authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, are the subject of NDA 010721, currently held by Casper Pharma LLC, and initially approved on February 14, 1957. ANTIVERT is indicated for the treatment of vertigo associated with diseases affecting the vestibular system.

ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Since 2011, the Agency has received four citizen petitions, submitted under 21 CFR 10.30, requesting that FDA determine whether one or more dosage forms and strengths of ANTIVERT were withdrawn from sale for reasons of safety or effectiveness.

- InvaGen Pharmaceuticals submitted a citizen petition dated January 14, 2011, and amendment dated February 24, 2011 (Docket No. FDA–2011–P–0047), requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, was withdrawn from sale for reasons of safety or effectiveness.
- Modavar Pharmaceuticals LLC submitted a citizen petition dated May 4, 2012, (Docket No. FDA–2012–P–0468) requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) tablets, 12.5 mg and 25 mg, were withdrawn from sale for reasons of safety or effectiveness.
- Lupin Pharmaceuticals, Inc. submitted a citizen petition dated September 18, 2015 (Docket No. FDA–2015–P–3400), requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) tablets, 12.5 mg, 25 mg, and 50 mg, were withdrawn from sale for reasons of safety or effectiveness.
- Zydus Pharmaceuticals submitted a citizen petition dated June 14, 2016 (Docket No. FDA–2016–P–1667), requesting that the Agency determine whether ANTIVERT (meclizine hydrochloride) tablets, 12.5 mg and 25 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, were not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, from sale. We have also independently evaluated relevant literature and data for possible post marketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list ANTIVERT (meclizine hydrochloride) chewable tablets, 25 mg, and tablets, 12.5 mg, 25 mg, and 50 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–06656 Filed 4–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Center for Scientific Review Advisory Council (CSRAC) was renewed for an additional two-year period on March 31, 2019.

It is determined that the CSRAC is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Acting Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail Code 4875), Telephone (301) 496–2123, or *harriscl@mail.nih.gov.*

Dated: April 1, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–06615 Filed 4–4–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request: A Generic Submission for Formative Research, Pretesting and Customer Satisfaction of NCI's Communication and Education Resources (NCI)

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, the National Institutes of Health, National Cancer Institute (NCI) will publish periodic summaries of propose 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: Ilene France, Branch Chief, Office of Communication and Public Liaison, National Cancer Institute, 9609 Medical Center Drive, Rockville, MD, 20850 or call non-toll-free number (240) 276–7787 or Email your request, including your address to: *nciocpl@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 minimizes 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: A Generic Submission for Formative Research, Pretesting and Customer Satisfaction of NCI's Communication and Education Resources (NCI), 0925–0046, Expiration Date 07/31/2019, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This information collection request is to approve the Generic Submission for Formative Research, Pretesting and Customer Satisfaction of NCI's Communication and Education Resources (NCI) for three years. As part of NCI's mandate from Congress to disseminate information on cancer research, detection, prevention, and treatment, the Institute develops a wide variety of messages and materials. Testing these messages and materials assesses their potential effectiveness in reaching and communicating with their intended audience while they are still in the developmental stage and can be revised. The formative research and pretesting process thus contributes to maximizing NCI's limited dollar resources for information dissemination and education. NCI also must ensure the relevance, utility, and appropriateness of the many educational programs and products that the Institute produces. Customer satisfaction studies help NCI identify modifications necessary to meet the needs of NCI's various target audiences. Since the previous submission, there have been 8 approved sub-studies (and 1 pending) with an approved request of 1,967 burden hours over 2.5 years. Approval is requested for the conduct of multiple studies annually using such methods as interviews, focus groups, and various types of surveys. The content, timing, and number of respondents to be included in each sub-study will vary, depending on the nature of the message/material/program being assessed, the methodology selected, and the target audiences.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 7,200.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Focus Groups, Individual In-Depth Interviews, Brief Interviews, Surveys, Website Usability Testing.	Individuals (General Public)	18,000	1	12/60	3,600
Focus Groups, Individual In-Depth Interviews, Brief Interviews, Surveys, Website Usability Testing.	Individuals (Health Care Professionals).	18,000	1	12/60	3,600
Total	.....	36,000	36,000	.....	7,200

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2019–06735 Filed 4–4–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

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

The meetings 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.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Center without Walls for