

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB
Display Date: 01-08-02
Publication Date: 01-09-02
Author: A. Corbin

[Docket No. 01N-0563]

Beauregard Plasma, Inc., Jackson Plasma, Inc., Baton Rouge Plasma, Inc., and Claiborne Plasma, Inc.; Opportunity for Hearing on a Proposal to Revoke 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 an opportunity for a hearing on a proposal to revoke 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, for the manufacture of Source Plasma. The proposed revocations are based on the fact that authorized FDA employees have been unable to gain access to these establishments' locations for the purpose of carrying out required inspections of the facilities, which are no longer in operation, and manufacturing of products has been discontinued to an extent that meaningful inspections cannot be made.

DATES: The establishments may submit written or electronic requests for a hearing by *[insert date 30 days after date of publication in the Federal Register]*, and any data and information justifying a hearing by *[insert date 60 days after date of publication in the Federal Register]*. Other interested persons may submit written or electronic comments on the proposed revocations by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocations to the Dockets Management Branch (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, 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 initiating proceedings to revoke 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 is initiating proceedings to revoke the licenses because authorized FDA employees have been unable to gain access to any of the establishments for the purpose of carrying out required inspections of the facilities, and manufacturing of products has been discontinued to an extent that meaningful inspections cannot 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 the manufacture of Source Plasma had been discontinued. 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 cannot be made, the Commissioner of Food and Drugs (the Commissioner) 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.

Because FDA has notified the establishments of the proposed license revocations and has received no response from the establishments, FDA is proceeding under 21 CFR 12.21(b) and publishing an opportunity for a hearing on a proposal to revoke the licenses.

FDA has placed a copy of the May 11, 2001, letter to the establishments on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. The document is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

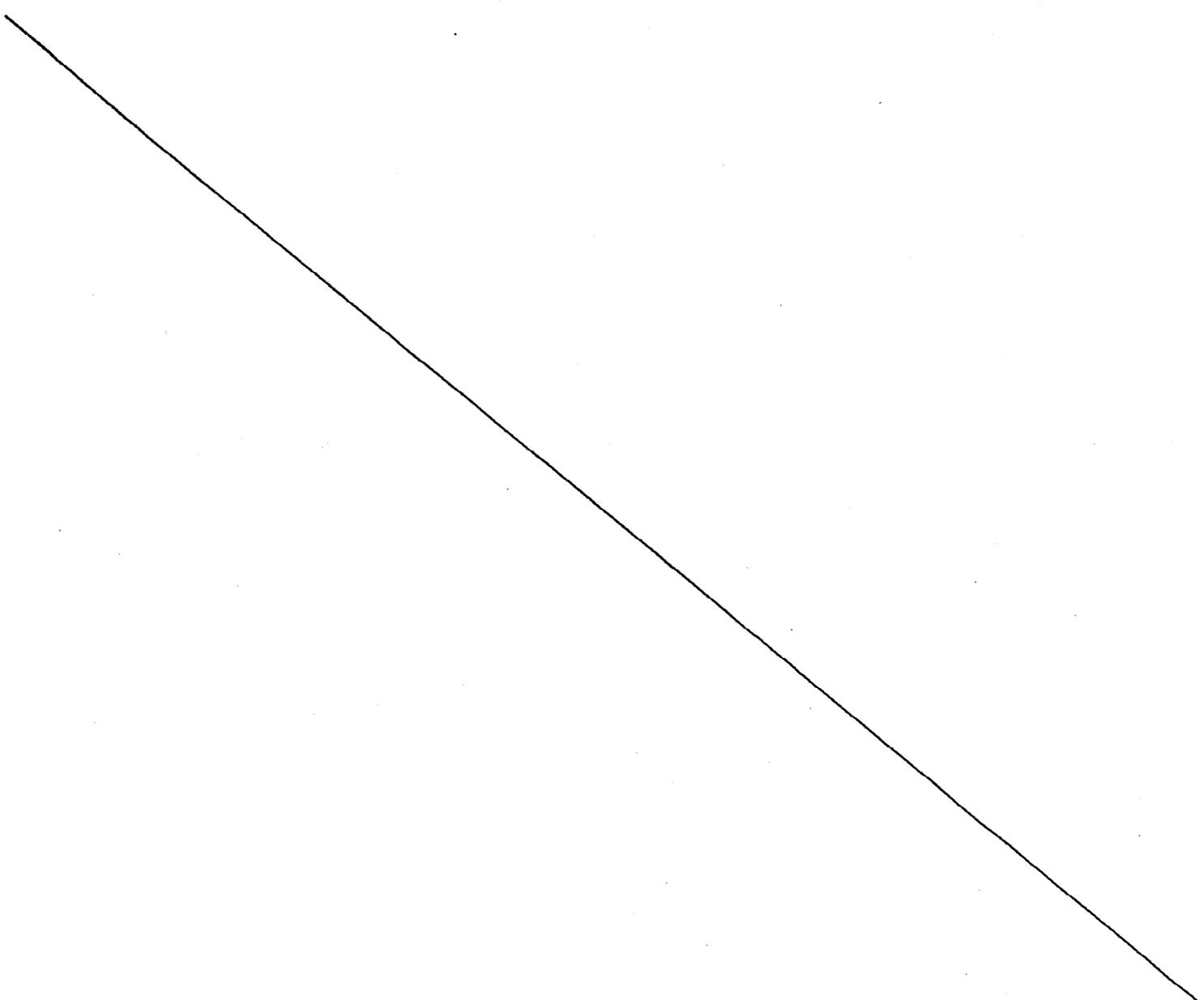
Beauregard Plasma, Inc.; Jackson Plasma, Inc.; Baton Rouge Plasma, Inc.; and Claiborne Plasma, Inc., may submit a written or electronic request for a hearing to the Dockets Management Branch by *[insert date 30 days after date of publication in the Federal Register]*, and any data and information justifying a hearing must be submitted by *[insert date 60 days after date of publication in the Federal Register]*. Other interested persons may submit written or electronic comments on the proposed license revocations to the Dockets Management Branch by *[insert date 60 days after date of publication in the Federal Register]*. The failure of the licensees to file timely written requests for hearings constitutes an election by the licensees not to avail themselves of the opportunity for a hearing concerning the proposed license revocations.

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must be set forth a genuine and substantial issue of fact. If the Commissioner determines upon review of any objections or requests for a hearing that a hearing is not justified, in whole or in part, or if a request for a hearing is not made within the required time with the required format or required analyses, the Commissioner will deny the hearing request, with an explanation for the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading

of this document. Such submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch between 9 a.m. or 4 p.m. Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.



321, 351, 352, 355, and 371), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: 12/27/01

December 27, 2001.

Mark Elengold

Mark Elengold,
Deputy Director for Operations,
Center for Biologics Evaluation and
Research.

[FR Doc. 01-2777 Filed 12-27-01; 8:45 am]

BILLING CODE 4160-01-S

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COPY OF THE ORIGINAL

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