TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

| 21 CFR section; activity | FDA Form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response [2] | Total hours |
|---|---|---|---|---|---|---|
| Total | | | | | | 4,883 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The calculation for 20 minutes uses 0.333 hour.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We base our estimate of the number of respondents in table 1 on registrations, process filings, and reports received. The hours per response reporting estimates are based on our experience with similar programs and information received from industry. The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is minimal because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. We estimate that we will receive one report annually under §§ 108.25(d) and 108.35(d) and (e). The report is expected to take 4 hours per response, for a total of 4 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR part | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 108, 113, and 114 | 10,392 | 1 | 10,392 | 250 | 2,598,000 |

[1] here are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of 10,392 recordkeepers in table 2 on the number of registered firms, excluding firms that were inactive or out of business, yet still registered. We estimate that 10,392 firms will each expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. No burden has been estimated for the third-party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: July 20, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–16037 Filed 7–23–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–5969]**

### John Seil Lee: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring John Seil Lee for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lee was convicted of one felony count under Federal law for conspiracy to import merchandise contrary to law and to defraud the United States and of one felony count under Federal law for importing merchandise contrary to law. The factual basis supporting both of Mr. Lee's convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lee was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 15, 2020 (30 days after receipt of the notice), Mr. Lee had not responded. Mr. Lee's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable July 24, 2020.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa (ELEM–4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On August 20, 2019, Mr. Lee was convicted, as defined in section 306(*l*)(1)(A) of the FD&C Act, in the U.S. District Court for the Central District of California, when the court accepted his plea of guilty and entered judgment against him for the felony offenses of conspiracy to commit offense or to defraud the United States in violation of 18 U.S.C. 371 and smuggling goods into

the United States; principals in violation of 18 U.S.C. 545 and 2(b).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: As contained in count 1 of the information in Mr. Lee's case, filed on January 7, 2019, to which Mr. Lee pleaded guilty, between 2011 and 2017 Mr. Lee owned, controlled, and operated four businesses for the purpose of manufacturing and distributing male sexual enhancement pills that he marketed as herbal remedies but that contained undisclosed tadalafil, a prescription drug product. Until February 22, 2017, Mr. Lee conspired with others to import bulk tadalafil, with labeling that was false and misleading, from suppliers in China contrary to law. Mr. Lee had his Chinese suppliers ship the bulk tadalafil under false labeling to commercial mailboxes that he controlled in New Jersey and Pennsylvania. Mr. Lee then had the commercial mailbox companies that received the Chinese shipment repackage the tadalafil shipments and forward them to mailboxes Mr. Lee controlled in California. After receiving the bulk tadalafil in California, Mr. Lee caused it to be manufactured into at least 5 and a half million pills that he sold to distributors across the United States. The pills Mr. Lee manufactured contained levels of tadalafil significantly higher than the levels in FDA-approved prescription drugs such as Cialis. Mr. Lee sold at least $11 million worth of these pills to distributors in packages with labeling that did not disclose the presence of tadalafil. When, as on a number of occasions, FDA announced that a brand of pills sold by one of Mr. Lee companies contained undeclared tadalafil, he would establish a new company and/or begin manufacturing identical pills with different brand names in an effort to evade FDA regulators.

As contained in count 2 of the information in Mr. Lee's case, to which Mr. Lee pleaded guilty, on or about February 9, 2017, Mr. Lee fraudulently and knowingly, and contrary to law, imported two parcels of the bulk drug tadalafil with labeling that was false and misleading as to the parcels' contents, labels that did not contain accurate statements of the quantity of the contents in terms of weight, measure, and numerical count, and labeling that did not bear adequate directions for use, contrary to sections 301(a) and 502(a)(1), (b), and (f) of the FD&C Act (21 U.S.C. 331(a), 352(a)(1), (b), and (f)).

As a result of these convictions, FDA sent Mr. Lee, by certified mail on February 10, 2020, a notice proposing to debar him for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Lee's felony conviction for one felony count under Federal law for conspiracy to import merchandise contrary to law and to defraud the United States was for conduct relating to the importation into the United States of any drug or controlled substance because he conspired to illegally import bulk tadalafil and repackage it into pills that he resold across the United States. The proposal was also based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Lee's felony conviction for one felony count under Federal law for importing merchandise contrary to law was for conduct relating to the importation into the United States of any drug or controlled substance because he also fraudulently and knowingly imported two parcels of bulk drug tadalafil into the United States contrary to sections 301(a) and 502(a)(1), (b), and (f) of the FD&C Act.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Lee's offenses, and concluded that these felony offenses warrant the imposition of a 10-year period of debarment.

The proposal informed Mr. Lee of the proposed debarment and offered Mr. Lee an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Lee received the proposal and notice of opportunity for a hearing on February 14, 2020. Mr. Lee failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. John Seil Lee has been convicted of two felony counts under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that each offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act. Under section 306(c)(2)(A) of the FD&C Act, in the case of a person debarred for multiple offenses, FDA may determine whether the periods of debarment shall run concurrently or consecutively. FDA has concluded that the 5-year period of debarment for each of the two offenses for which Mr. Lee was convicted will run consecutively, resulting in a total debarment period of 10 years.

As a result of the foregoing finding, Mr. Lee is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Lee is a prohibited act.

Any application by Mr. Lee for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–5969 and sent to the Dockets Management Staff (see **ADDRESSSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *http://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–16062 Filed 7–23–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–3277]**

### Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Chembio Diagnostic Systems, Inc. (''Chembio'') for the DPP Zika IgM Assay System. FDA revoked this Authorization on June 3, 2020, under