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]

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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

Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Samie Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1533, Silver Spring, MD 20993–0002, 301–796–6055, or Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the letters dated September 27, 2007, from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the U.S. Senate and the Chairman of the Committee on Energy and Commerce of the U.S. House of Representatives setting out the goals of section 201(c) of MDUFA II, Title II of the Food and Drug Administration Amendments of 2007 (FDAAA) (21 U.S.C. 379i note), FDA committed to developing a guidance document that describes an interactive review process between FDA and industry for specific medical device premarket submissions. Further, during discussions with representatives of the medical device industry in the development of the Agency's recommendations for MDUFA III, Title II of the Food and Drug Administration Safety and Innovation Act, Public Law 112–144 (July 9, 2012), 126 Stat. 1002 (21 U.S.C. 301 note), the Agency proposed process improvements to provide further transparency into the review process, including new communication commitments.

This guidance describes four types of communication that occur during the review of a medical device premarket submission. The four types of communication are: Acceptance Review Communication, Substantive Interaction, Interactive Review, and Missed MDUFA Decision Communication.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on communication during a medical device premarket submission review to provide further transparency into, and to increase the efficiency of, the review process. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* To receive ''Types of Communication During the Review of Medical Device Submissions,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1804 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: February 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05015 Filed 3–4–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0598]; (Formerly Docket No. 00D–1631)]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Revised Guidance for Industry on ''Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23(R)); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for industry (GFI #116) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23(R)). This draft revised guidance is a revision of a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of January 4, 2002, and has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). In this draft revised VICH guidance the recommendation for a second test to evaluate the potential of a chemical to produce chromosomal effects is being revised. The draft revised guidance indicates that the potential of a chemical to produce chromosomal effects can be evaluated using one of the the following three tests: An in vitro chromosomal aberrations test using metaphase analysis, which detects both clastogenicity and aneugenicity; an in vitro mammalian cell micronucleus test, which detects the activity of