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.

[FR Doc. 2016–31586 Filed 12–28–16; 8:45 am]

BILLING CODE 4164–01–P

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

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–2000–D–0103 for ''Botanical Drug Development.'' 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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2128, Silver Spring, MD 20993–0002, 301–796–2905.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Botanical Drug Development.'' This guidance describes the current thinking of the Center for Drug Evaluation and Research (CDER) on appropriate development plans for botanical drugs to be submitted in NDAs and specific recommendations on submitting INDs in support of future NDA submissions for botanical drugs. In addition, this guidance provides general information on the OTC drug monograph system for botanical drugs. Although this guidance does not intend to provide recommendations specific to botanical drugs to be marketed under BLAs, many scientific principles described in this guidance may also apply to these products.

This guidance specifically discusses several areas in which, due to the unique nature of botanical drugs, the Agency finds it appropriate to apply regulatory policies that differ from those applied to nonbotanical drugs, such as synthetic, semi-synthetic, or otherwise highly purified or chemically modified drugs, including antibiotics derived from microorganisms. Because this guidance focuses on considerations unique to botanical drugs, policies and recommendations applicable to both botanical and nonbotanical drugs are generally not covered in this document.

In the **Federal Register** of August 17, 2015 (80 FR 49240), FDA issued and sought comment on a draft guidance that revised the final guidance for industry ''Botanical Drug Products'' issued in June 2004. This guidance finalizes the August 2015 draft guidance ''Botanical Drug Development'' and replaces the June 2004 final guidance. The June 2004 final guidance, August 2015 draft guidance, and related public comments are publicly available in Docket No. FDA–2000–D–0103. The general approach to botanical drug development has remained unchanged since 2004; however, based on improved understanding of botanical drugs and experience acquired in the reviews of NDAs and INDs for these drugs, specific recommendations have been modified and new sections have been added to this guidance to better address late-phase development and NDA submission for botanical drugs. This guidance also addresses the minor comments received from stakeholders on the 2015 draft guidance and provides clarity on the application of the fixed-dose drug combination rule to botanicals.

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 botanical drug development. 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.

II. The 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 guidance explains the circumstances under which FDA regulations require approval of an NDA for marketing a botanical drug product and when such a product may be marketed under an OTC drug monograph. The regulations governing the preparation and submission of an NDA are in part 314 (21 CFR part 314), and the guidance does not contain any recommendations that exceed the requirements of these regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an NDA, and OMB has approved the burden under OMB control number 0910–0001. FDA anticipates that any NDAs submitted for botanical drug products would be included under the burden estimates approved by OMB for part 314.

The regulations on the procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing OTC drug monographs, are set forth in § 330.10 (21 CFR 330.10). FDA believes that any botanical drug products that may be eligible for inclusion in an OTC drug monograph under current § 330.10 have already been or are presently being considered for such inclusion.

The guidance also provides scientific and regulatory guidance to sponsors on conducting clinical investigations of botanical drugs. The regulations governing the preparation and submission of INDs are in part 312 (21 CFR part 312). The guidance does not

contain any recommendations that exceed the requirements in those regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an IND under part 312, and OMB has approved the reporting and recordkeeping burden under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31627 Filed 12–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Continuation of Use of the Early Career Reviewer Program Online Application and Vetting System—Center for Scientific Review (CSR)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, Center for Scientific Review, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Monica Basco, Early Career Reviewer Program Coordinator, Center for Scientific Review, 6701 Rockledge Drive, Room 3030, Bethesda, Maryland 20892 or call non-toll-free number (301)–300–3839 or Email your request, including your address to: *CSRearlyCareerReviewer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Early Career Reviewer Program Online Application and Vetting System—Center for Scientific Review (CSR), 0925—Extension of Information Collection Request, Center for Scientific Review (CSR), National Institutes of Health (NIH) (OMB Control Number: 0925–0695; Expiration: 04/30/2017).

Need and Use of Information Collection: The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. Our mission is to see that NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research. To accomplish this goal, Scientific Review Officers (SRO) form study sections consisting of scientists who have the technical and scientific expertise to evaluate the merit of grant applications. Study section members are generally scientists who have established independent programs of research as demonstrated by their publications and their grant award experiences.

The CSR Early Career Reviewer program was developed to identify and train qualified scientists who are early in their scientific careers and who have not had prior CSR review experience. The goals of the program are to expose these early career scientists to the peer review experience so that they become more competitive as applicants as well as to enrich the existing pool of NIH reviewers. Currently, online application software, the Early Career Reviewer Application and Vetting System, is accessed online by applicants to the Early Career Reviewer Program who provide their names, contact information, a description of their areas of expertise, their study section preferences, professional Curriculum Vitae and links to their professional Web site. This Information Collection Request (ICR) is to continue to use the Early Career Reviewer Application and Vetting System to process applications for the Early Career Reviewer program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 450.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Applicants	1,080	1	25/60	450
Total	1,080	1,080		450