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.

[FR Doc. 2010–8023 Filed 4–7–10; 8:45 am]

BILLING CODE 4160–01–S

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

nor an environmental impact statement is required.

Dated: March 17, 2010.

Mitchell A. Cheeseman,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2010–7955 Filed 4–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 7, 2010, from 8 a.m. to approximately 4:30 p.m.

Location: Hilton Hotel Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 7, 2010, in the morning, the committee will review and discuss available data regarding the unexpected finding of DNA originating from porcine circovirus type 1 (PCV 1) in Rotarix, a U.S. licensed vaccine manufactured by GlaxoSmithKline and indicated for the prevention of rotavirus gastroenteritis in infants. The committee will discuss what additional steps should be considered to address this finding. In the afternoon, the committee will discuss and make recommendations on the use of advanced analytical detection methods not currently applied for the characterization of cell substrates, viral seeds, and other biological materials used in the production of viral vaccines for human use.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 4, 2010. Oral presentations from the public will be scheduled between approximately 10:50 a.m. and 11:20 a.m. and 2:45 p.m. and 3:15 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 29, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 30, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 2, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–8025 Filed 4–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: May 13, 2010, 8:30 a.m. to 5 p.m. May 14, 2010, 8:30 a.m. to 3:30 p.m.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration Web site at *http://events.SignUp4.com/ACHDNC0510.* The registration deadline is Tuesday, May 11, 2010. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations should indicate their needs on the registration Web site. The deadline for special accommodation requests is Friday, May 7, 2010. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator, at *conferences@altarum.org.*

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established to advise