4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1360]

Teva Branded Pharmaceutical Products R&D, Inc.; Withdrawal of Approval of a New Drug Application for ZECUITY (sumatriptan iontophoretic transdermal system)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of the new drug application (NDA) for ZECUITY (sumatriptan iontophoretic transdermal system) held by Teva Branded Pharmaceutical Products R&D, Inc. (Teva), 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355. Teva requested withdrawal of this application and 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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: On January 17, 2013, FDA approved NDA 202278 for ZECUITY (sumatriptan iontophoretic transdermal system) for the acute treatment of migraine with or without aura in adults. On June 2, 2016, FDA issued a Drug Safety Communication announcing the FDA is investigating the risk of serious burns and potential permanent scarring with the use of ZECUITY for migraine headaches.

(https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-evaluating-risk-burns-and-scars-ZECUITY-sumatriptan-migraine-patch). On June 10, 2016, Teva suspended sales, marketing and distribution to investigate the cause of burns and scars associated with ZECUITY.

On July 19, 2019, Teva requested withdrawal of NDA 202278 for ZECUITY under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. In its letter requesting withdrawal of approval, Teva stated that it voluntarily discontinued manufacture and sale of products under NDA 202278 in 2016 for commercial reasons and has agreed to withdrawal of the application for those reasons only.

For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 202278 for ZECUITY (sumatriptan iontophoretic transdermal system), and all amendments and supplements thereto, is withdrawn under § 314.150(d).

Distribution of ZECUITY into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-14284 Filed: 7/1/2020 8:45 am; Publication Date: 7/2/2020]