*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,* email: *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) debarring Dr. DeLuca for 5 years from providing