



NDA 203214/S-023
NDA 208246/S-011

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Louis M. Ferrara
Director, Worldwide Safety and Regulatory
445 Eastern Point Road
Groton, CT 06340

Dear Mr. Ferrara:

Please refer to your supplemental New Drug Applications (sNDA) dated January 29, 2019, received January 29, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for XELJANZ (tofacitinib) tablets (5 mg and 10 mg) and XELJANZ XR (tofacitinib) extended-release tablet (11 mg).

We also refer to our approval letter dated August 30, 2019 which contained the following error: Incorrect numbers in the descriptive statistics for Study A3921139 (Study UC-IV) study in Section 14.3 of the Prescribing Information (PI).

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 30, 2019, the date of the original approval letter.

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 the following editorial change to the PI: added 10/2018 date to Dosage and Administration (2.3) under Recent Major Changes in Highlights.

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 and Medication Guide), 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.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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 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).

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, contact Kelly Richards, Senior Regulatory Health Project Manager, at (240) 402-4276 or kelly.richards@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD, MPH
Deputy Director for Safety
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
 - Medication Guide

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>.

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/

JOYCE A KORVICK
08/30/2019 12:00:00 AM