FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: NDA 202799 for OMONTYS (peginesatide) Injection, 1 milligram (mg)/0.5 milliliter (mL), 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL, 10 mg/mL, and 20 mg/2 mL, was received on May 8, 2011, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)). FDA approved NDA 202799 on March 27, 2012, for treatment of anemia due to chronic kidney disease in adult patients on dialysis.

On February 23, 2013, Affymax, Inc. and Takeda voluntarily recalled all lots of OMONTYS and suspended its marketing as a result of postmarketing reports of serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal.

Takeda subsequently requested that FDA withdraw approval of NDA 202799 under 21 CFR 314.150(d) (§ 314.150(d)) and waived its opportunity for a hearing. Accordingly, under § 314.150(d), approval of NDA 202799, and all amendments and supplements thereto, is withdrawn. Distribution of OMONTYS (peginesatide) Injection, 1 mg/0.5 mL, 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL, 10 mg/mL, and 20 mg/2 mL, without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: February 8, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02146 Filed 2–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–3597]

Determination That LOTRIMIN (Clotrimazole) Topical Solution, 1%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA or Agency) has determined that LOTRIMIN (clotrimazole) topical solution, 1%, was not withdrawn from sale for reasons of safety or effectiveness.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: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363.

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.

LOTRIMIN (clotrimazole) topical solution, 1%, is the subject of NDA 017613, held by Schering-Plough Healthcare Products Inc., and initially approved on February 3, 1975. LOTRIMIN is indicated for the topical treatment of candidiasis due to *Candida albicans* and tinea versicolor due to *Malassezia furfur.*

LOTRIMIN (clotrimazole) topical solution, 1%, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated August 31, 2005, Schering Corporation requested withdrawal of NDA 017613 for LOTRIMIN (clotrimazole). In the **Federal Register** of November 7, 2007 (72 FR 62858), FDA announced that it was withdrawing approval of NDA 017613, effective December 7, 2007.

Arent Fox LLP submitted a citizen petition dated September 21, 2018 (Docket No. FDA–2018–P–3597), under 21 CFR 10.30, requesting that the Agency determine whether LOTRIMIN (clotrimazole) topical solution, 1%, 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 LOTRIMIN (clotrimazole) topical solution, 1%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LOTRIMIN (clotrimazole) topical solution, 1%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LOTRIMIN (clotrimazole) topical solution, 1%, 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 LOTRIMIN (clotrimazole) topical solution, 1%, 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. In addition, FDA will continue to approve ANDAs for this drug product as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If the Agency 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: February 8, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02139 Filed 2–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Committee on Rural Health and Human Services

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

ACTION: Notice.

SUMMARY: The Secretary's National Advisory Committee on Rural Health and Human Services (NACRHHS) has scheduled a public meeting. Information about NACRHHS and the agenda for this meeting can be found on the NACRHHS website at *https://www.hrsa.gov/advisory-committees/rural-health/index.html.*

DATES:

April 3, 2019, 8:30 a.m.–5:15 p.m. Pacific Time (PT).

April 4, 2019, 8:30 a.m.–5:15 p.m. PT.

April 5, 2019, 8:30 a.m.–11:15 a.m. PT.

ADDRESSES: The meeting will be held in person. On April 3, the meeting will be held at The Residence Inn, Sacramento Downtown, 1121 15th Street, Sacramento, California 95814.

On the morning of April 4, NACRHHS will break into subcommittees. One subcommittee will travel to Northern Valley Indian Health Clinic, 207 N Butte St., Willows, California 95988. The other subcommittee will travel to Sierra Nevada Memorial Hospital, 155 Glasson Way, Grass Valley, California 95945. In the afternoon at approximately 4:00 p.m. PT, NACRHHS will reconvene at The Residence Inn, Sacramento Downtown, 1121 15th Street, Sacramento, California 95814.

On April 5, the meeting will be held at The Residence Inn, Sacramento Downtown, 1121 15th Street, Sacramento, California 95814.

FOR FURTHER INFORMATION CONTACT: Steven Hirsch, Administrative Coordinator at the Federal Office of Rural Health Policy, HRSA, 5600 Fishers Lane, 17W59D, Rockville, Maryland 20857; 301–443–7322; or *shirsch@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACRHHS provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning both rural health and rural human services.

During the April 2019 meeting, NACRHHS will discuss the issues of Cancer Prevention and Control in Rural America along with Supportive Services and Caregiving for the Rural Elderly. Agenda items are subject to change as priorities dictate. Refer to the NACRHHS 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 requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACRHHS should be sent to Steven Hirsch, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Steven Hirsch at the address and phone number listed above at least 10 business days prior to the meeting.

John R. Womack,

Acting Deputy Director, Division of the Executive Secretariat.

[FR Doc. 2019–02207 Filed 2–12–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: March 22, 2019, 10:00 a.m.–3:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* The deadline for online registration is 5:00 p.m. ET on March 20, 2019. Instructions on how to access the meeting via webinar will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *AHarris@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the March 2019 meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Tentative agenda topics include: (1) The condition nomination and evidence review process, (2) rare disease registries, and (3) implementation of conditions on the RUSP. Agenda items are subject to change as priorities dictate and the final meeting agenda will be available on ACHDNC's website: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Information about ACHDNC, a roster of members, as well as past meeting summaries are also available on the ACHDNC website.

Members of the public will have the opportunity to provide comments, which are part of the official committee record. To submit written comments or