



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0589]

Anneri Izurieta; Conviction Reversal; Final Order Withdrawing 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 (the FD&C Act), withdrawing its January 13, 2012, order debaring Anneri Izurieta from importing food or offering food for importation into the United States. FDA is issuing this order because the U.S. Court of Appeals for the Eleventh Circuit issued an order vacating the conviction and sentence of Anneri Izurieta.

EFFECTIVE DATE: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

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: In a notice published in the Federal Register on January 13, 2012 (77 FR 2070), FDA debarred Anneri Izurieta for a period of 30 years from importing articles of food or offering such articles for importation into the United States. FDA issued the debarment order under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)), which permits FDA to debar an individual from importing an article of food or offering such an article for importation 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.

The debarment was based on FDA's finding that Ms. 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. Ms. Izurieta, the president and director of Naver Trading, was convicted on May 11, 2011, and sentenced on July 29, 2011, for conspiracy to smuggle goods into the United States and smuggling goods into the United States. The basis for Ms. Izurieta's conviction was her alleged role in distributing shipments of dairy products that were adulterated and not authorized for entry into the United States. On August 3, 2011, Ms. Izurieta appealed her conviction and sentence.

On February 22, 2013, the U.S. Court of Appeals for the Eleventh Circuit issued an order vacating the conviction and sentence of Ms. Izurieta. A copy of the court's order is available in Docket No. FDA-2011-N-0589. By this order, the court vacated Ms. Izurieta's conviction. The order was issued as a mandate on April 23, 2013. Section 306(d)(3)(B)(i) of the FD&C Act (U.S.C. 335a(d)(3)(B)(i) states that "If the conviction which served as the basis for the debarment of an individual under subsection...(b)(3) is reversed, the Secretary shall withdraw the order of debarment."

Accordingly, the Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(d)(3)(B)(i) of the FD&C Act and under authority delegated to the Associate Commissioner (Staff Manual Guide 1410.21), issues this order withdrawing the order of debarment of Anneri Izurieta, thereby allowing her to import food or offer such articles for importation into the United States. This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: July 12, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs,

Office of Regulatory Affairs.

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