DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0592]

Yuri Izurieta: 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 Yuri Izurieta for a period of 20 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. Izurieta was convicted of six felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Izurieta was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 10, 2011 (30 days after receipt of the notice), Mr. Izurieta had not responded. Mr. Izurieta's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective January 25, 2012.

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, Division of Compliance Policy (HFC–230), 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 May 11, 2011, in the United States District Court for the Southern District of Florida, Mr. Izureita was convicted of one count of conspiracy to smuggle goods into the United States, in violation of 18 U.S.C. 371, and five counts of smuggling goods into the United States, in violation of 18 U.S.C. 545. The United States District Court for the Southern District of Florida entered judgment against Mr. Izurieta on July 29, 2011.

FDA's finding that debarment is appropriate is based on the felony conviction's referenced herein for conduct relating to the importation into the United States of any food. The factual basis for these convictions is as follows: As alleged in the indictment that was filed against Mr. Izurieta, beginning on or about April 18, 2007, and continuing through about December 23, 2010, in violation of 18 U.S.C. 371, Mr. Izurieta knowingly, and with the intent to further the object of the conspiracy, conspired with others to commit an offense against the United States—to fraudulently and knowingly import and bring into the United States merchandise contrary to law, in violation of 18 U.S.C. 545. Specifically, Mr. Izurieta conspired to distribute and sell imported dairy products that FDA had detained after receiving notice from FDA that the dairy products were suspected to be adulterated.

Mr. Izurieta worked at Naver Trading Corp., a registered Florida corporation engaged in the business of importing and distributing food, including dairy products, in local and interstate commerce. While working there, Mr. Izurieta caused dairy products and other food to be imported from Honduras and Nicaragua. Despite requests from FDA, Mr. Izurieta failed to disclose the location of shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *Escherichia coli, Staphylococcus aureus,* and *Salmonella.* Mr. Izurieta also distributed shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *E. coli, S. aureus,* and *Salmonella.* Mr. Izurieta failed to redeliver for destruction and exportation shipments of dairy products that FDA had determined to be adulterated with *E. coli, S. aureus,* and *Salmonella,* and that were not authorized for entry into the United States. Mr. Izurieta then imported and distributed dairy products that were adulterated and not authorized for entry into the United States. This conduct was in violation of 18 U.S.C. 545.

From approximately April 18, 2007, and continuing to approximately December 7, 2010, Mr. Izurieta fraudulently and knowingly imported and brought into the United States merchandise contrary to law. Further, Mr. Izurieta failed to redeliver, export, and destroy with FDA supervision the dairy products and other food products contained in these shipments after receiving notice from FDA regarding concerns about the adulteration of these products with *E. coli, S. aureus,* and/or *Salmonella.*

As a result of his conviction, on September 28, 2011, FDA sent Mr. Izurieta a notice by certified mail proposing to debar him for a period of 20 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. Izurieta was convicted of six felony counts 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 dairy products into the United States and imported and brought into the United States merchandise contrary to law. It 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. Izurieta should be subject to a 20-year period of debarment. The proposal also offered Mr. Izurieta 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. Izurieta 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. Yuri Izurieta has been convicted of six 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 20 years of debarment.

As a result of the foregoing finding, Mr. Izurieta is debarred for a period of 20 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. Izurieta is a prohibited act.

Any application by Mr. Izurieta for termination of debarment under section 306(d)(1) (21 U.S.C. 335a(d)(1)) of the FD&C Act should be identified with Docket No. FDA–2011–N–0592 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: January 11, 2012.

Armando Zamora,

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

[FR Doc. 2012–1489 Filed 1–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369; (Formerly Docket No. 2007D–0168)]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of May 31, 2007 (72 FR 30386), FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' explaining the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

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 comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by March 26, 2012.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations 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:

Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8608.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007, FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.* As described in that draft guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on the FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** of December 1, 2009 (74 FR 62793). This notice announces draft product-specific recommendations, either new or revised, that have been posted on the FDA's Web site in the period from December 1, 2009, through June 30, 2011.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing draft BE product-specific recommendations for drug products containing the following active ingredients:

A

Acetaminophen
Acetaminophen; Butalbital (multiple reference listed drugs (RLDs))
Acetaminophen; Butalbital; Caffeine (multiple RLDs)
Acetaminophen; Hydrocodone Bitartrate (multiple RLDs)
Acetaminophen Oxycodone (multiple RLDs)
Acetazolamide
Adapalene
Aliskiren Hemifumarate; Valsartan
Altretamine
Amantadine HCl (multiple RLDs)
Amiodarone HCl
Amitriptyline HCl (multiple RLDs)
Amlodipine Besylate; Telmisartan
Amlodipine; Hydrochlorothiazide; Valsartan
Amoxicillin; Clavulanate Potassium (multiple RLDs)
Aripiprazole
Aspirin; Butalbital; Caffeine (multiple RLDs)
Aspirin; Dipyridamole
Aspirin; Oxycodone
Aspirin; Butalbital; Caffeine; Codeine Phosphate
Atovaquone
Auranofin
Azelaic Acid (multiple RLDs)

B

Baclofen (multiple RLDs)
Benazepril HCl
Benzoyl Peroxide Clindamycin Phosphate (multiple RLDs)
Benzoyl Peroxide; Erythromycin (multiple RLDs)
Betamethasone Acetate; Sodium Phosphate
Betamethasone Dipropionate; Calcipotriene Hydrate (multiple RLDs)
Betamethasone Dipropionate; Clotrimazole
Betamethasone; Clotrimazole
Bexarotene
Bosentan
Buprenorphine HCl
Buprenorphine HCl; Naloxone HCl
Bupropion HBr
Bupropion HCl
Buspirone
Butoconazole Nitrate (multiple RLDs)

C

Calcipotriene (multiple RLDs)
Carbidopa; Levodopa
Carisoprodol
Carvedilol Phosphate
Cefaclor
Cefadroxil; Cefadroxil Hemihydrate
Cefditoren Pivoxil
Cefixime
Cefuroxime Axetil (multiple RLDs)
Cetirizine HCl
Chlorambucil
Chlorpheniramine Polistirex; Hydrocodone Polistirex