4164-01-P

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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 Accordingly, under § 314.150(d), approval of NDA 202799, and all amendments and supplements thereto, is withdrawn.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.

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