



NDA 209803/S-008
NDA 209805/S-017
NDA 209806/S-011

CORRECTED SUPPLEMENT APPROVAL

Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.
Attention: Joanna Cossman, MS
Director, Global Regulatory Affairs
351 N. Sumneytown Pike, P.O. Box 1000
UG2D-44
North Wales, PA 19454-1099

Dear Joanna Cossman:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 28, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Steglatro (ertugliflozin) tablets and Steglujan (ertugliflozin and sitagliptin) tablets.

We also refer to your sNDA dated and received June 28, 2024, and your amendments, submitted pursuant to section 505(b)(2) of the FDCA for Segluromet (ertugliflozin and metformin hydrochloride) tablets.

We also refer to our approval letter dated December 20, 2024, which contained the following error: the letter described the supplements as Prior Approval sNDAs when they should have been described as "Changes Being Effectuated" sNDAs.

This corrected action letter incorporates the correction of the error. The effective action date will remain December 20, 2024, the date of the original letter.

These "Changes Being Effectuated" sNDAs provide for the addition of "rash" to subsection 6.2 *Postmarketing Experience*, of section 6 *Adverse Reactions* of the Prescribing Information for Steglatro, Steglujan, and Segluromet.

The "Changes Being Effectuated" sNDA for Steglujan also provides for the addition "eGFR less than" 30 mL/min/1.73 m² to the *Contraindications* section in the Highlights of Prescribing Information, Sections 2.2 *Recommended Dosage*, 4 *Contraindications*, and 8.6 *Renal Impairment* of the Steglujan Prescribing Information.

Additional edits were made throughout the Steglatro, Steglujan, and Segluromet Prescribing Information to modernize with current labeling guidances, clarify language, improve readability and organization of information, and align with other products. These edits include, but are not limited to, revisions to Section 2, *Temporary*

Interruption for Surgery and to Section 5, Warnings and Precautions for Lower Limb Amputation and Hypoglycemia with Concomitant Use with Insulin or Insulin Secretagogues.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental applications, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Michael Oyewole, Regulatory Project Manager, at Michael.Oyewole@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Monika Houstoun, PharmD, MPH
Deputy Director for Safety
Division of Diabetes, Lipid Disorders, and Obesity
Office of Cardiology, Hematology, Endocrinology,
and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Steglatro Prescribing Information
 - Steglatro Medication Guide (version approved on September 12, 2023)
 - Steglujan Prescribing Information
 - Steglujan Medication Guide (version approved on September 12, 2023)
 - Segluromet Prescribing Information
 - Segluromet Medication Guide (version approved on September 12, 2023)

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MONIKA A HOUSTOUN
12/23/2024 05:26:19 PM