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).

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 28, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2013–06165 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–0222]

International Conference on Harmonisation; Proposed Change to Rodent Carcinogenicity Testing of Pharmaceuticals; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is considering a proposed change to the International Conference on Harmonisation (ICH) Sl guidance on rodent carcinogenicity testing. The goal of this potential change is to introduce a more comprehensive and integrated approach to address the risk of human carcinogenicity of small molecule pharmaceuticals, and to define conditions under which 2-year rodent carcinogenicity studies add value to that assessment. The basis of this proposed change is the retrospective analyses of several datasets that reflect three decades of experience with such studies. The datasets suggest that knowledge of certain pharmacologic and toxicologic data can sometimes provide sufficient information to anticipate the outcome of 2-year rodent studies and their potential value in predicting the risk of human carcinogenicity of a given pharmaceutical. FDA is requesting public comment regarding a proposed change in approach to carcinogenicity assessment, on the prospective evaluation period intended to test this new approach, and on the proposed weight-of-evidence factors for carcinogenicity assessment.

DATES: Submit electronic or written comments on the proposed change by May 17, 2013.

ADDRESSES: Submit electronic comments on the proposed change 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: Todd Bourcier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3102, Silver Spring, MD 20993–0002, 301–796–1179.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is considering a change in the current ICH S1 guidance on rodent carcinogenicity testing.[1] The goal of this potential change is to introduce a more comprehensive and integrated approach to address the risk of human carcinogenicity of small molecule pharmaceuticals, and to define conditions under which 2-year rodent carcinogenicity studies add value to that assessment.

Datasets evaluated by the ICH S1 expert working group (S1 EWG) suggest that knowledge of pharmacologic targets and pathways together with toxicological and other data can, in certain cases, provide sufficient information to anticipate the outcome of 2-year rodent studies and their potential value in predicting the risk of human carcinogenicity of a given pharmaceutical. It is hypothesized that consideration of this information can provide sufficient information to conclude that a given pharmaceutical in certain cases presents a negligible risk or, conversely, a likely risk of human carcinogenicity without conducting a 2-year rodent study. It is envisioned that sponsors of such pharmaceuticals would provide drug regulatory agencies (DRAs) a carcinogenicity assessment document (CAD) that could justify a ''waiver request'' that would seek to omit the conduct of 2-year rodent studies. The CAD would address the overall carcinogenic risk of the investigational drug as predicted by the endpoints discussed in this document and a rationale for why the conduct of 2-year rodent studies would or would not add value to that assessment.

Prospective evaluation of this proposed hypothesis is necessary to justify proceeding with revision of the ICH S1 guidance. A prospective evaluation period would be sought wherein sponsors would be requested to submit CADs to DRAs for all investigational pharmaceuticals with ongoing or planned 2-year rodent studies. DRAs from each region would independently review the submitted assessments to evaluate the degree of concordance with sponsors and between regulatory regions. During this prospective evaluation period, the waiver requests would not to be granted and rather are intended solely for gathering experience and hypothesis testing. Submitted assessments would be compared to the outcome of the 2-year rodent studies to evaluate the accuracy and relevance of the predictions to the actual experimental results. Experience from this prospective evaluation period is considered critical to informing the S1 EWG's efforts in revising the current paradigm of assessing the carcinogenicity of small molecules as described in the ICH S1 guidance. FDA is requesting public comment regarding the proposed change in approach to carcinogenicity assessment, on the prospective evaluation period intended to test this new approach, and on the weight-of-evidence (WOE) factors proposed for inclusion in CADs.

II. Past Experience With Carcinogenicity Assessment

The strategy of testing for carcinogenic potential was the first safety topic addressed by ICH. The main topics were the need to conduct a study (ICH S1A), the selection criteria for the rodent species (ICH S1B), and the criteria for selecting the maximum dose (ICH S1C). During the discussion in that period, the relevance of the lifetime carcinogenicity studies in rats and mice was already highly debated, but in the absence of an alternative, the outcome of the negotiations did not really change the basic strategy of testing pharmaceuticals for human use in two rodent species. A proposal to not use the mouse as a second species did not receive sufficient support, although it paved the way to introduce transgenic mice with a 6- to 9-month treatment as an appropriate alternative (ICH S1B).

In the following years, considerable resources have been spent to evaluate the approaches using the transgenic mice (Ref. 1). Also, other models and approaches received attention, especially the possibility to predict the outcome of carcinogenicity studies on the basis of the results of 3- to 6-month studies (Ref. 2).

[1] See the ICH S1 guidance documents, ''S1A The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals'' (ICH S1A), ''S1B Testing for Carcinogenicity of Pharmaceuticals'' (ICH S1B), and ''S1C(R2) Dose Selection for Carcinogenicity Studies of Pharmaceuticals'' (ICH S1C), available on the Internet at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*