

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

208647Orig1s000

Trade Name: Ezallor

Generic or Proper Name: rosuvastatin

Sponsor: Sun Pharma Global FZE

Approval Date: December 18, 2018

Indication: Ezallor is indicated for:

- adult patients with hypertriglyceridemia as an adjunct to diet;
- adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet;
- adults with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB

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APPROVAL LETTER



NDA 208647

NDA APPROVAL

Sun Pharma Global FZE
c/o Salamandra, LLC
Attention: Karin Kook, Ph.D.
One Bethesda Center
4800 Hampden Lane, Suite 900
Bethesda, MD 20814-2998

Dear Dr. Kook:

Please refer to your New Drug Application (NDA) dated and received August 28, 2015, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ezallor (rosuvastatin) capsules.

We acknowledge receipt of your amendment dated June 18, 2018, which constituted a complete response to our June 22, 2016, action letter.

This new drug application provides for the use of Ezallor (rosuvastatin) capsules for:

- adult patients with hypertriglyceridemia as an adjunct to diet;
- adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet;
- adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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 the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

We acknowledge your submission received, December 10, 2018, containing final printed carton and container labeling.

ADVISORY COMMITTEE

Your application for Ezallor (rosuvastatin) capsule 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 (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.

The following comment pertains to the hypertriglyceridemia and dysbetalipoproteinemia indications:

- We are waiving the pediatric study requirement for these indications because necessary studies are impossible or highly impracticable due to the rarity of these diseases.

The following comments pertain to the homozygous familial hypercholesterolemia (HoFH) indication:

- We are waiving the pediatric study requirement for ages 0 to 6 years of age (inclusive) for this indication because necessary studies are impossible or highly impracticable given that HoFH is an extremely rare genetic disease.
- We are deferring submission of your pediatric study for ages 7 to 17 years of age (inclusive) for this application. See Deferred Pediatric Assessments below.

Deferred Pediatric Assessments

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(C) of the FDCA. This required study is listed below.

3559-1 Assessment of Ezallor (rosuvastatin) capsules for the treatment of homozygous familial hypercholesterolemia in pediatric patients ages 7 to 17 years of age (inclusive).

The timetable you submitted on December 18, 2018, states that you will conduct this study according to the following schedule:

Final Report Submission: December 2022

Reports of this/these required pediatric postmarketing study(ies) must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information, Medication Guide, and Patient Package Insert (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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, call Richard Whitehead, M.S., Regulatory Project Manager, at (301) 796-4945.

Sincerely,

{See appended electronic signature page}

William Chong, M.D.
Deputy Director (Acting)
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Prescribing Information
Patient Package Insert
Instructions for Use
Carton and Container Labeling

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/

WILLIAM H CHONG
12/18/2018