Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

EE. All advertising and promotional descriptive printed matter relating to the use of the authorized DPP Ebola Antigen System shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories and facilities adequately equipped, trained and capable of testing for EVD (including treatment centers and public health clinics);
- This test has been authorized only for the detection of Ebola virus, species *Zaire ebolavirus*, and any other *Ebolavirus* species if so authorized; and
- This test is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

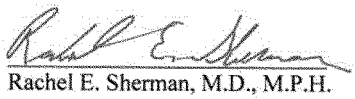
No advertising or promotional descriptive printed matter relating to the use of the authorized DPP Ebola Antigen System may represent or suggest that this test is safe or effective for the diagnosis of EVD.

The emergency use of the authorized DPP Ebola Antigen System as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,



Rachel E. Sherman, M.D., M.P.H.
Principal Deputy Commissioner

Enclosures

Dated: February 7, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02134 Filed 2–12–19; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0361]

Takeda Pharmaceuticals U.S.A., Inc.; Withdrawal of Approval of a New Drug Application for OMONTYS (peginesatide) Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of new drug application (NDA) 202799 for OMONTYS (peginesatide) Injection, held by Takeda Pharmaceuticals U.S.A., Inc. (Takeda USA). Takeda Development Center America, Inc., on behalf of Takeda USA, requested withdrawal of approval of this application under relevant FDA regulations and, in so doing, has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of February 13, 2019.

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