[2] Burden for manufacturers of sunscreen drug products.
[3] Burden for manufacturers of new OTC drug products.

Dated: August 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19985 Filed 8–12–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0305]

John Bonnes: 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 (the act) debarring John Bonnes for a period of 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 Mr. Bonnes was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Bonnes has notified FDA that he acquiesces to debarment, and therefore has waived his opportunity for a hearing concerning this action.

DATES: This order is effective April 19, 2010.

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

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any food. Section 306(l)(1)(C) of the act (21 U.S.C. 335a(l)(1)(C)) provides that, for purposes of section 306, a person is considered to have been convicted of a criminal offense "when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld."

On April 17, 2010, Mr. Bonnes entered into a deferred prosecution agreement with the United States Attorney's Office, Eastern District of New York. FDA's finding that debarment is appropriate is based on the following facts, as set forth in the deferred prosecution agreement. Between April 1, 2006, and August 1, 2006, Mr. Bonnes did knowingly and willfully make materially false, fictitious, and fraudulent statements and representations, in a matter within the jurisdiction of the executive branch of the Government of the United States, in violation of 18 U.S.C. 1001(a)(2). Specifically, Mr. Bonnes' company, Ameritech Laboratories, provided seventeen certificates of analysis to a client certifying that fresh produce the client wished to import into the United States from the Dominican Republic was free of any pesticides. Mr. Bonnes signed each of the certificates of analysis as the director of Ameritech Laboratories.

Each of these certificates of analysis was false. Although the certificates stated that Ameritech Laboratories performed pesticide tests on the produce, Ameritech Laboratories did not perform a chemical analysis to certify that the produce was free of any pesticides. Mr. Bonnes knew at the time he prepared the certificates that they were false, and he also knew that the client intended to submit certificates to FDA's District Office in Queens, New York, in support of importing the produce into the United States for sale as human food.

Mr. Bonnes' actions and his deferred prosecution agreement make him subject to permissive debarment as described under section 306(b)(3)(A) of the act. Pursuant to the deferred prosecution agreement, Mr. Bonnes expressly acquiesced to permissive debarment under section 306(b)(1)(C) of the act for the conduct described in this document. In accordance with section 306(c)(2)(B) of the act (21 U.S.C. 335a(c)(2)(B)), Mr. Bonnes notified FDA of his acquiescence to debarment in a letter dated April 19, 2010. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act (21 U.S.C. 335a(i)), but by acquiescing to debarment Mr. Bonnes waived his opportunity for a hearing and to raise any contentions concerning his debarment. The maximum period of debarment under section 306(c)(2)(A)(iii) of the act (21 U.S.C. 335a(c)(2)(A)(iii)) is 5 years. FDA concludes that the nature and scope of Mr. Bonnes' conduct supports the maximum possible period of debarment.

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mr. John Bonnes has entered into a deferred prosecution agreement as the result of conduct relating to the importation of an article of food into the United States that makes him subject to permissive debarment.

As a result of the foregoing finding, Mr. Bonnes 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 act (21 U.S.C. 331(cc)), 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 Mr. Bonnes is a prohibited act.

Any application by Mr. Bonnes for termination of debarment under section 306(d)(1) of the act should be identified with Docket No. FDA–2010–N–0305 and sent to the Division of Dockets Management (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 between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 2010.

Howard R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2010–19981 Filed 8–12–10; 8:45 am]

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