to commit offenses against the United States, to wit: Entry of Goods into the United States by means of False statements in violation of 18 U.S.C. 542 and Smuggled Goods into the United States in violation of 18 U.S.C. 545. Specifically, Mr. Fan owned and operated Blue Action Enterprise, Inc., 7 Tiger Enterprise, Inc., Honey World Enterprise, Inc., Kazak Food Corp., and Kashaka USA, Inc., through which he imported honey into the United States. Mr. Fan conspired to cause these companies to import, enter, and sell Chinese-origin honey into the United States and avoid payment of antidumping duties by falsely declaring to the U.S. Department of Homeland Security, Bureau of Customs and Border Protection that the imported honey originated from countries other than China, including India, South Korea, Taiwan, and Thailand, when in fact he knew that the honey originated in China. Mr. Fan's actions allowed him to avoid paying approximately $5,378,370 in antidumping duties to the United States.

Further, in or around January 2009, in violation of 18 U.S.C. 371 and 2, Mr. Fan agreed and conspired with others to enter into the commerce of the United States honey diluted and blended with approximately 20 to 30 percent artificial sugar, by means of false and fraudulent declarations and practices in violation of 18 U.S.C. 542, for the purpose of increasing his profits.

As a result of his conviction, on June 8, 2011, FDA sent Mr. Fan 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. Fan was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food because he conspired to commit offenses related to the importation of Chinese honey into the United States, and a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act that Mr. Fan should be subject to the maximum possible period of debarment. The proposal also offered Mr. Fan 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. Fan 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 Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mr. Hung Ta Fan has been convicted of a felony under Federal law for conduct relating to the importation of an article of food into the United States and that he is subject to the full period of debarment.

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

Any application by Mr. Fan for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2011–N–0183 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 8, 2011.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–20780 Filed 8–15–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0514]

Draft Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Section 522 Postmarket Surveillance Studies; 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 ''Procedures for Handling Section 522 Postmarket Surveillance Studies.'' This guidance document is intended to assist device manufacturers subject to a section 522 postmarket surveillance order imposed by FDA by providing an overview of section 522 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), procedural information on how to fulfill section 522 obligations, and recommendations on the format, content, and review of postmarket surveillance study submissions. 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 November 14, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Procedures for Handling Section 522 Postmarket Surveillance Studies'' 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. 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: Mary Beth Ritchey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4115, Silver Spring, MD 20993–0002, 301– 96–6638.

SUPPLEMENTARY INFORMATION:

I. Background

Postmarket surveillance under section 522 of the FD&C Act (21 U.S.C. 306l) is one means by which FDA can obtain additional information when it is necessary to protect the public health or provide safety and/or effectiveness data for a device after it has been cleared or approved. The Food and Drug Administration Amendments Act of 2007 amended section 522 of the FD&C

Act to expand the situations in which FDA may order postmarket surveillance and allow longer surveillance periods in certain circumstances. This guidance document is intended to assist device manufacturers subject to a section 522 postmarket surveillance order by providing an overview of section 522 of the FD&C Act, procedural information on how to fulfill section 522 obligations, and recommendations on the format, content, and review of postmarket surveillance study submissions.

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 ''Procedures for Handling Section 522 Postmarket Surveillance Studies.'' 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 *http://www.regulations.gov.* To receive ''Procedures for Handling Section 522 Postmarket Surveillance Studies'' you may either send an e-mail 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 1754 to identify the guidance you are requesting.

IV. 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 part 822 have been approved under OMB control number 0910–0449.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: August 10, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20727 Filed 8–15–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

2011 Parenteral Drug Association/Food and Drug Administration Joint Public Conference; Quality and Compliance in Today's Regulatory Enforcement Environment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), in cosponsorship with Parenteral Drug Association (PDA), is announcing a public conference entitled ''Quality and Compliance in Today's Regulatory Enforcement Environment.'' The conference will span 2½ days and cover current issues affecting the industry as well as explore strategies and approaches for ensuring conformance with regulations to facilitate the development and continuous improvement of safe and effective medical products. The conference establishes a unique forum to discuss the foundations, emerging technologies and innovations in regulatory science, as well as the current quality and compliance areas of concerns. Meeting participants will hear from FDA and industry speakers about the requirements and best practices to consider while implementing robust quality systems in order to deliver the best quality product.

Date and Time: The public conference will be held on September 19, 2011, from 7 a.m. to 6 p.m.; September 20, 2011, from 7:30 a.m. to 6:15 p.m.; and September 21, 2011, from 7:30 a.m. to 12:15 p.m.

Location: The public conference will be held at the Renaissance Hotel, 999 Ninth St., NW., Washington, DC 20001, 202–898–9000, FAX: 202–289–0947.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814, 301–656–5900, FAX: 301–986–1093, e-mail: info@pda.org.

Accommodations: Attendees are responsible for their own accommodations. To make reservations at the Renaissance Hotel at the reduced conference rate, contact the Renaissance Hotel (see *Location*)—cite the meeting code ''PDA.'' Room rates are: Single: $288, plus 14.5% state and local taxes and Double: $288, plus 14.5 percent state and local taxes. Reservations can be made on a space and rate availability basis.

Registration: Attendees are encouraged to register at their earliest convenience. The PDA registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted for the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space available basis on each day of the public conference beginning at 7 a.m. on September 19, 2011. The cost of registration is as follows:

COST OF REGISTRATION

Affiliation	Fee
PDA Members	$1,895
NonMembers	2,144
PDA Member Government/Health Authority	700
NonMember Government/Health Authority	800
PDA Member Academic	700
NonMember Academic	780
PDA Member Students	280
NonMember Students	310

Please visit PDA's Web site: *http://www.pda.org/pdafda2011* to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Wanda Neal (see *Contact*), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and e-mail address, along with a check or money order payable to ''PDA.'' Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814. To register via the