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: Mr. Stowell was the president and sole shareholder of United Seafood Imports, Inc. (United), a Florida based seafood wholesaler engaged in various aspects of purchasing, importing, processing, packing, selling, and exporting seafood products, including shrimp.

Beginning in or around January 25, 2007, and continuing through on or about August 7, 2009, Mr. Stowell did knowingly and with the intent to further the object of a conspiracy combine, conspire, confederate, and agree with others to commit an offense against the United States. Specifically, Mr. Stowell's company United purchased approximately one million pounds of shrimp in boxes labeled ''Shrimp, Product of Thailand,'' ''Shrimp, Product of Malaysia,'' and ''Shrimp, Product of Indonesia.'' Mr. Stowell then sent the shrimp to another company, Shifco, and instructed them to repackage and relabel the shrimp as ''Shrimp, Product of Panama,'' ''Shrimp, Product of Ecuador,'' and ''Shrimp, Product of Honduras.'' United, and employees under Mr. Stowell's direction and control, managed and directed the labeling operations of Shifco by providing instructions and other directives to them. Mr. Stowell's company then sold the shrimp that was relabeled to a company who in turn subsequently sold the shrimp to a supermarket chain. This was in violation of 18 U.S.C. 371.

On or about January 26, 2007, Mr. Stowell purchased 180 cases of shrimp valued at approximately $24,912 and knowingly created and caused to be created individual labels, preprinted bags, and other documents falsely identifying the shrimp as being ''Shrimp, Product of Ecuador,'' when in truth and in fact he knew the shrimp was a product of Malaysia. This was in violation of 16 U.S.C. 3372(d)(2) and 3373(d)(3)(A)(ii).

On or about July 2, 2009, Mr. Stowell knowingly engaged in an offense that involved the introduction and delivery for introduction into interstate commerce of a food that was misbranded, that is, approximately 52 cases of shrimp, with the intent to defraud or mislead, in that Mr. Stowell created and caused to be created individual labels, preprinted bags, and other documents falsely identifying the shrimp as being a product of Panama when in truth and in fact, he knew the shrimp was a product of Indonesia. This was in violation of 21 U.S.C. 331(a), 333(a)(2), and 343(a)(1).

As a result of his conviction, on September 24, 2012, FDA sent Mr. Stowell a notice by certified mail proposing to debar him for a period of 3 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. Stowell 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 falsely label and misbrand seafood, falsely labeled seafood under the Lacey Act, and misbranded food.

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 (21 U.S.C. 335a(c)(3)) that Mr. Stowell should be subject to a 3-year period of debarment. The proposal also offered Mr. Stowell 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. Stowell 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 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. Richard Stowell 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 3-year period of debarment.

As a result of the foregoing finding, Mr. Stowell is debarred for a period of 3 years from importing articles of food or offering such articles for import 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 an article of food by, with the assistance of, or at the direction of Mr. Stowell is a prohibited act.

Any application by Mr. Stowell for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2012–N–0714 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. 2013–04389 Filed 2–25–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0128] (formerly 2003D–0236)

Draft Guidance for Industry: Recommendations for Screening, Testing, and, Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis,'' dated March 2013. The draft guidance document provides revised recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The draft guidance is intended for blood establishments that collect Whole Blood or blood components, including Source Plasma. The guidance announced in this notice replaces the draft guidance entitled, ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis,'' dated June 2003. In addition, the draft guidance, when finalized, is intended to supersede the FDA memorandum to registered blood establishments dated December 12, 1991, entitled, ''Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.''

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 May 28, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., 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

FDA is announcing the availability of a draft document entitled, ''Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis,'' dated March 2013. The draft guidance document provides revised recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The recommendations described in the document are for blood establishments that use either non-treponemal or treponemal screening assays to test donors for serological evidence of syphilis infection.

In the **Federal Register** of June 26, 2003 (68 FR 38083), FDA announced the availability of the draft guidance entitled, ''Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis,'' dated June 2003. The draft guidance announced in this notice replaces the 2003 draft guidance and when finalized, is intended to supersede the FDA memorandum to all registered blood establishments dated December 12, 1991, entitled, ''Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.''

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 630.6 and 606.160 have been approved under OMB control number 0910–0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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*.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: February 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04281 Filed 2–25–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–0742] (formerly 1999D–4396)

Guidance for Clinical Investigators, Industry, and Food and Drug Administration Staff: Financial Disclosure by Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators.'' This guidance is intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators. This guidance provides FDA's responses to the most frequently asked questions regarding financial disclosure by clinical investigators. The guidance announced in this notice finalizes the draft guidance of the same title dated May 2011 and replaces the guidance entitled, ''Guidance for Industry: Financial Disclosure by Clinical Investigators,'' dated March 2001.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400), or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or 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 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.