

NDA 211929

NDA APPROVAL

Sun Pharma Global FZE
Attention: Ronak Patel
US Agent for Sun Pharma Global FZE
Sun Pharmaceutical Industries, Inc.
2 Independence Way
Princeton, NJ 08540

Dear Ronak Patel:

Please refer to your new drug application (NDA) dated April 22, 2019, received April 22, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ORTIKOS (budesonide) extended-release capsules, 6 mg and 9 mg.

We acknowledge receipt of your amendment dated April 22, 2019, which constituted a complete response to our April 18, 2019, action letter.

This new drug application provides for the use of ORTIKOS (budesonide) extended-release capsules, 6 mg and 9 mg for:

- Treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years and older.
- Maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults.

APPROVAL & LABELING

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 enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

- Updated revision date in Highlights of the Prescribing Information and Patient Information to reflect the month of approval.
- Removed version date at the end of the Full 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, Patient Package Insert) 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 via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

We acknowledge your May 21, 2019, submission containing final printed carton and container labeling.

We find your proposed expiration date format acceptable from a safety perspective. We note that the draft guidance “Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers” (available at <https://www.fda.gov/media/116304/download>) is not binding on the FDA or the public; however it reflects the Agency’s current thinking on what expiration date formats are optimal.

Specifically, where there are no space limitations, we recommend YYYY-MM-DD if using only numeric characters, or YYYY-MMM-DD if using alphanumeric characters. Where there are space limitations, we recommend YYYY-MM if using only numeric characters or YYYY-MMM if using alphanumeric characters.

However, please note that the United States Pharmacopeia (USP) has proposed a standard for formatting expiration dates that aligns with the format stated in the Draft Guidance: Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers FDA. Therefore, we recommend that you consider adopting the recommended format of FDA and USP for all expiration dates in your entire product line.

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

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>.

the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

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

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 *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

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 FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵ For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.⁶

REPORTING REQUIREMENTS

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

³ When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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

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

⁶ <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>

If you have any questions, contact Lawrence Allan, Regulatory Project Manager, at (240) – 402 – 2786.

Sincerely,

{See appended electronic signature page}

Jessica J. Lee, MD, MMSc
Associate Director
Division of Gastroenterology and Inborn
Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling
Prescribing Information
Patient Package Insert
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/

JESSICA J LEE
06/13/2019 02:20:23 PM