DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1951]

CHEMBIOMED, LTD.; Revocation of U.S. License No. 0916

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics license (U.S. License No. 0916) issued to CHEMBIOMED, LTD. (CHEMBIOMED) for the manufacture of Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal), Anti-Le[a] (Murine Monoclonal) and Anti-Le[b] (Murine Monoclonal). CHEMBIOMED did not respond to a notice of opportunity for a hearing on a proposal to revoke its license.

DATES: The revocation of the biologics license (U.S. License No. 0916) is effective July 7, 2015.

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

FDA is revoking the biologics license (U.S. License No. 0916) issued to CHEMBIOMED, 9515 107th St., Rm. 401, Edmonton AB T5K 2C3, Canada, for the manufacture of Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal), Anti-Le[a] (Murine Monoclonal) and Anti-Le[b] (Murine Monoclonal). Proceedings to revoke U.S. License No. 0916 were initiated under § 601.5(b) (21 CFR 601.5(b)) because FDA determined through various means that a meaningful inspection of CHEMBIOMED could not be conducted because the manufacturer was no longer in operation.

In a phone conversation that occurred on July 7, 1992, a former CHEMBIOMED employee informed FDA that CHEMBIOMED was no longer in business, had ceased the manufacture of licensed products, and had also ceased shipments of licensed products to the United States.

In a letter dated June 16, 1995, FDA requested from the Authorized Official (Responsible Head) of CHEMBIOMED a status update for the production of all of the products for which CHEMBIOMED held a U.S. license. This letter requested that the firm notify FDA in writing of the firm's status and also informed the Authorized Official that in the absence of a response to this letter that FDA would take action to revoke CHEMBIOMED's U.S. license. FDA did not receive a response to its letter dated June 16, 1995.

In a certified, return-receipt letter dated October 18, 1995, FDA requested that the Authorized Official of CHEMBIOMED inform FDA whether or not the firm intended to pursue a product license application supplement request dated May 6, 1987. In the October 18, 1995 letter, FDA also informed the Authorized Official that the product license application supplement request had been placed in the FDA inactive files. FDA did not receive a response to its certified, return-receipt letter dated October 18, 1995.

In a letter to CHEMBIOMED dated December 19, 2012, FDA provided notice of FDA's intent to revoke U.S. License No. 0916, and announced its intent to offer an opportunity for a hearing. FDA indicated that FDA registrations for CHEMBIOMED facilities have not been updated since May 12, 1994. The letter also advised the Authorized Official that, under § 601.5(b)(1)(i) and (ii) of FDA's regulations, proceedings for license revocation may be instituted when FDA finds that authorized FDA employees have been unable to gain access to an establishment for the purpose of carrying out an inspection, or when the manufacturing of a product has been discontinued to an extent that a meaningful inspection cannot be made at the establishment. The December 19, 2012 letter to CHEMBIOMED, sent via United Parcel Service, was returned as undeliverable.

In addition, Health Canada advised FDA that CHEMBIOMED was no longer in operation, according to the Industry Canada Web site: *www.ic.gc.ca.* CHEMBIOMED (Corporation No. 0228176 and Business No. 100938521RC0001 under the governing legislation of the Canada Business Corporations Act) was issued a Certificate of Incorporation on August 15, 1977, and later was issued a Certificate of Dissolution on March 17, 1999.

Under § 12.21(b) (21 CFR 12.21(b)), FDA published in the **Federal Register** of January 14, 2015 (80 FR 1917), a notice of opportunity for a hearing (NOOH) on a proposal to revoke the biologics license (U.S. License No. 0916) issued to CHEMBIOMED for the manufacture of Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal), Anti-Le[a] (Murine Monoclonal) and Anti-Le[b] (Murine Monoclonal). In the NOOH, FDA explained that the proposed license revocation was based on information that the firm was no longer in operation and the manufacture of its licensed products has been discontinued. FDA also noted in the NOOH that the documentation in support of the license revocation had been placed on file with the Division of Dockets Management under the docket number found in brackets in the heading of the notice.

The NOOH provided the firm 30 days to submit an electronic or written request for a hearing and 60 days to submit any data and information justifying a hearing. The NOOH provided other interested persons with 60 days to submit electronic or written comments on the proposed revocation. The firm did not respond within the 30-day time period with an electronic or written request for a hearing, and under § 12.21(b), the 30-day time period prescribed in the NOOH may not be extended. No comments from other interested persons were received within the 60-day time period.

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 and redelegated to the Director and Deputy Director of the Center for Biologics Evaluation and Research (FDA Staff Manual Guide 1410.203), the biologics license (U.S. License No. 0916) issued to CHEMBIOMED, LTD. for the manufacture of Anti-A (Murine Monoclonal), Anti-B (Murine Monoclonal), Anti-Le[a] (Murine Monoclonal) and Anti-Le[b] (Murine Monoclonal) is revoked, effective July 7, 2015.

Dated: June 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0169]

Chung Po Liu; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Chung