

processor for a total of 24,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 2,400 hours.

We estimate that all processors (15,000 processors) will maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing (§ 123.8(d)) at 47 records per processor for a total of 705,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 70,500 hours.

We estimate that all processors (15,000 processors) will maintain sanitation control records (§ 123.11(c)) at 280 records per processor for a total of 4,200,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 420,000 hours.

We estimate that all importers (4,100 importers) will maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123 (§ 123.12(c)). We estimate that 80 records will be prepared per importer for a total of 328,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 32,800 hours.

We estimate that 1 percent of all importers (41 importers) will require new written verification procedures to verify compliance of imports (§ 123.12(a)(2)). We estimate the burden for preparing the new procedures to be 4 hours per importer for a total burden of 164 hours.

Dated: December 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31424 Filed 12-28-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2495]

Submission of Warning Plans for Cigars; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry

entitled “Submission of Warning Plans for Cigars.” The guidance will help those involved in the manufacture, distribution, and sale of cigars in the United States understand the new cigar warning plan requirements under FDA’s final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The guidance reiterates the health warning statements and display and distribution requirements that should be provided in cigar warning plans and will help persons determine who should submit a warning plan, when a plan must be submitted, and what information should be included when submitting a plan.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments,

except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-2495 for “Submission of Warning Plans for Cigars; Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance 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.

FOR FURTHER INFORMATION CONTACT: Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, AskCTP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Submission of Warning Plans for Cigars." On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product as subject to FDA regulatory authority under section 901(b) of the FD&C Act (21 U.S.C. 387a(b)). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to cigars, among other products (81 FR 28973). Among the requirements that now apply to cigars are health warning statements prescribed under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), which permits restrictions on the sale and distribution of tobacco products that are "appropriate for the protection of public health." The regulation specifies the health warning statements to be displayed and also requires the submission of warning plans that provide for the random, equal display and random distribution of the statements on cigar packaging and advertising.

The guidance discusses the regulatory requirements to submit warning plans, who submits a warning plan, the scope of a warning plan, when to submit a warning plan, what information should be submitted in a warning plan, where to submit a warning plan, and what approval of a warning plan means.

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 current thinking of FDA on submission of warning plans for cigars. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 21 CFR part 1143 have been approved under OMB control number 0910-0768.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <https://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-D-0103]

Botanical Drug Development; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Botanical Drug Development." This guidance describes FDA's current thinking on appropriate development plans for botanical drugs to be submitted in new drug applications (NDAs) and specific recommendations for submitting investigational new drug applications (INDs) to support future NDA submissions for botanical drugs. In addition, this guidance provides general information on the over-the-counter

(OTC) drug monograph system for botanical drugs. Although this guidance does not intend to provide recommendations specific to botanical drugs to be marketed under biologics license applications (BLAs), many scientific principles described in this guidance may also apply to these products. This guidance replaces the guidance for industry entitled "Botanical Drug Products" issued in June 2004 and finalizes the August 2015 draft guidance entitled "Botanical Drug Development."

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

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- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."