4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1951]

CHEMBIOMED, LTD., Opportunity for a Hearing on a Proposal to Revoke U.S. License No. 0916

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 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). The proposed revocation is based on information that the firm is no longer in operation and the manufacture of its licensed products has been discontinued.

DATES: CHEMBIOMED may submit electronic or written 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 electronic or written comments on the proposed revocation by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic requests for a hearing, any data and information justifying a hearing, and comments to http://www.regulations.gov. Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed

revocation to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Reilly, 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:

I. Background

FDA is initiating proceedings to revoke 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 are being initiated under 21 Code of Federal Regulations (CFR) 601.5(b) because FDA has determined through various means that a meaningful inspection of CHEMBIOMED cannot be conducted because the manufacturer is no longer in operation. In addition, Health Canada has advised FDA that CHEMBIOMED is no longer in operation. According to the Industry Canada Web site (www.ic.gc.ca), CHEMBIOMED (Corporation No. 0228176 and Business No. (BN) 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.

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 21 CFR 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. The December 19, 2012 letter to CHEMBIOMED, sent via United Parcel Service (UPS), was returned as undeliverable.

II. Notice of Opportunity for Hearing

Because FDA has made reasonable efforts to notify CHEMBIOMED of the proposed revocation and no response has been received from the firm, FDA is proceeding under 21 CFR 12.21(b) and issuing this notice of opportunity for a hearing on a proposal to revoke the biologics license (US. 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).

FDA has placed copies of the documents relevant to the proposed revocation on file with the Division of Dockets Management (see ADDRESSES) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) A phone conversation record dated July 7, 1992 between FDA and a former CHEMBIOMED employee; (2) an FDA letter to the Authorized Official of CHEMBIOMED dated June 16, 1995; (3) a certified, return-receipt letter from FDA to the Authorized Official of CHEMBIOMED dated October 18, 1995; (4) a UPS Express Mail, signature required letter from FDA to the Authorized Official of CHEMBIOMED, dated December 19, 2012, and returned as undeliverable; and (5) Industry Canada information that documents CHEMBIOMED, Corporation No. 0228176 and BN 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. These documents are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

CHEMBIOMED may submit an electronic or written request for a hearing to the Division of Dockets Management by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], and any data and information justifying a

hearing to the Division of Dockets Management by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Other interested persons may submit electronic or written comments on the proposed license revocation to the Division of Dockets Management by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The failure of the licensee, CHEMBIOMED, to file a timely electronic or written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation (§ 12.22(b)).

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 and information to justify a hearing on a proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest on mere allegations or denials, but must set forth a genuine and substantial issue of fact that requires a hearing (§ 12.24(b)). If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs (the Commissioner) will deny the hearing request, making findings and conclusions that justify the denial (§ 12.24(b)(3)).

Only one copy of any submission need be provided to FDA. 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 examined in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at http://www.regulations.gov.

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 Acts (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to the Commissioner and redelegated to the Director and Deputy Director of the Center for Biologics Evaluation and Research (FDA Staff Manual Guide 1410.203).

Dated: January 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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