

nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, nominations for nonvoting representatives of industry interests are encouraged from the device manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0030]

Determination That BELVIQ (Lorcaserin Hydrochloride) Tablets, 10 Milligrams, and BELVIQ XR (Lorcaserin Hydrochloride) Extended-Release Tablets, 20 Milligrams, Were Withdrawn From Sale for Reasons of Safety or Effectiveness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 BELVIQ (lorcaserin hydrochloride) tablets, 10 milligrams (mg), and BELVIQ XR (lorcaserin hydrochloride) extended-release tablets, 20 mg, were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for lorcaserin hydrochloride tablets, 10 mg and 20 mg.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993-0002, 240-402-9674, Sungjoon.Chi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to seek approval to market a generic version of a previously approved drug product. In general, to obtain approval, the ANDA applicant must show, among other things, that the generic drug product has the same active ingredient(s); dosage form; route of administration; strength; conditions of use; and, with certain exceptions, labeling as the listed drug. In addition, the ANDA applicant must show that the generic drug product is bioequivalent to the listed drug.

Section 505(j)(7) of the FD&C Act 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 new drug application (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.

BELVIQ (lorcaserin hydrochloride) tablets, 10 mg, is the subject of NDA 022529, and BELVIQ XR (lorcaserin hydrochloride) extended-release tablets, 20 mg, is the subject of NDA 208524, both held by Eisai Inc. (Eisai), and initially approved on June 27, 2012, and July 15, 2016, respectively. BELVIQ and BELVIQ XR are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of:

- 30 kilograms per square meter (kg/m²) 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).

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that BELVIQ (lorcaserin hydrochloride) tablets, 10 mg, and

BELVIQ XR (lorcaserin hydrochloride) extended-release tablets, 20 mg, were withdrawn for reasons of safety or effectiveness.

In 2012, the Agency required the drug manufacturer to conduct a randomized, double-blind, placebo-controlled clinical trial to evaluate the risk of cardiovascular problems. The Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients—Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61) clinical trial was conducted to fulfill this requirement. An analysis of the CAMELLIA-TIMI 61 trial results suggests an imbalance in cancer in humans. Although chance effect cannot be ruled out, the imbalance persisted throughout multiple analysis approaches. The clinical findings corroborated by the evidence from the animal models informed the Agency’s assessment that the risk outweighs any potential benefits for the current indications. These findings were considered clinically meaningful and could not be adequately addressed through labeling. Additional evidence would be necessary to investigate this signal; however, the Agency has determined that it is unlikely that the necessary safety endpoints (*i.e.*, cancer and reproductive safety) can be readily or ethically investigated in a clinical trial. Because preclinical or clinical studies would first need to be conducted to address these concerns, the Agency has determined that this drug product would not be considered safe and effective if it were reintroduced to the market.

FDA issued a Drug Safety Communication on January 14, 2020, 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 (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 submitted a request to FDA to withdraw approval of NDA 022529 for BELVIQ and NDA 208524 for BELVIQ XR under 21 CFR 314.150(d) and waived its opportunity for a hearing. As requested by Eisai, the Agency issued a **Federal Register** notice on September 17, 2020 (85 FR 58063), withdrawing approval of the

applications for BELVIQ (lorcaserin hydrochloride) tablets, 10 mg, and BELVIQ XR (lorcaserin hydrochloride) extended-release tablets, 20 mg, effective September 17, 2020.

Accordingly, the Agency will remove BELVIQ (lorcaserin hydrochloride) tablets, 10 mg, and BELVIQ XR (lorcaserin hydrochloride) extended-release tablets, 20 mg, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

“Low Income Levels” Used for Various Health Professions and Nursing Programs Authorized in Titles III, VII, and VIII of the Public Health Service Act

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

ACTION: Notice.

SUMMARY: HRSA is updating income levels used to identify a “low income family” for the purpose of determining eligibility for programs that provide health professions and nursing training to individuals from disadvantaged backgrounds. These various programs are authorized in Titles III, VII, and VIII of the Public Health Service Act.

SUPPLEMENTARY INFORMATION: HHS periodically publishes in the **Federal Register** low-income levels to be used by institutions receiving grants and cooperative agreements to determine eligibility for programs providing training for (1) disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from low-income families.

Many health professions and nursing grant and cooperative agreement awardees use the low-income levels to determine whether potential program participants are from an economically disadvantaged background and would be eligible to participate in the program, as well as to determine the amount of funding the individual receives. Awards are generally made to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary

medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, and chiropractic; public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice; and other public or private nonprofit health or educational entities to assist individuals from disadvantaged backgrounds to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for students from disadvantaged backgrounds.

A “low-income family/household” for programs included in Titles III, VII, and VIII of the Public Health Service Act is defined as having an annual income that does not exceed 200 percent of the Department’s poverty guidelines. A family is a group of two or more individuals related by birth, marriage, or adoption who live together.

Most HRSA programs use the income of a student’s parent(s) to compute low income status. However, a “household” may potentially be only one person. Other HRSA programs, depending upon the legislative intent of the program, the programmatic purpose related to income level, as well as the age and circumstances of the participant, will apply these low income standards to the individual student to determine eligibility, as long as he or she is not listed as a dependent on the tax form of his or her parent(s). Each program announces the rationale and choice of methodology for determining low income levels in program funding opportunities or applications.

Low-income levels are adjusted annually based on HHS’s poverty guidelines. HHS’s poverty guidelines are based on poverty thresholds published by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index. The income figures below have been updated to reflect the Department’s 2021 poverty guidelines as published in 86 FR 19 (February 1, 2021).

LOW INCOME LEVELS BASED ON THE 2021 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Persons in family/household *	Income level **
1	\$25,760
2	34,840
3	43,920
4	53,000
5	62,080
6	71,160
7	80,240

LOW INCOME LEVELS BASED ON THE 2021 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA—Continued

Persons in family/household *	Income level **
8	89,320

For families with more than 8 persons, add \$9,080 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2020.

LOW INCOME LEVELS BASED ON THE 2021 POVERTY GUIDELINES FOR ALASKA

Persons in family/household *	Income level **
1	\$32,180
2	43,540
3	54,900
4	66,260
5	77,620
6	88,980
7	100,340
8	111,700

For families with more than 8 persons, add \$11,360 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2020.

LOW INCOME LEVELS BASED ON THE 2021 POVERTY GUIDELINES FOR HAWAII

Persons in family/household *	Income level **
1	\$29,640
2	40,080
3	50,520
4	60,960
5	71,400
6	81,840
7	92,280
8	102,720

For families with more than 8 persons, add \$10,440 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2020.

Separate poverty guidelines figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period since the U.S. Census Bureau poverty thresholds do not have separate figures for Alaska and Hawaii. The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. Puerto Rico and other outlying jurisdictions shall use income