4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2020-N-1735]

Eisai, Inc.; Withdrawal of Approval of Two New Drug Application for BELVIQ (lorcaserin hydrochloride) and BELVIQ XR (lorcaserin hydrocholoride)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of two new drug applications for BELVIQ (lorcaserin hydrochloride (HCl)) tablets and BELVIQ XR (lorcaserin HCl) extended-release tablets held by Eisai, Inc., 155 Tice Blvd., Woodcliff Lake, NJ 07677 (Eisai). Eisai requested withdrawal of these applications 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DATES: Approval is withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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: FDA approved NDA 022529 for BELVIQ (lorcaserin HCl) 10 milligrams (mg) tablets and NDA 208524 for BELVIQ XR (lorcaserin HCl) 20 mg extended-release tablets on June 27, 2012 and July 15, 2016, respectively, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese) or
- 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes).

On January 14, 2019, FDA issued a Drug Safety Communication alerting the public that results from a clinical trial assessing the risk of heart-related problems show a possible increased risk of cancer with BELVIQ and BELVIQ XR (see https://www.fda.gov/drugs/drug-safety-and-availability/safety-clinical-trial-shows-possible-increased-risk-cancer-weight-loss-medicine-belviq-belviq-xr). On February 13, 2020, FDA announced it had asked Eisai to voluntarily withdraw BELVIQ and BELVIQ XR from the U.S. market because a safety clinical trial showed an increased occurrence of cancer (see https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market).

On February 13, 2020, Eisai requested that FDA withdraw approval of NDA 022529 for BELVIQ and NDA 208524 for BELVIQ XR under § 314.150(d) (21 CFR 314.150(d)), and waived its opportunity for a hearing.

For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 022529 BELVIQ (lorcaserin HCl) tablets and 208524 BELVIQ XR (lorcaserin HCl) extended-release tablets, and all amendments and supplements thereto, are withdrawn under § 314.150(d). Distribution of BELVIQ 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: September 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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