The preliminary design is included as follows:

TABLE 1—STUDY DESIGN

Medical condition	Disease outcome information	Format of disease information		Control (no disease information)
		Integrated	Separated	
Condition A	No Outcomes			
	Outcomes			
Condition B	No Outcomes			
	Outcomes			
Condition C	No Outcomes			
	Outcomes			

FDA estimates the burden of this collection of information as follows: We estimate the response burden to be 20 minutes in the pretests and the study, for a burden of 1,985 hours. This will be a one time (rather than annual) collection of information. The questionnaire is available upon request.

The response burden chart is listed as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN[5]

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener	6,750	1	6,750	0.03 (2 min.)	203
Pretests	900	1	900	0.33 (20 min.)	297
Study	4,500	1	4,500	0.33 (20 min.)	1,485
Total					1,985

Dated: August 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20814 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–N–0183]

Hung Ta Fan: 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 Hung Ta Fan 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. Fan was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Fan was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 13, 2011 (30 days after receipt of the notice), Mr. Fan had not responded. Mr. Fan's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 16, 2011.

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 (HFC–230), Food and Drug Administration, 5600 Fishers Lane, 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 August 4, 2010, the United States District Court for the Northern District of Illinois accepted Mr. Fan's guilty plea and entered judgment against him for the offense of conspiracy, in violation of 18 U.S.C. 371 and 2, for conspiring to defraud the United States and to violate 18 U.S.C. 542 (entry of Goods into the United States by means of false statements) and 18 U.S.C. 545 (importation contrary to law).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the importation into the United States of any food. The factual basis for this conviction is as follows: In or around March 2005 and continuing until in or around November 2006, in violation of 18 U.S.C. 371 and 2, Mr. Fan agreed and conspired with others to defraud the United States and

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

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.

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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