



NDA 22307/S-013

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Anindita Sen, M.S., Ph.D.
Director, Global Regulatory Affairs – US
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Sen:

Please refer to your Supplemental New Drug Application (sNDA) dated 22 July 2015, received 22 July 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Effient (prasugrel hydrochloride) 5 mg and 10 mg Tablets.

This Prior Approval labeling supplement to your application proposes the following changes to the carton and container labeling:

- Repositioning the statements related to dispensing Effient in original container from the side panel to the principal display panel (PDP) to increase the prominence of these statements.
- Repositioning the equivalency statement which is currently on the PDP to a side panel.
- Adding the word “only” to the instruction: “Keep and dispense only in original container. Keep container closed and do not remove dessicant from bottle.”

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below.

- For the Identi-dose® blistercard carton labeling, please ensure the lot number and expiration date in the black square placeholder on the carton labeling are clearly identified as such.

The following comments are not linked to this supplement, but should be considered with your next update to the Full Prescribing Information (FPI) and Medication Guide:

1. Please add the word “only” to the following instructions found in Section 16.2 (**HOW SUPPLIED/STORAGE AND HANDLING/Storage and Handling**) of the FPI and

Medication Guide: “Keep and dispense only in original container,” in order to maintain consistency with the revised Effient container labels.

2. Information should be added to Section 17 (**PATIENT COUNSELING INFORMATION**) of the FPI and the Medication Guide to emphasize that the tablets should not be broken.
3. Please add the following statement that is already in the Medication Guide to FPI Section 17 “Inform patients to keep Effient in the container in which it comes, and keep the container closed tightly with the gray cylinder (desiccant) inside.”

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, except with the revisions listed above, 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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 22307/S-013.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, please call:

Alison Blaus, RAC
Senior Regulatory Project Manager
(301) 796-1138

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, MD, PhD
Director
Division of Cardiovascular & Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE
01/14/2016