



NDA 021695/S-019

SUPPLEMENT APPROVAL

Lupin Pharmaceuticals, Inc.
US Agent for Lupin Atlantis Holdings SA
Attention: Debashis Mohanty
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21201

Dear Mr. Mohanty:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 1, 2018, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Antara (fenofibrate) capsules, 30 mg, 43 mg, 87 mg, 90 mg, and 130 mg.

We refer to our letters dated February 6, 2018, and October 3, 2018, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for fenofibrate products. This information pertains to the risk of severe cutaneous adverse drug reactions, anaphylaxis and angioedema, and photosensitivity. Supplement -017 was approved May 18, 2018, and pertains to the currently branded Antara products, 30 mg, and 90 mg. Supplement -019 pertains to the remaining strength capsules, 43 mg, 87 mg, and 130 mg.

This sNDA provides for revisions to the labeling for Antara strengths 43 mg and 130 mg. The agreed upon changes to the language included in our October 3, 2018, letter are as follows (additions are noted by underline and deletion are noted by ~~strikethrough~~).

Under Section 6.2 (ADVERSE REACTIONS, Postmarketing Experience):

Photosensitivity reactions have occurred days to months after initiation;-(b) (4); in some of these cases, patients (b) (4)-reported a prior photosensitivity reaction to ketoprofen.

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.

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), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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).

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.

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

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 Kati Johnson, Senior Regulatory Project Manager, at 301-796-1234.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:

Content of Labeling

Prescribing Information (43 mg and 130 mg strengths)

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
11/07/2018