



NDA 021203/S-009, NDA 021656/S-029, NDA 022224/S-015

SUPPLEMENT APPROVAL

AbbVie Inc.
Aansh Jarmarwala, PharmD, RAC
Senior Manager, Global Regulatory Strategy
Dept. PA77, Bldg. AP30-1
1 North Waukegan Road
North Chicago, IL 60064

Dear Dr. Jarmarwala:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received September 28, 2018, and your amendments, submitted under section 505(b) (Tricor) and pursuant to 505(b)(2) (Trilipix) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 021203/S-009; Tricor (fenofibrate) tablets, 54 mg, 160 mg
NDA 021656/S-029; Tricor (fenofibrate) tablets, 48 mg, 145 mg
NDA 022224/S-015; Trilipix (fenofibric acid) capsules, 45 mg, 135 mg

These “Changes Being Effected” supplemental new drug applications provide for revision to the ADVERSE REACTIONS section, 6.2 Postmarketing Experience subsection, of the prescribing information to add “interstitial lung disease”.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 these NDAs, 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 applications, 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

ENCLOSURES:

Content of Labeling
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/

WILLIAM H CHONG
03/28/2019 10:09:21 AM