41018, Telephone (859) 334–4611, Fax (859) 334–4619.

Status: Open to the public, but without an oral public comment period.

The USA toll-free, dial-in number is 1–866–659–0537 with a pass code of 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2013.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Discussed: The agenda for the Subcommittee meeting includes: dose reconstruction program quality management and assurance activities, including: Current findings from NIOSH internal dose reconstruction blind reviews; discussion of dose reconstruction cases under review (sets 8–9, Savannah River Site, Rocky Flats Plant, and Los Alamos National Laboratory cases from sets 10–13); and selection of ''blind dose reconstructions'' from set 16.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Contact Person for More Information: Theodore Katz, Designated Federal Official, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, email *ocas@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dana Redford,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–04969 Filed 3–4–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0777]

Adrian Vela: 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 FD&C Act) debarring Adrian Vela 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. Vela was convicted of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Vela was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 3, 2012 (30 days after receipt of the notice), Mr. Vela had not responded. Mr. Vela's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 5, 2013.

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, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

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 November 21, 2011, Mr. Vela was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, when the U.S. District Court for the Southern District of Florida accepted his plea of guilty and entered judgment against him for the following offenses: One count of conspiracy to falsely label and misbrand food, in violation of 18 U.S.C. 371; one count of false labeling of seafood under the Lacey Act, in violation of 16 U.S.C. 3372(d)(2); and one count of misbranding food in violation of 21 U.S.C. 331(a).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the importation into the United States of any food. The factual basis for these convictions is as follows: As alleged in the criminal information filed against Mr. Vela, he was the operating manager and sole shareholder of Sea Food Center, a seafood wholesaler engaged in various aspects of purchasing, importing, processing, packing, selling, and exporting seafood products.

Beginning on or about June 30, 2008, and continuing through on or about June 29, 2009, he knowingly combined, conspired, confederated, and agreed with his co-conspirators to commit an offense against the laws of the United States related to the importation of food. The purpose of the conspiracy was for Mr. Vela and his co-conspirators to unlawfully enrich themselves by

introducing what the criminal information describes as a less marketable substituted seafood product into the U.S. seafood market. Those products—''Shrimp, Product of Thailand,'' ''Shrimp, Product of Malaysia,'' and ''Shrimp, Product of Indonesia''—were misbranded, marketed, and intended to be marketed as ''Shrimp, Product of Panama,'' a seafood product that the criminal information describes as more readily marketable. Mr. Vela instructed employees at Sea Food Center's Tampa facility to divide the shrimp received from Thailand, Malaysia, and Indonesia into smaller portions, and mark them as ''Shrimp, product of Panama,'' on the individual packages, and then place them in boxes, also marked as ''Shrimp, product of Panama.'' Employees under the direction of Mr. Vela's co-conspirator managed and directed the labeling operations at Sea Food Center by providing instructions and other directives to Mr. Vela. The relabeled shrimp were then sold to a food wholesaler based in Keene, NH, which in turn sold the shrimp to a supermarket chain headquartered in Landover, MD. This conduct was in violation of 18 U.S.C. 371.

On or about July 8, 2008, Mr. Vela knowingly engaged in an offense that involved the sale and purchase of, the offer of sale and purchase of, and the intent to sell and purchase shrimp, with a market value greater than $350.00. He knowingly made and caused to be made individual labels, pre-printed bags, and other documents falsely identifying the shrimp as being ''Shrimp, Product of Panama,'' when in fact the shrimp were ''Shrimp, Product of Thailand,'' ''Shrimp, Product of Malaysia,'' and ''Shrimp, Product of Indonesia.'' This conduct was in violation of 16 U.S.C. 3372(d)(2).

On or about July 8, 2008, Mr. Vela engaged in an offense that involved the introduction or delivery for introduction into interstate commerce of a food that was misbranded, with the intent to defraud or mislead, in that he created or caused to be created individual labels, pre-printed bags, and other documents falsely identifying the shrimp. This conduct was in violation of 21 U.S.C. 331(a).

As a result of his conviction, on September 28, 2012, FDA sent Mr. Vela a notice by certified mail proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Vela was convicted of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food because he: Conspired to and committed offenses related to the importation of shrimp into the United States, falsely conveyed information about the shrimp's country of origin; introduced or delivered for introduction misbranded food into interstate commerce; and falsely labeled seafood under the Lacey Act. The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Vela should be subject to a 5-year period of debarment. The proposal also offered Mr. Vela 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. Vela failed to respond 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 Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Associate Commissioner (Staff Manual Guide 1410.21), finds that Mr. Adrian Vela has been convicted of three felony counts under Federal law for conduct relating to the importation of an article of food into the United States and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Vela 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 (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. Vela is a prohibited act.

Any application by Mr. Vela for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2012–N–0777 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: February 8, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2013–05062 Filed 3–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0147]

Draft Guidance for Industry and Food and Drug Administration Staff; Types of Communication During the Review of Medical Device Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Types of Communication During the Review of Medical Device Submissions.'' The purpose of this guidance is to update the Agency's approach to Interactive Review to reflect FDA's implementation of the Medical Device User Fee Act of 2007 (MDUFA II) Commitment Letters and of undertakings agreed in connection with the Medical Device User Fee Amendments of 2012 (MDUFA III) and to incorporate additional types of communication, all of which increase the efficiency of the review process. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 3, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Types of Communication During the Review of Medical Device Submissions'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and