



NDA 021324/S018

SUPPLEMENT APPROVAL

Perrigo Pharma International DAC
Attention: Jocelyn Clark-Greuel MS, PhD, RAC, CRC
Senior Manager, Regulatory Affairs (US Agent)
Paddock Laboratories, LLC
3940 Quebec Avenue North
Minneapolis, MN 55427

Dear Jocelyn Clark-Greuel:

Please refer to your Supplemental New Drug Application (sNDA) dated December 14, 2017, and your amendments submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ENTOCORT EC (budesonide) extended-release capsules, 3 mg.

This Prior Approval supplemental new drug application provides for changes to the Prescribing Information and Patient Prescribing Information (PPI) labeling to:

- allow the capsules to be opened and administered by sprinkling on soft foods, for patients who are unable to swallow an intact capsule; and
- change the dosage form nomenclature from “capsules” to “extended-release capsules”

APPROVAL & LABELING

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

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, Instructions for Use, and Medication Guide), with the addition of any

labeling changes in pending “Changes Being Effectuated” (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 titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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).

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

- 3075 – 1 An in-vivo study to compare pharmacokinetics of budesonide after administration of ENTOCORT EC (budesonide) as whole capsules and as granules sprinkled on soft food such as apple sauce or apple juice.

We have reviewed your submission and conclude that the above commitment was fulfilled.

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 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 Prescribing Information

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
01/18/2019 11:48:33 AM