Agency or any component thereof; or

b. any employee of the Agency in his or her official capacity; or

c. any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

d. the United States Government; is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computer diskette and on magnetic storage media.

RETRIEVABILITY:

Information can be retrieved by the name and assigned UserID number.

SAFEGUARDS:

CMS has safeguards for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, CMS has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the IACS system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines; e.g., security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management (IRM) Circular #10, Automated Information Systems Security Program; CMS Automated Information Systems (AIS) Guide, Systems Securities Policies; and OMB Circular No. A–130 (revised), Appendix III.

RETENTION AND DISPOSAL:

Records are maintained in a secure storage area with identifiers. Disposal occurs three years from the time the individual no longer requires access to the HDC.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Technology Services Group, Office of Information Services, CMS, Room N1–19–18, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is 410–786–4067.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, health insurance claim number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), social security number (SSN) (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay), address, date of birth, and sex.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Sources of information contained in this records system include data collected from applications submitted by the individuals requiring access to computer services.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–19022 Filed 7–25–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; System of Records Notice

AGENCY: Office of Family Assistance (OFA) and the Office of Planning, Research, and Evaluation (OPRE), ACF, DHHS.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), the Office of Family Assistance and the Office of Planning, Research and Evaluation, Administration for Children and Families (ACF), are publishing a notice of a new system of records entitled TANF (Temporary Assistance for Needy Families) Data System. The collection of the data elements for this system is authorized by title IV–A of the Social

Security Act (Act) (42 U.S.C. 601–619). The TANF Data System includes the data elements on individual TANF recipients that States report under sections 403 and 411 of the Act.

Information in the TANF Data System is used for three major purposes: (1) To determine whether States are meeting certain requirements prescribed by the Act; (2) to report to Congress on the TANF program; and (3) to compute the scores and rank States on their performance in assisting TANF recipients to obtain and retain employment in connection with the award of High Performance Bonus funds.

DATES: We invite interested parties to submit comments on this notice within August 26, 2002. Pursuant to paragraph 4c of Appendix I to Office of Management and Budget (OMB) Circular No. A–130, Federal Agency Responsibilities for Maintaining Records About Individuals, we have sent copies of this notice as required by 5 U.S.C. 552(a) to the Committee on Government Reform and Oversight of the U.S. House of Representatives, the Committee on Governmental Affairs of the U.S. Senate, and the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB). The new system of records is proposed to be established effective September 2, 2002, unless ACF receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to: Sean D. Hurley, Director, Division of TANF Data Collection and Analysis, Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, SW.; Suite 706, Washington, DC 20447, Phone: 202–401–9297, Fax: 202–205–3598, E-mail: *shurley@acf.hhs.gov.*

Comments received will be available for public inspection at the address specified above from 9 a.m. to 5 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sean D. Hurley, Director, Division of Data Collection and Analysis, at the above address.

SUPPLEMENTARY INFORMATION: The Temporary Assistance for Needy Families program under title IV–A of the Act became effective on August 22, 1996. In order to monitor the progress of States (*i.e.,* the 50 States, District of Columbia, Puerto Rico, U.S. Virgin Islands and Guam) implementing the TANF program, Congress specified mandatory data collection and reporting requirements in section 411 of the Act. This section also requires the Department to transmit to Congress an annual report on the Department's findings as to whether States are:

- Meeting the work participation rates; and,
- Increasing the employment and earnings of needy families, increasing child support collections, and decreasing out-of-wedlock pregnancies and child poverty.

The annual report must also describe:

- The demographic and financial characteristics of families applying for, receiving, and becoming ineligible for TANF;
- The characteristics of State TANF programs; and,
- The trends in employment and earnings of needy families with minor children living at home.

In addition to the foregoing requirements, the statute also allows (but does not require) States to compete for an award of High-Performance Bonus funds. These funds are awarded to applicant States which successfully assist TANF recipients in obtaining and retaining employment.

Until the regulations for the TANF program and the High Performance Bonus system were finalized, including the data collection requirements, States were required to meet minimal reporting requirements under the Emergency TANF Data Report, which did not include any individual identifiers.

Final rules published on April 12, 1999, expanded TANF data collection and reporting requirements. These requirements, published at 45 CFR part 265, required States to report specific individual identifiers, including the Social Security Numbers (SSNs) of TANF recipients collected pursuant to section 1137 of the Act. States are required to collect the prescribed data elements monthly and report the data quarterly to ACF. States may report these data elements on the entire universe of families that receive assistance in a reporting month or for a representative sample of recipients. Approximately 30 States currently report universe data.

Final rules regarding the award of TANF High Performance Bonus (HPB) funds were published on August 30, 2000 and amended on December 4, 2000 and May 10, 2001. These rules, which are found at 45 CFR part 270, specify the data and other information which States must report in order to compete for bonus awards.

Consistent with the requirements noted above, the Office of Family Assistance and the Office of Planning, Research, and Evaluation propose to establish a new system of records: The TANF Data System (TDS). In addition, since States that wish to compete on the four work measures in the HPB system in FY 2002 or later are required to provide the Social Security Numbers (SSNs) of all adult recipients in each fiscal quarter, such SSNs will also be included in the TDS. These SSNs are used to obtain information on the employment and earnings of TANF recipients by matching them with the National Directory of New Hires (NDNH) data set maintained by the Office of Child Support Enforcement (OCSE), ACF.

The records in this system will be maintained in a secure manner compatible with their content and use. Approved users will be required to adhere to the provisions of the Privacy Act. The System Manager will control access to the data.

Dated: June 19, 2002.

Andrew S. Bush,

Director, Office of Family Assistance.

Dated: June 18, 2002.

Howard Rolston,

Office of Planning, Research, and Evaluation.

09–90–0151

SYSTEM NAME:

Temporary Assistance for Needy Families (TANF) Data System, Administration for Children and Families, Department of Health and Human Services.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

The TANF data are reported by the individual States for each (Federal) fiscal quarter. (The term State is used in this notice to refer to the 50 States, the District of Columbia, and the jurisdictions of Puerto Rico, the U.S. Virgin Islands, and Guam). States (CIT) of the National Institutes of Health (NIH) located at Building 12A, Bethesda, MD 20892. The State data are pooled to create a national database for each quarter, which is also kept in the computer system of CIT. The whole system is maintained under the technical and management control of: (1) The Office of Information Systems, Office of Administration, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447; and (2) the Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The TANF Data System (TDS) contains information on: (1) Members of families (as defined by regulation at 45 CFR 265.2) who received assistance under the TANF program in any month, and (2) members of families (as defined by regulation at 45 CFR 265.2) in which an individual was assisted by a Separate State Program (SSP) which is not subject to Federal work or time limit requirements but for which expenditures are or will be claimed by the State to satisfy TANF Maintenance of Effort (MOE) requirements.

CATEGORIES OF RECORDS IN THE SYSTEM:

There are three distinct groups of data in the TDS: family-level data; adult-level or minor-child-head-of-household data; and child data.

Family level data maintained in the TDS may include the following items of information on every family that received assistance during one or more months: State Federal Information Processing Standard (FIPS) code; Region code; county FIPS code; report year and month; stratum code; case identification number (assigned by the State); Zip code; funding stream; disposition status; new applicant status; number of family members; type of family for work participation; receipt of subsidized housing; receipt of medical assistance; receipt of food stamp assistance; amount of food stamp assistance; receipt of subsidized child care; amount of subsidized child care; amount of child support; amount of family's cash resources; cash, or cash equivalent, amount of assistance and number of months of that assistance; TANF child care (amount, number of children covered, and number of months of assistance); transportation assistance (amount and number of months of assistance); transitional services (amount and number of months of assistance); other assistance (amount and number of months of assistance); amount of reductions in assistance; reason for assistance reductions (sanctions, recoupment of prior over payment, and other); waiver evaluation experimental and control group status; exemption status from the federal time-limit provisions; and new child-only-family status.

Adult-level or minor child-head-of-household data maintained in the TDS may include: case identification number (same as the family's identification number); report year and month, State FIPS code; family affiliation; non-custodial parent indicator; date of birth; SSN; race and ethnicity; gender; receipt of disability benefits; marital status; relationship to head of household; parent-with-minor-child-in-the-family status; needs of a pregnant woman; education level; citizenship; cooperation with child support; number of months countable towards Federal time-limit; number of countable months remaining under State's time-limit; exemption status of the reporting month from the State's time-limit; employment status; work participation status; unsubsidized employment hours; subsidized private and public sector employment hours; work experience hours; on-the-job training hours; job search and job readiness assistance hours; community service program hours; vocational educational training hours; hours of job skills training directly related to employment; hours of education directly related to employment for individuals with no high school diploma or certificate of high school equivalency; hours of satisfactory school attendance for individuals with no high school diploma or certificate of high school equivalency; hours of providing child care services to an individual who is participating in a community service program; hours of additional work activities permitted under a Waiver demonstration; hours of other work activities; required hours of work under a Waiver demonstration; amount of earned income; and amount of unearned income (earned income tax credit, Social Security benefit, Supplemental Security Income (SSI), worker's compensation, and other unearned income).

Child data (i.e., data pertaining to every child in a recipient TANF family) may include: case identification number (same as the family's identification number); State FIPS code; report year and month; family affiliation; date of birth; SSN; race and ethnicity; gender; receipt of disability benefits; relationship to head of household; parent-with-minor-child-in-the-family status; education level; citizenship; amount of unearned income (SSI and other).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Legal authority for the collection and maintenance of the system is contained in Title IV-A of the Social Security Act (Act), 42 U.S.C. 601–619. TANF data collection and reporting regulations are found in 45 CFR part 265. Legal authority for the collection of information for the High Performance Bonus award program is found in section 403 of the Social Security Act and in 45 CFR part 270.

PURPOSE(S):

Information in the TANF Data System is used for three major purposes: (1) To determine whether States are meeting certain requirements prescribed by the Act, including prescribed work and time-limit requirements; (2) to compile information used to report to Congress on the TANF program; and, (3) to compute State scores on work measures and rank States on their performance in assisting TANF recipients to obtain and retain employment in connection with the award of High Performance Bonus funds.

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

Records containing data collected pursuant to section 411 of the Social Security Act may be disclosed :

1. To supply raw or tabulated data without personal identifiers in response to specific requests from private and public entities.

2. To supply raw (untabulated) data for research purposes in response to requests from researchers who have agreed in writing not to use such data to identify any individual whose information is included therein.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

States electronically transmit the TANF data for each fiscal quarter to a computer in the Center for Information Technology (CIT) of the National Institute of Health. The data sets received from the States in accordance with the requirements of section 411 of the Social Security Act and 45 CFR part 265 are pooled to create a national database for each fiscal quarter. The national database thus created for a given fiscal year is also kept in a computer disk on the mainframe of the CIT for up to 24 months after the end of such fiscal year. Afterwards, the database is copied to compact discs (CDs) and securely kept in ACF under lock and key or on personal computers by individuals whose access to the CDs has been authorized by OPRE and/or the ACF's Office of Information Services, Office of Administration.

Although SSNs of adult TANF recipients collected from States which have chosen to compete for High-Performance bonuses are stored on the CIT as well, they are also provided to Office of Child Support Enforcement for

matching with records of individual employment information contained in the National Directory of New Hires portion of OCSE's Location and Collection System, No. 09–90–0074, last published at **Federal Register**, Vol. 65, No. 187, pages 57817–57820, dated September 26, 2000. Thereafter, match results are transmitted back to OPRE without SSNs in a form which is not individually identifiable and the SSNs supplied to perform the match are destroyed by OCSE.

RETRIEVABILITY:

The national database kept in the CIT is accessed by authorized users of the data following established procedures. The authorized users are selected individuals in the Office of Administration, ACF (including its contractors who may handle processing of the data and the creation of the national database), and selected individuals in the Division of Data Collection and Analysis, Office of Planning, Research, and Evaluation, ACF (who perform analyses of the data). The database is accessed and downloaded by authorized individuals to secure personal computers (PCs). Sharing of the data downloaded to individual PCs is allowed only with permission of the System Manager. Although all data elements in the database can be retrieved, the SSNs are not generally included in any retrieval, since they are not used in the routine analyses of the data.

SAFEGUARDS:

1. *Physical security:* The CIT of NIH, as a U.S. government facility, abides by all U.S. government policies with regard to the physical security of the data kept there. The CIT has the following: an uninterruptible power supply; climate control; a central backup and recovery system; a disaster recovery program; security procedures for data access; and normal physical and system security procedures (restricted physical access to computer machine rooms and output handling areas, which is enforced by a round-the-clock security guard stationed at the main entrance to the area, valid government identification (ID) badge or photo identification and registration with the security guard to obtain a temporary entry badge for a specifically authorized purpose, such as maintenance service or repair of equipment, etc.). The outputs generated at the facility are placed in locked boxes that can be accessed only by users knowing the correct box access code. To ensure physical security of data kept on tapes or other portable media, the CIT requires that the sponsor of an account authorize the removal of them from the CIT. When such items are taken out, the person receiving the items provides the following to the production unit staff of the CIT: name and signature; ID badge number; driver's license number and State; and organization's (which is represented by the person) name and phone number. Only after confirming these items of information by the production unit staff will the items be given to the person. Data older than 24 months is downloaded by authorized individuals to secure PCs, then copied to CDs which are then kept under lock and key. After copying the data to CDs, the data on the PCs are deleted.

2. *Authorized access:* Access to the data is strictly regulated with passwords and other controls. Only individuals whose work responsibilities specifically include accessing the data system (either for processing or for analysis) are allowed to access these data. They include designated individuals (including contractors) in the Division of Application Development Services, Office of Information Services, Office of Administration, ACF (mostly for processing incoming data and database creation), and designated individuals in the Division of Data Collection and Analysis, OPRE, ACF.

3. *Procedural and technical safeguards:* The individuals who are authorized to access the data have been adequately instructed on the privacy and confidentiality of the data, and they have been trained to handle the data in such a manner as to protect its privacy and confidentiality. Release of any personal identification particulars by these individuals is strictly forbidden, and release of even tabulated data is allowed only under specific authorization. Established clearance procedures must be observed before any release of the information contained in the data system.

RETENTION AND DISPOSAL:

The data transmitted by a State for a fiscal quarter to the CIT's computer are backed up to a computer tape after the initial processing of the data. The backed-up version of the data is kept only for a period of 30 days.

The data transmitted by the States for a fiscal quarter, after processing and acceptance, are pooled to create a national database for the quarter. The national database is stored in the CIT's computer for up to 24 months after the end of the fiscal year. Afterwards, the database is copied to a compact disc, and the original data in CIT's computer is scratched. The data on the compact disc is securely maintained by ACF for up to 20 years in order to facilitate research on caseload trends, changes in the characteristics of TANF recipients, or other pertinent research. The eventual disposal of the data will be by means of physical destruction of the CD's containing the data. The Office of Information Systems of the Office of Administration and OPRE, ACF, are responsible for the retention and disposal of the data system.

The SSNs obtained for the HPB award program for a performance year, although initially kept in an electronic file in the CIT, are erased after identifying the States that merited awards for that performance year. The erasing of these SSN data file will be done within a year after the award year, which immediately follows the performance year. Aggregate data files based on information provided for the HPB award program are also erased.

SYSTEM MANAGER(S) AND ADDRESS:

1. Director, Division of Applications Development Services, Office of Information Services, Office of Administration, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447.

2. Director, Division of Data Collection and Analysis, Office of Planning, Research, and Evaluation, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to either of the System Managers noted above. The Privacy Act provides that, except under certain conditions specified in the law, only the subject of the records may have access to them. All requests must be submitted in the following manner: Identify the system of records that is desired to be searched; have the request for search notarized certifying the identity of the requestor; and indicate that the requestor is aware that the knowing and willful request for or acquisition of Privacy Act record under false pretenses is a criminal offense subject to a $10,000 fine. The letter of request should also provide sufficient particulars to enable the System Manager to distinguish among records on subject individuals with the same name.

RECORD ACCESS PROCEDURES:

Write to either of the System Managers listed above to obtain access to the records. Requestors should provide a detailed description of the record contents they are seeking.

CONTESTING RECORD PROCEDURES:

Write to either of the System Managers listed above, at the address noted, identifying the record and specifying the information to be contested and corrective action sought, together with supporting justification to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

All items of information contained in the system of records are obtained from the States.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–18885 Filed 7–25–02; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0563]

Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc.; Revocation of U.S. License Nos. 1030, 1031, 1032, and 1033

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics licenses (U.S. License Nos. 1030, 1031, 1032, and 1033) issued to Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc., for the manufacture of Source Plasma. These establishments did not respond to a notice of opportunity for a hearing on a proposal to revoke their licenses.

DATES: The revocation of the biologics licenses (U.S. License Nos. 1030, 1031, 1032, and 1033) is effective July 26, 2002.

FOR FURTHER INFORMATION CONTACT: Earline Robinson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is revoking the biologics license (U.S. License No. 1030) issued to Beauregard Plasma, Inc., P.O. Box 96, Hwy. 27, DeQuincy, LA 70633; the biologics license (U.S. License No. 1031) issued to Jackson Plasma, Inc., P.O. Box 788, Hwy. 68, Jackson, LA 70748; the biologics license (U.S. License No. 1032) issued to Baton Rouge Plasma, Inc., P.O. Box 174, Hwy. 74, St. Gabriel, LA 70776; and the biologics license (U.S. License No. 1033) issued to Claiborne Plasma, Inc., Route 2, Box 75, Homer, LA 71040, for the manufacture of Source Plasma. FDA initiated proceedings to revoke the licenses because authorized FDA employees were unable to gain access to any of the establishments to carry out required inspections of the facilities, and manufacturing of products had been discontinued to an extent that meaningful inspections could not be made.

In a certified, return-receipt letter dated May 11, 2001, FDA notified the authorized official of the establishments that attempts to conduct inspections of the establishments were unsuccessful because the establishments were apparently no longer in operation and had apparently discontinued the manufacture of Source Plasma. The letter advised the authorized official that, under 21 CFR 601.5(b)(1)(i) and (b)(1)(ii) (formerly codified as 21 CFR 601.5(b)(1) and (b)(2)), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection under 21 CFR 600.21 or that manufacturing of a product has been discontinued to an extent that a meaningful inspection could not be made, the Commissioner of Food and Drugs shall institute proceedings for license revocation. In the same letter, FDA notified the establishments of FDA's intent to revoke U.S. License Nos. 1030, 1031, 1032, and 1033 and its intent to offer an opportunity for a hearing.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of January 9, 2002 (67 FR 1223), a notice of opportunity for a hearing on a proposal to revoke the license of Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc. In the notice, FDA explained that the proposed license revocations were based on the inability of authorized FDA employees to conduct a meaningful inspection of the facilities because they were no longer in operation, and noted that documentation in support of license revocation had been placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The notice provided the establishments 30 days to submit a written or electronic request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons 60 days to submit written or electronic comments on the proposed revocation. The notice also stated that a licensee's failure to file timely written requests for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation. The establishments did not respond within the 30-day time period with a written or electronic request for a hearing, and under 21 CFR 12.21(b), the 30-day time period prescribed in the notice of opportunity for a hearing may not be extended. No other comments were received.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), the biologics licenses (U.S. License Nos. 1030, 1031, 1032, and 1033), issued to Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc., respectively, are revoked, effective July 26, 2002.

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19017 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0533]

Determination That Cyanocobalamin Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that cyanocobalamin injection (Rubramin PC), 1 milligram (mg)/milliliter (mL) in a 10 mL vial (cyanocobalamin injection) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cyanocobalamin injection.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Borgerding, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price