



NDA 022350/S-023
NDA 200678/S-024
NDA 209091/S-004
NDA 210874/S-001

SUPPLEMENT APPROVAL

AstraZeneca AB
c/o AstraZeneca Pharmaceuticals LP
Attention: Nicole Shepard
Associate Director of Regulatory Affairs
One MedImmune Way
Gaithersburg, MD 20878

Dear Ms. Shepard:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 17, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Onglyza (saxagliptin) tablets, Kombiglyze XR (saxagliptin and metformin hydrochloride extended-release) tablets, Qtern (dapagliflozin and saxagliptin) tablets, and Qternmet XR (dapagliflozin, saxagliptin, and metformin hydrochloride) extended-release tablets.

We also refer to our letter dated May 3, 2019, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for dipeptidyl peptidase-4 (DPP-4) inhibitors, including Onglyza, Kombiglyze XR, Qtern, and Qternmet XR. This information pertains to the risk of rhabdomyolysis.

These supplemental new drug applications provide for revisions to the labeling for Onglyza, Kombiglyze XR, Qtern, and Qternmet XR, consistent with our May 3, 2019 letter.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 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 *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).

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.

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

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>.

NDA 022350/S-023
NDA 200678/S-024
NDA 209091/S-004
NDA 210874/S-001
Page 3

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 Richard Whitehead, M.S., Regulatory Project Manager, at (301) 796-4945.

Sincerely,

{See appended electronic signature page}

William Chong, M.D.
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 and Medication Guides) for Onglyza, Kombiglyze XR, Qtern, and Qternmet XR

U.S. Food and Drug Administration



Find authenticated court documents without watermarks at docketalarm.com.

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
07/01/2019 07:50:31 AM