ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Data collection method	Number of respondents	Number of responses per respondent	Average burden per response
General Public and Special Populations	Screening and Recruitment	20,000	1	2/60
	In-depth Interviews (In Person, telephone, etc.).	67	1	1
	Focus Groups (In Person)	160	1	1.5
	Focus Groups (Online)	120	1	1
	Short Surveys	6,500	1	10/60
	(Online, Bulletin Board, etc.)			
	Medium Surveys	8,500	1	25/60
	(Online)			
	In-depth Surveys (Online)	1,500	1	1

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–27928 Filed 11–20–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0573]

Determination That BANZEL (Rufinamide) Tablet, 100 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that BANZEL (rufinamide) tablet, 100 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for rufinamide tablet, 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Olivia Morris, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6260, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which 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 (§ 314.162 (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.

BANZEL (rufinamide) tablet, 100 mg, is the subject of NDA 21–911, held by Eisai Inc., and initially approved on November 14, 2008. BANZEL is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults.

Eisai Inc., has never marketed BANZEL (rufinamide) tablet, 100 mg. In previous instances (see, e.g., 72 FR 9763, 61 FR 25497), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lupin Pharmaceuticals, Inc., submitted a citizen petition dated May 9, 2013 (Docket No. FDA–2013–P–0573), under 21 CFR 10.30, requesting that the Agency determine whether BANZEL (rufinamide) tablet, 100 mg, was withdrawn or discontinued from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that BANZEL (rufinamide) tablet, 100 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BANZEL (rufinamide) tablet, 100 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BANZEL (rufinamide) tablet, 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BANZEL (rufinamide) tablet, 100 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. ANDAs that refer to BANZEL (rufinamide) tablet, 100 mg, may 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 this drug product should be revised

to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27874 Filed 11–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review, 30-Day Comment Request: Certificate of Confidentiality Electronic Application System

SUMMARY: Under the provisions of Section 3507(a) (1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research (OER), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 29, 2013, page 2590 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of Extramural Research (OER), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-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. Ann Hardy, NIH Extramural Human Research Protections Officer and NIH Coordinator, Certificates of Confidentiality, 3701 Rockledge Dr., Rm. 3002, Bethesda, MD 20892, or call non-toll-free number (301) 435–2690 or Email your request, including your address to: *hardyan@od.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Certificate of Confidentiality Electronic Application System, 0925-New, Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This application system will provide one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. § 241(d)), CoCs are issued by the agencies of Department of Health and Human Services (DHHS), including NIH, to authorize researchers conducting sensitive research to protect the privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). The NIH ICs collectively issue approximately 1000 new CoCs each year for eligible research projects. However, the process for submitting a CoC request is not consistent across the ICs which creates confusion for applicants. To make the application process consistent across the entire agency, OER is proposing to use an electronic application system that will be accessed by research organizations that wish to request a CoC from any NIH IC. Having one system for all CoC applications to NIH will be efficient for both applicants and NIH staff who process these requests. As is currently done, NIH will use the information in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,500.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
CoC Applicants-Private	400	1	90/60	600
CoC Applicants-State/local	450	1	90/60	675
CoC Applicants-Small business	50	1	90/60	75
CoC Applicants-Federal	100	1	90/60	150

Dated: November 13, 2013.

Seleda Perryman,

Chief, Project Clearance Officer, Office of Policy for Extramural Research Administration, National Institutes of Health.

[FR Doc. 2013–27966 Filed 11–20–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 2–3, 2013.

Time: December 2, 2013, 8:30 a.m. to 5:00 p.m.