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Dated: April 5, 2010.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2010-7985 Filed 4-7-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: ORR Requirements for Refugee Cash Assistance; and Refugee Medical Assistance (45 CFR part 400).

OMB No.: 0970-0036.

Description: As required by section 412(e) of the Immigration and Nationality Act, the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is requesting the information from Form

ORR-6 to determine the effectiveness of the State cash and medical assistance, social services, and targeted assistance programs. State-by-State Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA) utilization rates derived from Form ORR-6 are calculated for use in formulating program initiatives, priorities, standards, budget requests, and assistance policies. ORR regulations require that State Refugee Resettlement and Wilson-Fish agencies, and local and Tribal governments complete Form ORR-6 in order to participate in the above-mentioned programs.

Respondents: State Refugee Resettlement and Wilson-Fish Agencies, local, and Tribal governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-6	50	3	3.88	582

Estimated Total Annual Burden Hours: 582

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 5, 2010.

Robert Sargis,
Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0286]

Kevin Xu: 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 act) permanently debarring Kevin Xu from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Xu was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Xu was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of September 23, 2009, Mr. Xu has failed to respond. Mr. Xu's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective April 8, 2010.

ADDRESSES: Submit applications for special 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), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-463-6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On January 20, 2009, the U.S. District Court for the Southern District of Texas entered judgment against Mr. Xu for one count of participating in a conspiracy to traffic and attempt to traffic in counterfeit goods, to cause the introduction and delivery for introduction of misbranded prescription drugs into interstate commerce, and to cause the counterfeiting of trademarks in violation of 18 U.S.C. 371, three counts of causing the introduction and delivery for introduction of misbranded prescription drugs into interstate commerce in violation of 21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2), and one count of trafficking in counterfeit goods

in violation of 18 U.S.C. 2320(a) and 18 U.S.C. 2320(a)(2).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for those convictions is as follows: From July 2006 until on or about July 2007, Mr. Xu did knowingly, intentionally, and willfully conspire and agree with other persons to import pharmaceutical drug products that bore the trademarks ZYPREXA, TAMIFLU, CASODEX, PLAVIX, and ARICEPT without the authorization of the manufacturer of these drugs, and then to resell these products to the public.

On or about December 8, 2007, Mr. Xu used an Internet email address to send an email listing the tracking numbers connected to the sale of counterfeit pharmaceuticals. On or about April 9, 2007, Mr. Xu caused coconspirators residing in the Republic of China to place in interstate commerce for shipment to the United States various blister strips containing counterfeit TAMIFLU, CASODEX, ZYPREXA, and PLAVIX.

On or about December 8, 2006, with the intent to defraud or mislead, Mr. Xu caused the introduction and delivery for introduction into interstate commerce of drugs that were misbranded, namely a shipment containing blister strips of TAMIFLU capsules that were labeled in a manner to falsely represent that these blister strips contained genuine TAMIFLU.

On or about January 3, 2007, with the intent to defraud or mislead, Mr. Xu caused introduction and delivery for introduction into interstate commerce of drugs that were misbranded, namely a shipment containing blister strips of ZYPREXA pills that were labeled in a manner to falsely represent that these blister strips contained genuine ZYPREXA.

On or about February 20, 2007, with the intent to defraud or mislead, Mr. Xu caused the introduction and delivery for introduction into interstate commerce of drugs that were misbranded, namely a shipment containing blister strips of PLAVIX pills that were labeled in a manner to falsely represent that these blister strips contained genuine PLAVIX.

On or about December 8, 2006, Mr. Xu intentionally trafficked in goods, namely pharmaceutical drugs, and knowingly used a counterfeit mark, the ZYPREXA trademark, on and in connection with such goods.

As a result of his conviction, on August 17, 2009, FDA sent Mr. Xu a notice by certified mail proposing to

permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the act that Kevin Xu was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. The proposal also offered Mr. Xu 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. Xu failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the act, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Kevin Xu has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Xu is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see section 306(c)(1)(B) and (c)(2)(A)(ii) and section 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Kevin Xu, in any capacity during Mr. Xu's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Xu provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Xu during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Xu for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2009-N-0286

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: March 15, 2010.

Brenda Holman,

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-2010-F-0103]

Nisso America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nisso America, Inc., has filed a petition proposing that the food additive regulations for hydroxypropyl cellulose be amended by lowering the minimum viscosity from 145 centipoises (cPs) to 10 cPs and to permit its use as a binder in dietary supplements.

FOR FURTHER INFORMATION CONTACT:

Laura Dye, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1275.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 0A4780) has been filed by Nisso America, Inc., 45 Broadway, suite 2120, New York, NY 10006. The petition proposes to amend the food additive regulations in § 172.870 *Hydroxypropyl cellulose* (21 CFR 172.870) by lowering the minimum permitted viscosity of hydroxypropyl cellulose identified in paragraph (a)(1) of this regulation from 145 cPs to 10 cPs and to permit its use as a binder in dietary supplements.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment