EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

| Form name | Number of respondents | Total burden hours | Average hourly wage rate | Total cost burden |
|---|---|---|---|---|
| PHQ–9 | 150 | 22.5 | *$24.98 | $562.05 |
| FIBSER | 200 | 20 | *24.98 | 499.6 |
| Clinician Survey | 15 | 1.25 | #39.42 | 49.28 |
| Total | 365 | 42.5 | 24.98 | 1,110.93 |

*Based on the mean wages for all occupations, 00–0000. May 2018 National Occupational Employment and Wage Estimates. U.S. Department of Labor, Bureau of Labor Statistics. Available at: *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

#Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. May 2018 National Occupational Employment and Wage Estimates. U.S. Department of Labor, Bureau of Labor Statistics. Available at: *https://www.bls.gov/oes/current/oes_nat.htm#29-0000.*

**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 19, 2019.

**Virginia L. Mackay-Smith,**

*Associate Director.*

[FR Doc. 2019–18113 Filed 8–21–19; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Informational Meeting: The Importation of Infectious Biological Agents, Infectious Substances and Vectors; Public Webcast

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of public webcast.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), is hosting a public webcast to address import permit regulations for infectious biological agents, infectious substances, and vectors. Besides CDC, presenters for this webcast may include representatives from the U.S. Department of Transportation, U.S. Department of Agriculture, Department of Homeland Security, and U.S. National Authority for Containment (NAC) of Polioviruses.

**DATES:** The webcast will be held on December 4, 2019, from 11 a.m. to 4 p.m. (EST). Registration instructions are found on the HHS/CDC Import Permit Program website, *https://www.cdc.gov/cpr/ipp/index.htm.*

**ADDRESSES:** The webcast will be broadcast from the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia 30329.

**FOR FURTHER INFORMATION CONTACT:** Samuel S. Edwin, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H–21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

**SUPPLEMENTARY INFORMATION:** This webcast is an opportunity for all interested parties (*e.g.,* academic institutions; biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities; and educational facilities) to obtain specific guidance and information regarding import permit regulations for the importation of infectious biological agents, infectious substances and vectors. The webcast will also provide assistance to those interested in applying for an import permit from federal agencies within the United States. Instructions for registration are found on the HHS/CDC Import Permit Program website, *https://www.cdc.gov/cpr/ipp/index.htm.*

Participants must register by November 22, 2019. This is a webcast-only event and there will be no on-site participation at the HHS/CDC broadcast facility.

Dated: August 19, 2019.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

[FR Doc. 2019–18100 Filed 8–21–19; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–P–0076]**

### Determination That ZONEGRAN (Zonisamide) Capsules, 50 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 or Agency) has determined that ZONEGRAN (zonisamide) capsules, 50 milligrams (mg), was 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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993–0002, 301–796–6650, *Daniel.Gottlieb@fda.hhs.gov.*

**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 (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.

ZONEGRAN (zonisamide) capsules, 50 mg, is the subject of NDA 020789, held by Sunovion Pharmaceuticals Inc., and initially approved on August 22, 2003. ZONEGRAN (zonisamide) is indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy. ZONEGRAN (zonisamide) capsules, 50 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Unichem Pharmaceuticals (USA), Inc., submitted a citizen petition dated December 28, 2018 (Docket No. FDA–2019–P–0076), under 21 CFR 10.30, requesting that the Agency determine whether ZONEGRAN (zonisamide) capsules, 50 mg, was withdrawn 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 ZONEGRAN (zonisamide) capsules, 50 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZONEGRAN (zonisamide) capsules, 50 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZONEGRAN (zonisamide) capsules, 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 this drug product. Additional ANDAs for this drug product 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 16, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–18089 Filed 8–21–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Meeting of the National Advisory Council on Migrant Health

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's National Advisory Council on Migrant Health (NACMH) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html.*

**DATE:** November 6–7, 9 a.m.–5 p.m. Eastern Time (ET).

**ADDRESSES:** 5600 Fishers Lane, 5W07, Rockville, Maryland 20857 (in-person).

**FOR FURTHER INFORMATION CONTACT:** Esther Paul, NACMH Designated Federal Officer (DFO), Strategic Initiatives and Planning Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, 16N38B, Rockville, Maryland 20857; 301–594–4300; or *epaul@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** NACMH provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning the activities under section 217 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 218). Specifically, NACMH consults with and makes recommendations to the Secretary of HHS concerning the organization, operation, selection, and funding of migrant health centers, and other entities under grants and contracts under section 330 of the PHS Act (42 U.S.C. 254b). NACMH meets twice each calendar year, or at the discretion of the DFO in consultation with the NACMH Chair.

During the November 6–7, 2019, meeting, NACMH will discuss issues related to migrant and seasonal agricultural worker health. Agenda items are subject to change as priorities dictate. Refer to the NACMH website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are received and may be limited as time allows. Requests to submit a written statement or make oral comments to NACMH should be sent to Esther Paul, DFO, using the contact information above at least three business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Esther Paul at the address and phone number listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present