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/RulesRegulations/Guidance/default.htm.


Leslie Kux,
Associate Commissioner for Policy.
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 applied to nonbotanical drugs, such as synthetic, semi-synthetic, or otherwise.

Supplementary information includes the following:

- Confidentia...
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.


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

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