

product or otherwise relating to the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 2 years is appropriate.

As a result of the foregoing findings, Dr. Noonan is debarred for 2 years from providing services in any capacity to a person with an approved or pending drug product application under section 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 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved, or pending, drug product application, who knowingly uses the services of Dr. Noonan, in any capacity during his period of debarment, will be subject to civil money penalties. If Dr. Noonan, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Noonan during his period of debarment.

Any application by Dr. Noonan for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2010-N-0300 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. Persons with access to the Internet may obtain documents in the Docket at <http://www.regulations.gov/>.

Dated: February 24, 2015.

**Stephen Ostroff,**

*Director, Office of the Chief Scientist.*

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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-0001]

**Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges." The purpose of the public workshop is to provide updates on accomplishments, challenges, and ongoing efforts in the use of clinical outcome assessments (COAs), and plan for the future of COA development and utilization in drug development programs, including how to incorporate the patient voice in drug development using well-defined and reliable patient-centered outcome measures. The public workshop will also discuss standards for COA use and collaborative processes for COA development and dissemination.

**Date and Time:** The public workshop will be held on April 1, 2015, from 8:30 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and routine security checks before the workshop.

**Location:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, The Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Attendees are responsible for their own accommodations.

The public workshop will also be available to be viewed online via Webcast at <https://collaboration.fda.gov/COApublicworkshop2015>. Persons interested in participating by Webcast must register online by March 27, 2015.

**Contact Person:** Michelle Campbell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6471, Silver Spring,

MD 20993-0002, 240-402-6019, email: [COApublicworkshop@fda.hhs.gov](mailto:COApublicworkshop@fda.hhs.gov).

**Registration:** Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited to 150 attendees. Workshop space will be filled in order of receipt of registration. Those accepted in to the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. If registration is filled, attendance to the workshop will be available only through the Webcast.

To register, visit <http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm>. For those without Internet access, please call Michelle Campbell (See *Contact Person*) to register.

If you need special accommodations due to a disability, please contact Michelle Campbell (See *Contact Person*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** The Center for Drug Evaluation and Research (CDER) reviews COAs, including patient-reported outcome measures, clinician-reported outcome measures, and observer-reported outcome measures, when submitted with an investigational new drug application, a new drug application, or a biologics licensing application. CDER also reviews a COA when submitted for qualification as a drug development tool. Qualification of a COA is a regulatory determination that the COA is well-suited for a specific context of use in drug development. Following a public announcement of the qualification decision by FDA, the COA will be publicly available for use in any appropriate drug development program.

This workshop will focus on current challenges and opportunities in COA development and use, including establishing appropriate standards for use; current efforts to encourage inclusion of well-defined and reliable patient-centered outcome measures in drug development; use of collaborative efforts in developing and utilizing COAs through various partnerships; and future efforts to address challenges and gaps of COA development and use for patient-centered drug development and medical product labeling.

For more information on this public workshop, visit <http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm>.

The Agency encourages patient advocates, health care providers, researchers, regulators, individuals from academia, industry, and other interested persons to attend this public workshop.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20857. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm> approximately 45 days after the workshop.

Dated: February 27, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-05017 Filed 3-4-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0147]

#### **Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry entitled “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.” This guidance provides information in response to questions that FDA has received from manufacturers on demonstrating the substantial equivalence of a new tobacco product, including questions on when a modification to the label requires a premarket submission and review by FDA.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions” to the Center for Tobacco Products, Food and Drug

Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

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

#### **FOR FURTHER INFORMATION CONTACT:**

Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002; 1-877-287-1373, [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov), email: [annette.marthaler@fda.hhs.gov](mailto:annette.marthaler@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.” In this guidance, FDA addresses questions from manufacturers on demonstrating the substantial equivalence of a new tobacco product. In the **Federal Register** of September 9, 2011 (76 FR 55927), FDA announced the availability of the draft guidance of the same title. After carefully reviewing and considering comments and information submitted in response to the draft guidance, which covered a range of topics on demonstrating the substantial equivalence of a new tobacco product, FDA is finalizing this guidance on many of the topics, including modifications to labels and changes to product quantity and intends to address the other topics in future regulatory documents.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

### **III. Paperwork Reduction Act of 1995**

This guidance refers to previously approved information collections found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in sections 905(j) and 910 of the FD&C Act (21 U.S.C. 387e(j) and 387j), as amended by the Tobacco Control Act, have been approved under OMB control number 0910-0673; the collections of information in 21 CFR part 25 have been approved under OMB control number 0910-0322.

### **IV. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### **V. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: February 27, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-05023 Filed 3-4-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0303]

#### **William F. DeLuca, Jr.; Denial of Hearing; Final Debarment Order**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Dr. William F. DeLuca, Jr. and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debaring Dr. DeLuca for 5 years from providing