

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.

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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]

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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 debaring 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