H1N1 as it relates to the mission of NVAC. Representatives of state and local health associations will also provide their perspective.

For this special meeting, members of the public are invited to attend by teleconference via a toll-free call-in phone number. The call-in number will be operator assisted to provide members of the public the opportunity to provide comments to the Committee. Public comment will be limited to no more than three minutes per speaker. Pre-registration is required for public comment only. Individuals who plan to attend and need special assistance, such as accommodation for hearing impairment or other reasonable accommodations, should notify the designated contact person at least one week prior to the meeting.

Any members of the public who wish to have printed material distributed to NVAC should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business one week before the meeting (conference call). A draft agenda and any additional materials will be posted on the NVAC Web site (*http://www.hhs.gov/nvpo/nvac/*) prior to the meeting.

Dated: October 15, 2009.

Bruce Gellin,

Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. E9–25366 Filed 10–20–09; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Performance Review Board Members

Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires notice of appointment of individuals to serve as a member of the Performance Review Board shall be published in the **Federal Register**.

The following individuals are hereby appointed to serve on Performance Review Boards within the Department of Health and Human Services. These individuals supplement membership on existing Performance Review Boards.

Office of the Secretary

Moulds, Donald, Principal Deputy Assistant Secretary.

Monahan, John, Director, Office of Global Health Affairs.

Centers for Disease Control and Prevention

Branche, Christine, Associate Director for NIOSH.

Health Resources and Services Administration (HRSA)

Morford, Thomas G., Associate Administrator, Office of Operations.

Indian Health Service (IHS)

Karol M.D., Susan, Chief Medical Officer.

Dated: October 16, 2009.

Antonia T. Harris,

Deputy Assistant Secretary for Human Resources, Department of Health and Human Services.

[FR Doc. E9–25452 Filed 10–20–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0287]

Wallace E. Gonsalves, Jr., MD: 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 Wallace E. Gonsalves, Jr., MD, from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Gonsalves was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Dr. Gonsalves failed to request a hearing. Dr. Gonsalves' failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective October 21, 2009.

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), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6844.

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 relating to the regulation of any drug product under the act. On September 15, 2004, the U.S. District Court for the District of Rhode Island entered judgment against Dr. Gonsalves for two counts of product tampering in violation of 18 U.S.C. 1365(a) and two counts of drug adulteration in violation of 21 U.S.C. 331(k) and 333(a)(2). On September 14, 2004, the U.S. District Court for the District of Rhode Island accepted Dr. Gonsalves' plea of guilty, made under a plea agreement, and entered judgment against Dr. Gonsalves for one count of conspiracy to sell drug samples in violation of 18 U.S.C. 371 and 21 U.S.C. 333(a)(2) and 353(c)(1), one count of unlawful sale of drug samples in violation of 21 U.S.C. 331(t), 333(b)(1), and 353(c)(1), and one count of health care fraud in violation of 18 U.S.C. 1347(a) and 2.

FDA's finding that debarment is appropriate is based on two convictions relating to adulteration of a drug (two separate vaccines) and one conviction relating to sale of drug samples. The factual basis for those convictions is as follows: From March of 2000 until on or about August 26, 2002, with the intent to defraud and mislead, Dr. Gonsalves caused a quantity of Measles, Mumps, and Rubella (MMR) and Varicella Virus (varicella) vaccine to be adulterated while the vaccine was being held for sale and administered to patients after being shipped in interstate commerce, by reducing the quality and strength of the vaccine and by failing to properly store and maintain the vaccine, thereby causing the vaccines to become adulterated.

From July 3, 2000, and continuing until at least on or about August 16, 2002, Dr. Gonsalves knowingly sold and offered to sell quantities of drug samples for cash or other consideration. As a result of his convictions, FDA sent Dr. Gonsalves by certified mail on August 7, 2009, a notice 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 Dr. Gonsalves 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 Dr. Gonsalves 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. Dr. Gonsalves did not request a hearing 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 Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the act and under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Dr. Gonsalves 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, Dr. Gonsalves 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) of the act 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 Dr. Gonsalves, in any capacity, during Dr. Gonsalves' debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6)). If Dr. Gonsalves, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, 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 Dr. Gonsalves during his debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Gonsalves for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2009–N–0287 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: September 29, 2009.

Brenda Holman,

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

[FR Doc. E9–25322 Filed 10–20–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0508]

Draft Guidance for Industry on Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' The draft guidance document is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA under The Family Smoking Prevention and Tobacco Control Act (FSPTCA).

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 comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 30, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 301–796–4800, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the FSPTCA (Public Law 111–31) into law. The FSPTCA amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(b) of the act (21 U.S.C. 395(b)), as amended by the FSPTCA, requires that ''every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products'' register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(i)(1) of the act, as amended by the FSPTCA, requires that all registrants ''shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,'' along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements.

While electronic submission of registration and listing information is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing. This tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions.