OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–8164 Filed 4–5–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0450]

Maria Carmen Palazzo: 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 FD&C Act) permanently debarring Maria Carmen Palazzo, M.D. 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. Palazzo was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of any drug product under the FD&C Act. Dr. Palazzo was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Palazzo failed to respond. Dr. Palazzo's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective April 6, 2011.

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, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) and (B) of the FD&C Act (21 U.S.C. 335a(a)(2)(A) and (B)) require debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of any drug product under the FD&C Act.

On August 19, 2010, the United States District Court for the Eastern District of Louisiana accepted Dr. Palazzo's plea of guilty, and entered judgment against her for 15 counts of failure to prepare and maintain records with intent to defraud or mislead in violation of 21 U.S.C. 331(e), 333(a)(2), and 18 U.S.C. 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the development or approval, including the process for development or approval, of any drug product and otherwise relating to the regulation of any drug product under the FD&C Act. The factual basis for those convictions is as follows: Dr. Palazzo was a licensed medical doctor with offices located in New Orleans, Louisiana. SmithKline Beecham, Corporation, d.b.a. GlaxoSmithKline (SKB) was a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products including Paroxetine, also known as "Paxil." Under the FD&C Act and its implementing regulations, SKB had to apply to FDA for approval to market Paxil. SKB was required to demonstrate, through clinical investigations in which Paxil was given to human subjects, the safety and effectiveness of the drug in order to receive approval from FDA.

SKB hired Dr. Palazzo to be a clinical investigator for the Paxil study. As a participating investigator, Dr. Palazzo signed, on multiple occasions, an FDA Form 1572 committing to conduct the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations. Dr. Palazzo agreed to conduct the study in strict compliance with the criteria set forth in the study protocol, to personally review all Case Report Forms, and, in return, SKB agreed to pay for each subject who completed the study.

FDA regulations require that a clinical investigator on a drug study prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each study subject and provide that information to the drug sponsor. From on or about October 23, 2000, through May 24, 2001, Dr. Palazzo, with intent to defraud and mislead, failed to prepare and maintain records required under 21 U.S.C. 355(i) and 21 CFR 312.62(b), all in violation of 21 U.S.C. 331(e), 333(a)(2), and 18 U.S.C. 2.

As a result of her convictions, on January 11, 2011, FDA sent Dr. Palazzo a notice by certified mail proposing to permanently debar her 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)(A) and (B) of the FD&C Act, that Dr. Palazzo was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product and otherwise relating to the regulation of any drug product under the FD&C Act. The proposal also offered Dr. Palazzo an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Palazzo failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) and(B) of the FD&C Act, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Maria Carmen Palazzo has been convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product and otherwise relating to the regulation of any drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Palazzo 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 FD&C

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 sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 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. Palazzo, in any capacity during Dr. Palazzo's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Palazzo provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Palazzo during her period of debarment (section 306(c)(1)(B) of the FD&C Act.

Any application by Dr. Palazzo for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2010–N–0450 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 28, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–8152 Filed 4–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative and Request for Nominations for a Nonvoting Industry Representative on an FDA Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on its Allergenic Products Advisory Committee notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nomination will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by May 6, 2011 for vacancies listed in the notice. Concurrently, nomination material for prospective candidates should be sent to FDA by May 6, 2011.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Gail Dapolito (*see* **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Gail Dapolito, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–1289, FAX: 301–827–0294, e-mail: *gail.dapolito@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Agency requests nominations for a nonvoting industry representative on the Allergenic Products Advisory Committee. The Allergenic Products Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of allergenic products. This Committee has nine voting members. Members are asked to provide their expert scientific and technical advice to FDA to help make sound decisions on the safety, effectiveness, appropriate use, and labeling of allergenic biological products.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (*see* **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document. Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the Allergenic Products Advisory Committee.

The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person within the 30 days following nomination. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the allergenic product manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: March 31, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8125 Filed 4–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; 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: