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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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under 21 CFR 10.30, requesting that the Agency determine whether ZONEGRAN (zonisamide) capsules, 50 mg, was withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that ZONEGRAN (zonisamide) capsules, 50 mg, was not withdrawn for reasons of safety or effectiveness.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

government-issued identification prior to entry.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–18117 Filed 8–21–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; the Stem Cell Therapeutic Outcomes Database, OMB No. 0915–0310–Revision

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 23, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, Public Law 114–104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain recordkeeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers, under contract, by the Medical College of Wisconsin's Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. Over time, there is an expected increase in the number of recipients for whom data are reported as an increasing number of transplants are performed annually and survivorship after transplantation improves.

A 60-day notice was published in the **Federal Register** on March 7, 2019, vol. 84, No. 45; pp. 8334–8335. There were no public comments.

Need and Proposed Use of the Information: HRSA uses the information to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and provide the Secretary of HHS with an annual report of transplant center specific survival data. Modifications of these forms fall into several categories: Consolidating questions and removing duplicate questions across the forms, implementing 'check all that apply' formatting to reduce data entry time, and removing items no longer clinically significant (*e.g.,* drugs). These modifications reduced the overall hours of burden inventory.

Likely Respondents: Transplant Centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents [1]	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Baseline Pre-Transplant Essential Data (TED)	200	48	9,600	[2] 0.68	6,560
Disease Classification	200	48	9,600	[3] 0.43	4,160
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	45	9,000	1.00	9,000
100-day Post-TED	200	48	9,600	0.85	8,160
6 month Post-TED	200	43	8,600	0.85	7,310
1 year Post-TED	200	40	8,000	0.65	5,200
2 year Post-TED	200	34	6,800	0.65	4,420
3+ years Post-TED	200	172	34,400	[4] 0.52	17,773
Total	200	.....	95,600	.....	62,583

[1] The total of 200 is the number of centers completing the form; the same group will complete all of the forms.
[2] The decimal is rounded down, and the actual number is .683333333.
[3] The decimal is rounded down, and the actual number is .433333333.
[4] The decimal is rounded up, and the actual number is .516667.