

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 97N-0445]

**Intermountain Health Care, Inc.;
Revocation of U.S. License No. 0729**
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. 0729) and the product licenses issued to Intermountain Health Care, Inc., for the manufacture of Whole Blood, Red Blood Cells, Cryoprecipitated AHF, Plasma, and Platelets. The firm voluntarily surrendered its licenses as part of a Consent Decree of Permanent Injunction.

DATES: The revocation of the establishment license (U.S. License No. 0729) and the product licenses became effective October 8, 1997.

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. 0729) and product licenses issued to Intermountain Health Care, Inc., Eighth Ave. and C St., Salt Lake City, UT 84143, for the manufacture of Whole Blood, Red Blood Cells, Cryoprecipitated AHF, Plasma, and Platelets. The revocation affects all locations under the license which included: Salt Lake City, Ogden, Provo, Logan, and St. George, UT.

FDA inspected Intermountain Health Care, Inc., facilities located in Ogden, UT, December 3 through December 18, 1996; Provo, UT, February 13, 1997, through March 14, 1997; and Salt Lake City, UT, March 17, 1997, through April 18, 1997. These inspections revealed numerous serious deviations from applicable Federal regulations and the standards established in the firm's license. Based on the serious nature of the deficiencies identified, FDA determined that a danger to health existed. The deficiencies noted included, but were not limited to, the following: (1) Failure to operate equipment in a manner for which it was designed (21 CFR 606.60(a)); and (2) failure to perform and document a thorough investigation, including conclusions and followup, of: (a) Any

unexplained discrepancy or the failure of any lot or unit to meet any of its specifications; (b) any reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of either blood collection or transfusion (21 CFR 606.100(c) and 606.170(a)); (c) failure to adequately determine donor suitability (21 CFR 640.3(b)); (d) failure to adequately prepare the skin of the donor at the site of phlebotomy by a method that provides maximum assurance of a sterile container of blood (21 CFR 640.4(f)); (e) failure to assure that personnel responsible for the collection, processing, compatibility testing, storage, or distribution of blood or blood products have adequate training and experience (§ 606.20(b) (21 CFR 606.20(b))); and (f) failure to maintain complete, accurate, and concurrent records (21 CFR 606.160).

FDA determined that these deficiencies constituted a danger to the public health that warranted suspension under 21 CFR 601.6(a). These deficiencies also demonstrated management's failure to exercise control over the establishment in all matters relating to compliance and to ensure that personnel are adequate in number, adequately trained and supervised, and have a thorough understanding of the procedures that they perform, as required by 21 CFR 600.10(a) and (b) and § 606.20(a) and (b).

In a letter to the firm dated April 28, 1997, FDA suspended the establishment license (U.S. License No. 0729) and product licenses for the manufacture of Whole Blood, Red Blood Cells, Cryoprecipitated AHF, Plasma, and Platelets. As required by a Consent Decree of Permanent Injunction signed by the court on July 9, 1997, Intermountain Health Care, Inc., waived its opportunity for a hearing, and in a letter to FDA dated July 11, 1997, surrendered its licenses.

FDA has placed copies of the letters previously discussed on file under the docket number found in brackets in the heading of this notice with the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. 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 21 CFR 601.5(a), section 351 of the Public Health Service 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. 0729) and the product licenses for the manufacture of the aforementioned products issued to Intermountain Health Care, Inc., were revoked, effective October 8, 1997.

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

Dated: November 12, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
**Biological Response Modifiers
Advisory Committee; Notice of
Subcommittee Meeting**
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Subcommittee meeting of the Biological Response Modifiers Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on December 17, 1997, 9 a.m. to 6 p.m.

Location: DoubleTree Hotel, Plaza Ballrooms I and II, 1750 Rockville Pike, Rockville, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12388.

Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 17, 1997, the Xenotransplantation Subcommittee will discuss the following public health issues concerning cross-species transplantation: (1) Development of appropriate assays for detection and identification of infectious retroviruses, (2) limitations of current screening and diagnostic tools, (3) diagnostic testing and clinical care of patients post-transplant, (4) impact of diagnostic screening results on clinical trial