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.

[FR Doc. 2015–16562 Filed 7–6–15; 8:45 am]

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

Po Liu's (Liu) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Liu for 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Liu was convicted of a felony for conduct relating to the importation of an article of food into the United States. In determining the appropriateness and period of Liu's debarment, FDA has considered the relevant factors listed in the FD&C Act. Liu has failed to file with the Agency information and analysis sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective July 7, 2015.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8618.

SUPPLEMENTARY INFORMATION:

I. Background

On August 26, 2010, Chung Po Liu pleaded guilty to the felony crime of entering honey, a food, into the commerce of the United States by means of a false statement, in violation of 18 U.S.C. 542 and 2. Liu admitted that he had caused his customs broker to declare Thailand to be the country of origin of one honey shipment, although the majority of the honey originated in China, and to declare the Philippines to be the country of origin of a second honey shipment, although the honey originated in China. Liu admitted that, in each instance, he had documents in his possession establishing that the honey originated in China, that the declaration of country of origin was false, and that he was without reasonable cause to believe it was true. Liu also admitted that the United States began requiring the deposit of estimated anti-dumping duties of between 183 percent and 221 percent on all non-exempt honey of Chinese origin beginning in 2001. Liu did not deposit estimated anti-dumping duties for either of these two shipments of imported honey. Liu also pleaded guilty to the misdemeanor crime of introducing adulterated food into interstate commerce in violation of sections 301(a), 303(a)(1), and 402(a)(2)(C)(i) of the FD&C Act (21 U.S.C. 331(a), 333(a)(1), and 342(a)(2)(C)(i)). Liu admitted that he had introduced honey that contained the unsafe food additive ciprofloxacin, an antibiotic, into interstate commerce. On December 20, 2010, the U.S. District Court for the Western District of Washington entered a criminal judgment against Liu under his guilty plea.

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) authorizes FDA to debar a person from importing articles of food or offering food for importation into the United States based on a finding, under section 306(b)(3) of the FD&C Act, that the person was convicted of a felony for conduct relating to the importation of food into the United States. By letter dated April 25, 2011, in accordance with section 306(i) of the FD&C Act and 21 CFR 10.50(c)(20) and 12.21(b), FDA, Office of Regulatory Affairs (ORA) notified Liu that the Agency proposed to debar him for 5 years from importing any articles of food or offering such articles for importation into the United States and offered an opportunity to request a hearing on the proposed order of debarment to resolve disputed issues of material fact. ORA advised Liu that a request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing.

In a letter dated May 24, 2011, Liu requested a hearing on his proposed debarment. On June 11, 2011, Liu submitted materials in support of his hearing request. In these materials, which were submitted in accordance with 21 CFR 12.22, Liu acknowledges his felony conviction. However, he urges FDA not to exercise its authority to debar him based on that conviction. In the alternative, he argues that any debarment should be limited to the 1-year period of supervised release that the court ordered him to serve after his release from custody after serving his sentence of incarceration of 1 year and 1 day.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (the Director) has considered Liu's submission. FDA will grant a hearing only if the material submitted shows that there is a genuine and substantial issue of fact for resolution at the hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)). Based on this review, the Director has concluded that Liu has failed to raise a genuine and substantial issue of fact for resolution at a hearing and that a hearing is not justified. Accordingly, Liu's request for a hearing is denied, and FDA is issuing this notice to explain the basis for this decision (see 21 CFR 12.24(a) and 12.28).

II. Arguments

Liu raises two primary arguments in support of his hearing request. Liu first contends generally that debarment is ''unwarranted in law and without justification by the facts in the case.'' He also urges that FDA should not debar him due to his advanced age and ill health, or, alternatively, that FDA should debar him for a time period of less than 5 years, the debarment period proposed in the Notice of Opportunity for Hearing.

Liu notes that, under section 306(b), the decision whether to debar him is committed to FDA's discretion, and that FDA is authorized to debar him ''as a result of conviction of certain crimes'' (June 21 submission at 1). Indeed, section 306(b)(3) of the FD&C Act states that a person is subject to debarment if the person has been convicted of a felony for conduct relating to the importation into the United States of any food. Liu does not dispute that he was convicted of a felony crime in violation of 18 U.S.C. 542 and 2, or that his conviction was based on conduct relating to the importation of honey, a food. In the plea agreement Liu signed, which he does not now refute, he admitted that: (1) He entered or introduced, or attempted to enter or introduce, into the commerce of the United States, imported merchandise; (2) he did so by means of any fraudulent or false invoice, declaration, affidavit, letter, paper, or by means of any false statement, written or verbal; and (3) he was without reasonable cause to believe the truth of such statement or procured the making of any such false statement as to any matter material thereto without reasonable cause to believe the truth of such statement (Plea Agreement at 2). He further admitted that this conduct related to the importation of honey, a food (see, for example, Plea Agreement at 11–12, June 21 submission at 2–3). Accordingly, Liu is subject to debarment under section 306(b)(3) on the basis of that felony conviction.

Since Liu's felony conviction for conduct relating to the importation into the United States of honey establishes a predicate from which FDA may choose to exercise its authority to debar him, Liu's June 21 submission in support of his request for a hearing attempts to raise factual issues concerning the

application of the factors in section 306(c)(3) that FDA is required to consider in determining the appropriateness and the period of debarment. These are the applicable criteria: (1) The nature and seriousness of any offense involved; (2) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense; (3) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including . . . full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing) . . . and any other actions taken to substantially limit potential or actual adverse effects on the public health; (4) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future; and (5) prior convictions under the FD&C Act or under other Acts involving matters within the jurisdiction of FDA.

Significantly, the health and age of an individual subject to debarment are not included as factors relevant to FDA's exercise of the Agency's debarment authority. Although a defendant may sometimes argue that poor health and advanced age should be considered in mitigation of punishment, debarment under 21 U.S.C. 335a is not a punitive sanction. Instead it is remedial in purpose. (See *DiCola* v. *FDA,* 77 F.3d 504, 507 (D.C. Cir. 1996) (permanent debarment of convicted individual is not punishment, but instead is a remedy to protect the integrity of the drug industry and public confidence in that industry); *Bae* v. *Shalala,* 44 F.3d 489, 493 (7th Cir. 1995) (purpose of statute establishing debarment authority was to restore consumer confidence in generic drugs by eradicating widespread corruption in generic drug approval process).) In determining whether to debar Liu, as well as the length of a term of debarment, FDA acts to protect the public health and not to punish Liu. Because we are acting for this remedial, not punitive, purpose, Liu's arguments concerning his health and age are not relevant to this proceeding.

I address each of the relevant factors in turn.

A. The Nature and Seriousness of the Offense

Liu emphasizes that he was not convicted of the charge for which he was originally indicted, conspiracy to violate 18 U.S.C. 545 by conspiring to enter goods into the United States through false statement, and to smuggle goods. He urges that conviction under the original charge would have required proof that he acted ''knowingly and intentionally'' (June 21 submission at 3). He devotes much of his submission to his argument that he did not act ''knowingly and intentionally.'' According to Liu's June 21 submission, Liu's accomplices, Yong Xiang Yan, the owner of Changge Jixiang Bee Products, Ltd. of Henan China, and Boa Zhong Zhang, a vice-president and part owner of Changge, established a scheme to transship and import into the United States Chinese honey, using Indigo Distribution Corp. in the Philippines. He disclaims knowledge of the nature and extent of their operations (June 21 submission at 4).

However, these allegations are not relevant. Liu's conviction was not for violating, or conspiring to violate, 18 U.S.C. 545. The offense that must be considered is his felony violation of 18 U.S.C. 542 and 2, which was based on Liu's causing the false declarations to be made even though he was without reasonable cause to believe the truth of such statements. Even in his June 21 submission, Liu expressly acknowledges that he had documents in his possession indicating that, as described in the Plea Agreement and as charged in the superseding information to which he pleaded guilty, two shipments of honey he imported actually originated in China (June 21 submission at 3). He leaves unchallenged the factual basis for his conviction: That, without reasonable cause to believe the truth of the statements, he caused his customs broker to falsely state that the shipments originated in Thailand (December 20, 2006, shipment) and the Philippines (February 14, 2007, shipment). Although he dismisses these as a ''few emails . . . among many hundreds of documents relating to the importation of honey found in Mr. Liu's house'' (June 21 submission at 3), he fully admits that these communications were in his possession. Liu has raised no factual issue for resolution at a hearing concerning whether he acted without reasonable cause to believe the truth of the statements concerning where the honey was produced.

We further note that the statement of facts, which Liu admitted in his plea agreement, provides additional information concerning his actions which demonstrate the financial motive behind this offense. Had Liu instructed his customs broker to declare the country of origin as China, he and his companies would have been responsible for anti-dumping duties in the amount of 221 percent of the value of the honey (Plea Agreement at 11–12). Liu's misrepresentation was thus both material and meaningful in the imports process, and it could not have been lost on Liu how important the country of origin was in the context of the anti-dumping duties for Chinese honey.

Finally, I note that Liu's conviction did not rest on a single false statement. Instead, he pleaded guilty to a superseding information that included false statements with respect to two separate entries of imported Chinese honey, 2 months apart. His conviction did not rest on a single isolated incident, but on a repeated violation.

Therefore, it is undisputed that Liu was responsible for multiple material false statements that resulted in the avoidance of significant duties for the importation of two shipments of honey with a total declared value of $186,912. As such, I agree with ORA's evaluation of this consideration and find that the nature and seriousness of Liu's felony offense weighs strongly in favor of debarment.

B. The Nature and Extent of Management Participation in the Offense

Next, I consider whether Liu's response raised specific facts showing that there is a genuine and substantial issue of fact that requires a hearing concerning the nature and extent of management participation in the offense, including whether corporate policies and practices encouraged the offense, and whether inadequate institutional controls contributed to the offense.

In the Notice of Opportunity for a Hearing, ORA stated, ''As the owner of the importing companies, you were responsible for the accuracy of declarations made to United States customs officials. You were without reasonable cause to believe the truth of these declarations regarding the origins of the honey. Further, you directly profited from the domestic sale of the imported honey.''

Liu has not challenged these statements, and all of the descriptions of Liu's actions in the June 21 submission show him to act alone, as the individual responsible for importing these two shipments of honey. I agree with ORA that, based upon these facts, the nature and extent of Liu's management participation in the offense weighs in favor of debarment.

C. The Nature and Extent of Voluntary Steps To Mitigate the Impact on the Public

Next, I consider whether Liu has raised specific facts showing that there is a genuine and substantial issue of fact that requires a hearing concerning the nature and extent of voluntary steps to mitigate the impact of his offense on the public, including full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health.

In the Notice of Opportunity for a Hearing, ORA stated, ''You took no steps to mitigate the impact on the public of your actions.'' Liu has not challenged this statement. As such, I agree with ORA that the nature and extent of Liu's voluntary steps to mitigate the impact to the public weighs in favor of debarment.

D. The Impact of Changes in Ownership, Management, or Operations

In the Notice of Opportunity for Hearing, ORA determined that this factor was not applicable for consideration. Liu has not challenged that determination.

E. Prior Convictions Under the FD&C Act or Related Acts

In the Notice of Opportunity for Hearing, ORA acknowledged that the Agency was unaware of any prior convictions involving matters within the jurisdiction of FDA. The lack of previous violations of the FD&C Act or related statutes by Liu weighs against debarment.

III. Findings and Order

The Director of the Office of Scientific Integrity, under section 306(b)(3)(A) of the FD&C Act and under authority delegated to him, finds that Liu has been convicted of a felony for conduct relating to the importation of food into the United States. Accordingly, FDA may debar Liu from importing articles of food or offering such articles for import into the United States for a period of not more than 5 years.

I have considered the arguments raised by Liu regarding the relevant factors listed in section 306(c)(3) of the FD&C Act and have determined that Liu has raised no genuine and substantial issues of fact that require resolution at an evidentiary hearing. I have considered the factors in section 306(c)(3) of the FD&C Act. The nature and seriousness of Liu's offense, Liu's management participation in the offense, and the lack of any voluntary steps to mitigate the impact of the offense weigh in favor of debarring. Although Liu appears to have no prior criminal convictions involving matters within the jurisdiction of FDA, that consideration does not counterbalance to a sufficient degree the remaining considerations to warrant decreasing the period of debarment. Of particular note is the nature and seriousness of the offense, in light of the volume of honey that was imported, the amount of duties that were avoided, and the fact that false statements were made with regard to two shipments of honey. I agree with ORA's proposed period of debarment and find that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Liu is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Under section 301(cc) of the FD&C Act, the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Liu is a prohibited act.

Any application by Liu for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA–2011–N–0169 and sent to the Division of Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at *http://www.regulations.gov*.

Dated: June 25, 2015.

Nathan Doty,

Director, Office of Scientific Integrity.

[FR Doc. 2015–16561 Filed 7–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice of Meeting

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting of the National Advisory Council on Nurse Education and Practice (NACNEP).

DATES: July 28 and 29, 2015, 8:30 a.m.–5 p.m. EST.

ADDRESSES: This meeting will be via Webinar Format. U.S. Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: For additional information regarding NACNEP, please contact Jeanne Brown, Staff Assistant, National Advisory Council on Nurse Education and Practice, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. The telephone number is: (301) 443–5688. The email is *jbrown@hrsa.gov*.

SUPPLEMENTARY INFORMATION:

Status: This advisory council meeting will be open to the public.

Purpose: The purpose of the 131st National Advisory Council on Nurse Education and Practice (NACNEP) meeting is to provide advice and recommendations on policy and program development related to the role of nursing in Interprofessional Education (IPE) and Practice. The purpose is to discuss existing IPE models in an academic setting and the intersect between education and practice as it relates to Health Care delivery reform. The goal of the meeting is to solicit recommendations for IPE in an academic setting and the intersect important to IPE and practice. Strengths, challenges, achievable solutions, and replicable models required and/or available to move from discussion to action will be identified. Additionally, the meeting will discuss topics for future work of the council. This meeting will conclude with a formulation of recommendations and form the basis for NACNEP's mandated Thirteenth Annual Report to the Secretary of the U.S. Department of Health and Human Services and Congress.

Agenda: A final agenda will be posted on the *NACNEP Web site* 3 days prior to the meeting. Agenda items are subject to change as priorities dictate.

Further information regarding NACNEP including the roster of members, reports to Congress, and minutes from previous meetings is available at the NACNEP Web site. Members of the public and interested parties may request to participate in the meeting by contacting Staff Assistant, Jeanne Brown. Access to the meeting will be granted on a first come, first-served basis and space is limited. Public participants may submit written statements in advance of the scheduled meeting. If you would like to provide oral public comment during the meeting