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