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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–2019–N–2430]

Request for Nominations on Device Good Manufacturing Practice Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organization interested in participating in the selection of a nonvoting industry representative to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) in the Center for Devices and Radiological Health notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. A nominee may either be self-nominated or nominated by an organization to serve as a

nonvoting industry representative. Nominations will be accepted for an upcoming vacancy effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by *April 5, 2021* (see sections I and III of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by April 5, 2021.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing FDA's Advisory Committee Membership Nomination Portal at <https://www.accessdata.fda.gov/scripts/FACTRSportal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT:

Margaret Ames, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993–0002, 301–796–5960, margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 520 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j), as amended, provides that DGMPAC shall be composed of two representatives of interests of the device manufacturing industry. The Agency is requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. FDA is publishing a separate document announcing the request for notification for voting members on DGMPAC.

I. Function of DGMPAC

DGMPAC reviews proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packaging, storage, installation, and servicing of devices, and makes

recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

II. Qualifications

Persons nominated for DGMPAC should possess appropriate qualifications to understand and contribute to the committee's work as described in the committee's function.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the

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