DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0751]

Biosera, Inc.; Revocation of U.S. License No. 1059

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. 1059) and the product license issued to Biosera, Inc., for the manufacture of Source Plasma. Biosera, Inc., has facilities in Denver, CO, and San Diego and Orange, CA. In a letter to FDA dated April 2, 1998, the firm voluntarily requested revocation of its establishment and product licenses. In a letter dated May 12, 1998, FDA informed the firm that the establishment and product licenses for all its locations were revoked.

DATES: The revocation of the establishment license (U.S. License No. 1059) and the product license for all locations became effective May 12, 1998.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, 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 has revoked the establishment license (U.S. License No. 1059) and the product license for the manufacture of Source Plasma issued to Biosera, Inc., at the following locations: (1) 717 Yosemite Circle, Denver, CO 80220 (U.S. License 1059–001); (2) 9040 Friars Rd., suite 430, San Diego, CA 92108 (U.S. License 1059–002); and (3) 265 South Anita Dr., No. 10, Orange, CA 92668 (U.S. License 1059–003).

FDA inspected facilities of Biosera, Inc., in Denver, CO, from June 23, 1997, through August 11, 1997; in San Diego, CA, from June 23, 1997, through July 11, 1997; and in Orange, CA, from June 23, 1997, through September 3, 1997. These inspections revealed serious deviations from applicable Federal regulations. The deficiencies noted included, but were not limited to, the following: (1) Failure to maintain accurate records concurrently with the performance of each significant step in the collection, processing, storage, and distribution of blood and blood components so that all steps can be clearly traced (21 CFR 211.180, 600.12, 606.160, and 606.165); (2) failure to adequately determine the suitability of donors (21 CFR 640.3 and 640.63); (3) failure to have the selection and scheduling of the injection of the antigen performed by a qualified licensed physician (21 CFR 640.66); (4) failure to maintain and follow adequate standard operating procedures for all steps to be followed in the collection, processing, storage, and distribution of blood and blood components (21 CFR 211.100 and 606.100); (5) failure to report important proposed changes in manufacturing methods to the agency prior to implementation (21 CFR 601.12); (6) failure to maintain adequate records of reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of blood collection or transfusion (21 CFR 606.170); and (7) failure to observe, standardize, and calibrate equipment used in the collection, processing, storage, and distribution of blood and blood components (21 CFR 606.60). In addition to the deficiencies noted previously, FDA obtained official samples of red blood cells for immunization from inventory during the inspection of the Orange, CA facility. Analysis by FDA revealed that vials of red blood cells for immunization were falsely labeled with incorrect donor information.

The deficiencies identified during the inspections represented a comprehensive failure of the firm to maintain control over critical aspects of its manufacturing process, as well as to exercise control over the establishment in all matters relating to compliance, and to assure that personnel were adequately trained and supervised and had a thorough understanding of the procedures they performed, as required by 21 CFR 211.25 and 600.10(a) and (b). In addition, FDA determined that the firm's red blood cells for immunization were misbranded within the meaning of sections 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) and section 351(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 262(b)). The serious nature and extent of the deficiencies observed at Biosera, Inc., led the agency to conclude that they were the consequence of a careless disregard for the applicable regulations and the standards in the firm's license. FDA determined that these deficiencies constituted a danger to the public health that warranted suspension under § 601.6(a) (21 CFR 601.6(a)). By letter dated October 17, 1997, to Biosera, Inc., FDA suspended the firm's establishment license (U.S. License No. 1059) and product licenses for Source Plasma effective October 20, 1997. The letter stated that FDA intended to proceed under § 601.6(b) to revoke the establishment license and the product licenses.

In a letter to FDA dated October 22, 1997, Biosera, Inc., requested that the matter of license revocation be held in abeyance. In a letter to Biosera, Inc., dated March 13, 1998, FDA stated that the inspectional history of the firm demonstrated a distinct pattern of noncompliance with those requirements designed to ensure the safety, purity, identity, and quality of plasma, as well as the standards for donor protection that are intended to ensure a continuous and healthy donor population. FDA determined, under 601.5(b) (21 CFR 601.5(b)), that the firm had willfully acted with careless disregard of the applicable regulations and standards, and denied the firm's request that the revocation of license be held in abeyance. In the same letter, FDA provided notice to the firm of FDA's intent to initiate proceedings to revoke all establishment and product licenses encompassed under U.S. License No. 1059 issued to Biosera, Inc., and to issue a notice of opportunity for hearing under § 601.5(b). In a letter to FDA dated April 2, 1998, Biosera, Inc., requested voluntary revocation of U.S. License No. 1059, and thereby waived its opportunity for a hearing.

FDA has placed copies of the letters relevant to the license revocation on file under the docket number found in brackets in the heading of this document with the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These letters are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under § 601.5(a), section 351 of the PHS Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 1059) and the product licenses for the manufacture of the aforementioned product issued to Biosera, Inc., were revoked, effective May 12, 1998.

This notice is issued and published under 21 CFR 601.8 and the redelegation under 21 CFR 5.67(c).

Dated: September 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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