TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs
Submission of rotational plans for health warning label statements	100	1	100	60	6,000	$1,200

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

FDA estimates a total of 100 respondents at 1 response each and 60 burden hours per response for a total of 6,000 burden hours (100 respondents × 1 response × 60 burden hours = 6,000 total burden hours). In addition, capital costs are based on all 100 respondents mailing in their submission at a postage rate of $12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to be $1,200.

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06127 Filed 3–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0206]

Center for Drug Evaluation and Research Medical Policy Council; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments for topics from interested parties, including academic institutions, regulated industry, patient representatives, and other interested organizations, on medical policy issues that may be considered by the CDER Medical Policy Council (Council) in FDA's Center for Drug Evaluation and Research (CDER). These comments will help the Agency identify and address medical policy issues that need clarification through guidance, notice and comment procedures, or other means.

DATES: Submit either electronic or written comments by July 16, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–301), 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: Sandra J. Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042, FAX: 301–847–3529, email: *cdermedicalpolicycouncil@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In January 2012, CDER established the Council to ensure better coordination of medical policy development and implementation within CDER and consistent, predictable communication of medical policy decisions to the public through guidance, notice and comment procedures, or other means.

Chaired by CDER's Associate Director for Medical Policy, the Council provides a senior-level forum through which medical policy issues can be raised, considered, developed, and implemented. Council members include the following senior clinical leaders: The Center Director, the Deputy Center Director for Clinical Science, the Director of the Office of New Drugs, and the Director of the Office of Surveillance and Epidemiology. Experts from within CDER and other FDA offices provide expertise as needed for specific policy topics under consideration. By establishing this docket, FDA encourages the public to recommend specific topics for consideration by the Council. The Agency believes that this process will also ensure additional transparency in CDER's approach to medical policy development and implementation.

II. Range of Medical Policy Issues To Be Considered

FDA envisions a variety of topics that may be relevant for consideration by the Council. Specific topics could address issues related to the following: (1) Clinical evidence of effectiveness or safety, (2) clinical study/trial design, (3) professional and patient labeling, (4) prescription drug promotion, (5) human subjects protection, (6) bioresearch monitoring, (7) good clinical practice, (8) counter-terrorism drug development (such as in the application of the Animal Rule, 21 CFR 314.600), and (9) postmarketing surveillance. To be considered by the Council, a medical policy issue typically would meet one or more of the following criteria:

- A novel medical policy issue requiring senior management input;
- An issue on which CDER seems to have taken inconsistent positions;
- An existing medical policy position that should be reconsidered in light of scientific or regulatory advances;
- A complex safety management issue requiring senior management input;
- A medical policy that may be triggered by a specific product, but that will be applicable to other products; or
- Strategies for implementation of a new policy.

III. Establishment of a Docket and Request for Comments

FDA is requesting public suggestions, recommendations, and comments for topics (including scientific, clinical, regulatory, or other topics) on existing or novel medical policy issues that may warrant consideration by the Council. Comments should describe the following: (1) The medical policy issue recommended for discussion, (2) the rationale for doing so (e.g., clarifying previous advice or precedents, reconciling apparently differing perspectives within CDER or between CDER and regulated industry), (3) recommendations on how the medical policy issue could be addressed or implemented; and (4) existing policy documents (e.g., final guidance) relevant to the medical policy issue. Note that policy issues concerning any draft guidance should be submitted to the docket for that draft guidance.

The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the

comment. In general, medical policy decisions reached by the Council are communicated and implemented in accordance with FDA's good guidance practices regulation (21 CFR 10.115) or notice and comment procedures.

IV. Request for Comments

Interested persons may submit either written comments regarding this notice to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06142 Filed 3–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1044]

Shu Bei Yuan: 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 Shu Bei Yuan 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 Ms. Yuan was convicted of one felony count under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Yuan was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of December 31, 2012 (30 days after receipt of the notice), Ms. Yuan had not responded. Ms. Yuan's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective March 18, 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, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On June 22, 2012, Ms. Yuan was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, when the U.S. District Court for the Northern District of Illinois accepted her plea of guilty and entered judgment against her for the following offense: One count of entry of goods into the United States by means of false statements, in violation of 18 U.S.C. 542.

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 2005, Ms. Yuan conducted a scheme to fraudulently enter goods into the United States by means of false statements and documents in violation of 18 U.S.C. 542. The purpose of Ms. Yuan's scheme was to import, enter, and sell Chinese-origin honey into the United States and avoid the payment of antidumping duties by falsely declaring to the U.S. Department of Homeland Security, Bureau of Customs and Border Protection (CBP) that the imported honey originated from countries other than China, including South Korea, when in fact Ms. Yuan knew that the honey originated from China.

Between August and November 2005, Ms. Yuan and others caused the fraudulent import and entry into the United States of approximately 26 entries of Chinese origin honey falsely declared as Korean honey, having a total declared entry value of approximately $808,287, thereby avoiding antidumping duties totaling approximately $1,485,631.

As a result of her conviction, on November 30, 2012, FDA sent Ms. Yuan a notice by certified mail proposing to debar her 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 Ms. Yuan was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food because she committed an offense related to the importation of Chinese honey into the United States by means of false statements.

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 Ms. Yuan should be subject to a 5-year period of debarment. The proposal also offered Ms. Yuan an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Yuan failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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 Ms. Shu Bei Yuan 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 she is subject to a 5-year period of debarment.

As a result of the foregoing finding, Ms. Yuan 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 Ms. Yuan is a prohibited act.

Any application by Ms. Yuan for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2012–N–1044 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).