were provided to subjects to participate in the study; (10) a description of how the sponsor(s) monitored the study and ensured that the study was carried out consistently with the study protocol; and (11) a description of how investigators were trained to comply with GCP and to conduct the study in accordance with the study protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained.

Section 312.120(c) specifies how sponsors or applicants can request a waiver for any of the requirements under § 312.120(a)(1) and (b). Under § 312.120(c)(1), a waiver request must contain at least one of the following: (1) An explanation why the sponsor's or applicant's compliance with the requirement is unnecessary or cannot be achieved, (2) a description of an alternative submission or course of action that satisfies the purpose of the requirement, or (3) other information justifying a waiver. A waiver request may be submitted in an IND or in an information amendment to an IND, or in an application or in an amendment or supplement to an application submitted under 21 CFR part 314 or 601. Section 312.10 sets forth requirements for sponsors who request waivers from FDA for compliance with any of the provisions in part 312, and § 314.90 sets forth requirements for applicants who request waivers from FDA for compliance with §§ 314.50 through 314.81.

FDA has approval for the submission of these waiver requests under OMB control numbers 0910–0014 for part 312 and 0910–0001 for part 314. In addition to the reporting requirements set forth in table 1 of this document, there is also a recordkeeping provision in § 312.120(d) stating how long sponsors and applicants must retain records required by § 312.120. In addition, § 312.120(b) states that any signed written commitments by investigators must be maintained by the sponsor or applicant and made available for Agency review upon request, and also specifies sponsor recordkeeping of IEC-related information. Under § 312.120(d), if a study is submitted in support of an application for marketing approval, records must be retained for 2 years after an Agency decision on that application; if a study is submitted in support of an IND but not an application for marketing approval, records must be retained for 2 years after the submission of the IND. The retention requirements in § 312.57(c) for records and reports required under part 312 apply to these provisions, and are approved under OMB control number 0910–0014.

We estimate that 237 companies will submit a total of approximately 1,185 non-IND foreign clinical studies in support of an IND or application for marketing approval for a drug or biological product. Hour burden estimates vary due to differences in size, complexity, and duration across studies, and we estimate that complying with § 312.120 would take sponsors between 18 and 32 hours annually for each non-IND foreign clinical trial, totaling 37,920 hours ($32 \times 1{,}185$).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
312.120	237	5	1,185	32	37,920

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04422 Filed 2–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0714]

Richard Stowell: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Richard Stowell for a period of 3 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. Stowell was convicted, as defined in section 306(*l*)(1)(B) of the FD&C Act (21 U.S.C. 335a(*l*)(1)(B)), of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Stowell was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of December 14, 2012, Mr. Stowell had not responded. Mr. Stowell's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective February 26, 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 (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On July 27, 2011, Mr. Stowell 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 seafood, 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 3373(d)(3)(A)(ii); and one count of misbranding food, in violation of 21 U.S.C. 331(a), 343(a)(1), and 333(a)(2).

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: 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]

BILLING CODE 4160–01–P

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.''