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. 2014–25563 Filed 10–27–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15CI]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Mental Health Profile of Congolese Refugees—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The central objective of this collection is to compile a mental health profile of Congolese refugees departing from Uganda, and to describe some of the mental health conditions most often experienced by this population. The specific objectives are (1) through a survey and focus groups, collect more detailed and systematic data on exposure to trauma and symptoms of PTSD, anxiety, and depression among a sample of Congolese refugees from Uganda prior to their resettlement in the United States; and, (2) to better inform state and local healthcare providers in the United States and in Uganda about the mental health needs of the Congolese refugee populations come to their states. As CDC have seen in previous surveys, although there may be similarities in the mental health problems that refugee populations may experience over all, there are also very specific differences in terms of cultural background, coping styles, severity, and risk factors. Without doing a survey, it would not be possible to provide specific recommendations for Congolese refugees who are coming to the U.S.

The respondents in this study will be Congolese refugees 15 years of age or older who have been referred for U.S. resettlement in settlement and urban sites in Uganda and who consent to a supplemental mental health assessment after their required overseas medical exam or security screening interview.

Individual level data will not be collected. Aggregated data will collected during focus groups and surveys to form a 'profile' of Congolese refugee regarding their levels of anxiety, depression, PTSD, ability to cope, physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, and social function.

The focus group discussion tool poses eight open-ended questions and will be moderated by a professional in the appropriate language for the specific Congolese refugee group.

For the survey tool, CDC proposes to the use a compilation of the Hopkins Symptom Checklist, Harvard Trauma Questionnaire, the Medical Outcomes Assessment 36-Item Short-Form Health Survey (SF–36), a limited number of questions from The Coping Strategy Indicator, and questions concerning history of mental illness or substance abuse. Each of these tools has been used in similar populations that have experienced trauma or in conflict environments.

The sample population will be a convenience sample of the Congolese refugee population ages 15 or older in Uganda and will be selected from the available population being examined during the International Organization for Migration (IOM) medical or Resettlement Support Center (RSC) screening interviews. As refugees are waiting for their IOM exam or RSC interview, staff will introduce the assessment with the help of an interpreter, and make arrangements for obtaining consent from refugees who meet the inclusion and exclusion criteria prior to the assessment.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 386.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Refugee	Focus Group Discussion Tool	16	1	1	16
Refugee	Survey Tool	370	1	1	370

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