CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

209805Orig1s000

Trade Name:	Steglujan tablets, 5 mg/100 mg and 15 mg/100 mg
Generic or Proper Name:	ertugliflozin and sitagliptin
Sponsor:	Merck Sharp & Dohme Corp.
Approval Date:	December 19, 2017
Indication:	For the use of Steglujan (ertugliflozin and sitagliptin) tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209805

NDA APPROVAL

Merck Sharp & Dohme Corp.
Attention: Vivian Fuh, M.D., F.A.C.P.
Executive Director, Global Regulatory Affairs
126 E. Lincoln Avenue, P.O. Box 2000
Mail Drop: RY34-B188
Rahway, NJ 07065

Dear Dr. Fuh:

Please refer to your New Drug Application (NDA) dated and received December 19, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Steglujan (ertugliflozin and sitagliptin) tablets, 5 mg/100 mg and 15 mg/100 mg.

This new drug application provides for the use of Steglujan (ertugliflozin and sitagliptin) tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions listed, the enclosed labeling (text for the prescribing information and Medication Guide). 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*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 209805**." Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for Steglujan (ertugliflozin and sitagliptin) was not referred to an FDA advisory committee because this drug is not the first in its class.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 through 9 years (inclusive) because necessary studies are impossible or highly impracticable. This is because there are too few children in this age range with type 2 diabetes mellitus to study.

We are waiving the pediatric study requirement for ages 10 through 17 years (inclusive) because this product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age range **and** is not likely to be used in a substantial number of pediatric patients in this age range. This determination was made based on the following:

> Appropriate studies to support the safety and effectiveness of this fixed dose combination product would require enrollment of patients who require treatment with three or more antihyperglycemic agents. The population of patients appropriate for such a study are small (estimated to be 1% of the pediatric type 2 diabetes mellitus population) and are impractical. Additionally, the fixed dose combination product does not provide any meaningful therapeutic benefit over the use of the separate individual products.

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