ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Total					386

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. 2014–25562 Filed 10–27–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–P–0979]

Determination That DIAMOX (Acetazolamide) Intravenous, 500 Milligrams Base/Vial, and DIAMOX (Acetazolamide) Tablets, 125 Milligrams and 250 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 DIAMOX (acetazolamide) intravenous, 500 milligrams (mg) base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 240–402–4191.

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.

DIAMOX (acetazolamide) intravenous, 500 mg base/vial, is the subject of NDA 009–388, held by Teva Branded Pharmaceutical Products R&D, Inc., and initially approved on June 25, 1954. DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, are the subject of NDA 008–943, held by Teva Branded Pharmaceutical Products R&D, Inc., and initially approved on July 27, 1953. DIAMOX (acetazolamide) intravenous, 500 mg base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, are indicated for adjunctive treatment of: Edema due to congestive heart failure; drug-induced edema; centrencephalic epilepsies (petit mal, unlocalized seizures); and chronic simple (open-angle) glaucoma, secondary glaucoma, and preoperatively in acute angle-closure glaucoma where delay of surgery is desired in order to lower intraocular pressure. DIAMOX (acetazolamide) intravenous, 500 mg base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, are also indicated for the prevention or amelioration of symptoms associated with acute mountain sickness in climbers attempting rapid ascent and in those who are very susceptible to acute mountain sickness despite gradual ascent.

DIAMOX (acetazolamide) intravenous, 500 mg base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Emcure Pharmaceuticals USA, Inc., submitted a citizen petition dated July 3, 2014 (Docket No. FDA–2014–P–0979), under 21 CFR 10.30, requesting that the Agency determine that DIAMOX (acetazolamide) intravenous, 500 mg base/vial, was discontinued for reasons unrelated to safety and effectiveness. Although the citizen petition did not address DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, since those products have also been discontinued, on our own initiative, we therefore determined whether DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that DIAMOX (acetazolamide) intravenous, 500 mg base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that DIAMOX (acetazolamide) intravenous, 500 mg base/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DIAMOX (acetazolamide) intravenous, 500 mg base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 mg from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that these products were

withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DIAMOX (acetazolamide) intravenous, 500 mg base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 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 ANDAs that refer to DIAMOX (acetazolamide) intravenous, 500 mg base/vial, and DIAMOX (acetazolamide) tablets, 125 mg and 250 mg. Additional ANDAs that refer to these 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: October 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25534 Filed 10–27–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Generic Clearance for Satisfaction Surveys of Customers (CSR)

SUMMARY: Under the provisions of Section 3507(a)(l)(D) of the Paperwork Reduction Act of 1995, the 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 August 21, 2014, page 49523 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 Center for Scientific Review (CSR), 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 31, 2014, 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. Mary Ann Guadagno, Project Clearance Liaison, Center for Scientific Review, NIH, Room 3182, 6701 Rockledge Drive, Bethesda, MD 20892, or call non-toll-free number (301) 435–1251 or Email your request, including your address to: *guadagma@csr.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Generic Clearance for Satisfaction Surveys of Customers (CSR), 0925–0474—extension, Center for Scientific Review (CSR), National Institutes of Health (NIH).

Need and Use of Information Collection: The information collected in these surveys will be used by the Center for Scientific Review management and personnel: (1) To assess the quality of the modified operations and processes now used by CSR to review grant applications; (2) To assess the quality of service provided by CSR to our customers; (3) To enable identification of the most promising biomedical research that will have the greatest impact on improving public health by using a peer review process that is fair unbiased from outside influence, timely, and (4) To develop new modes of operation based on customer need and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities to enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The major initiatives ongoing at the present time include: Evaluation of the peer review process, surveys of new and early stage investigators, satisfaction with study section meetings using alternative review platforms, quick feedback for peer review, satisfaction with new reviewer orientation sessions, teleworker space needs, improving study section alignment to ensure the best reviews, and others. Surveys will be collected via Internet or in focus groups. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, organization of, and services provided by the Center.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4323.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
A	Adult scientific professionals (via Mail/Telephone/Internet)	7925	1	30/60	3963
B	Adult scientific professionals (via focus groups)	240	1	90/60	360