

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section/form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Color Additive Petitions						
70.25, 71.1	2	1	2	1,337	2,674	\$5,600
Food Additive Petitions						
171.1	3	1	3	7,093	21,279	0
Form FDA 3503	6	1	6	1	6	0
Total					23,959	5,600

¹ There are no capital costs associated with this collection of information.

Our estimate of burden attributable to food additive or color additive petitions is based on our experience with the information collection, which has not changed since our last review, and we therefore retain the currently approved burden. This estimate reflects the average number of petitions we have received annually over a period of 10 years. The attendant burden we estimate also reflects an industry average, although burden associated with individual petitions may vary depending on the complexity of the petition, and the amount and type of data needed for scientific analysis.

Color additive petitions are subject to fees. The listing fee for a color additive petition ranges from \$1,600 to \$3,000, depending on the intended use of the color additive and the scope of the requested amendment. A complete schedule of fees is set forth in § 70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is \$2,600 and the maximum color additive petition fee for a Category B petition is \$3,000. Because an average of 2 CAPs are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to \$5,600 ((1 × \$2,600) + (1 × \$3,000) listing fees = \$5,600). There are no capital costs associated with CAPs. The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive

regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: March 10, 2020.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3131]

Jagen D. Lewicki: 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 Jagen Lewicki for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lewicki was convicted, as defined in the FD&C Act, of one felony count under Federal law for conspiracy to distribute Human Growth Hormone

(HGH) imported from China for a purpose other than the treatment of a disease or other recognized medical condition, the use of which had been authorized by the Secretary of Health and Human Services, and not pursuant to an order of a physician, in violation of the FD&C Act. The factual basis supporting this felony conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lewicki was given notice of the proposed debarment and, in accordance with the FD&C Act and FDA’s regulations, was given an opportunity to request a hearing to show why he should not be debarred. As of October 28, 2019 (30 days after receipt of the notice), Mr. Lewicki had not responded. Mr. Lewicki’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 March 17, 2020.

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

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 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 the 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 December 20, 2018, Mr. Lewicki was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty for the offense of conspiracy to distribute HGH imported from China for unapproved purposes in violation of 18 U.S.C. 371 and 21 U.S.C. 333(e) (section 303(e) of FD&C Act).

The FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Stipulation of Facts incorporated into the Plea Agreement, filed on December 20, 2018, from on or about January 2017 to February 2018, Mr. Lewicki conspired with certain other known and unknown individuals to unlawfully distribute HGH imported from China. Specifically, Mr. Lewicki submitted periodic orders, and gave money, for HGH to co-conspirators, for the purchase of HGH from manufacturers based in China. In addition, Mr. Lewicki set up various post office boxes at private carriers in the Eastern District of Virginia. The Chinese based manufacturers delivered vials of HGH from China to Mr. Lewicki at post office boxes he set up. Mr. Lewicki received approximately 90 packages from Chinese manufacturers, each containing 200 vials of HGH. Mr. Lewicki would then sell these vials to individual customers throughout the United States for bodybuilding and other unapproved purposes. Mr. Lewicki's actions were in violation of 18 U.S.C. 371 and 21 U.S.C. 333(e) (section 303(e) of the FD&C Act).

As a result of this conviction FDA sent Mr. Lewicki, by certified mail on September 25, 2019, a notice proposing to debar him for 5 years 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. Lewicki's felony conviction for conspiracy in violation of 18 U.S.C. 371 and section 303(e) of the FD&C Act was for conduct relating to the importation into the United States of any drug or controlled substance because on multiple occasions, he imported HGH from China and conspired to distribute it within the United States. 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. Lewicki's offense and, for the reasons detailed in the notice,

concluded that his offense warranted a 5-year period of debarment under section 306(c)(2)(A)(iii).

The proposal informed Mr. Lewicki of the proposed debarment and offered Mr. Lewicki 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. Lewicki received the proposal and notice of opportunity for a hearing on September 28, 2019. Mr. Lewicki 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. Lewicki has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years.

As a result of the foregoing finding, pursuant to section 306(b)(1)(D) of the FD&C Act, Mr. Lewicki is debarred for a period of 5 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 (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of, Mr. Lewicki is a prohibited act.

Any application by Mr. Lewicki for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2019-N-3131 and sent to the Dockets Management Staff (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.

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: March 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3474]

Zhang Xiao Dong: 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) debaring Zhang Xiao Dong for a period of 5 years from importing articles of food (including dietary supplements) or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Dong was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Dong was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 19, 2019 (30 days after receipt of the notice), Mr. Dong has not responded. Mr. Dong'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 March 17, 2020.

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

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

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) 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 food.

On December 20, 2018, Mr. Dong was convicted as defined in section