guidance takes into consideration the feedback received and is intended to serve as a focus for continued discussions among the Agency, pharmaceutical sponsors, the academic community, and the public on this topic.

The draft guidance focuses on drug development and trial design issues that are specific to the study of NRT drug products. NRT drug products are typically studied and labeled for use as adjuncts to behavioral self-help materials and to date have involved single treatment regimens that begin on the patient's quit day. Alternate treatment regimens (*e.g.,* pretreatment before quit day, quitting by gradual reduction (reduce to quit), using multiple NRT drug products together) are discussed in the guidance.

As outlined in the guidance, NRT drug products can be developed for smoking cessation and/or reduction in risk of relapse. NRT drug products that first have demonstrated efficacy for at least one of these indications can also include additional information in labeling by demonstrating efficacy in certain secondary endpoints. Sponsors can evaluate reduction in the urge to smoke or relief of cue-induced craving in former smokers, as secondary endpoints. Additionally, sponsors that can demonstrate, via a secondary endpoint, that the drug product provides relief of withdrawal symptoms in smokers *who are not trying to quit smoking,* may be able to include labeling instructions to address situations when such individuals are required to abstain and therefore experience withdrawal symptoms (*e.g.,* while traveling on an airplane).

FDA is aware of the serious risks associated with smoking and is committed to facilitating the development of therapies to support smoking cessation efforts. Both the regulatory pathway for an NRT drug product and the amount of nonclinical or clinical data needed to support approval will depend on the characteristics of the proposed NRT drug product relative to an approved NRT drug product. This guidance outlines general considerations for NRT drug development and trial design, and FDA encourages sponsors to contact FDA for feedback on their proposed development plans. Sponsors developing an over-the-counter drug product should bear in mind that it is often not possible to answer all regulatory questions in a single trial, and additional sequential steps may be needed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft 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 collection of information in 21 CFR part 314 for the submission of new drug applications (NDAs), including the submission of labeling under §§ 314.50(e)(2)(ii) and 314.50(l)(1)(i), as well as the submission of 505(b)(2) applications and abbreviated new drug applications, has been approved under OMB control number 0910–0001. The submission of biologics license applications (BLAs) has been approved under OMB control number 0910–0338. The collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014.

The submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 50 and 56 (*Protection of Human Subjects: Informed Consent; Institutional Review Boards*) have been approved under OMB control number 0910–0755.

The collection of information in the draft guidance for industry entitled ''Formal Meetings Between FDA and Sponsors and Applicants for PDUFA Products,'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm590547.pdf*) including requests for pre-NDA and pre-BLA meetings, has been approved under OMB control number 0910–0429.

The submission of special protocol assessments has been approved under OMB control number 0910–0470.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

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

Dated: February 15, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03064 Filed 2–21–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, March 1, 2019, 11:00 a.m. to March 1, 2019, 5:00 p.m., St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036 which was published in the **Federal Register** on February 5, 2019, 84 FR 1766.

The meeting is cancelled.

Dated: February 15, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03027 Filed 2–21–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.