BLA 761071/S-019

SUPPLEMENT APPROVAL

Sandoz Inc.
100 College Road West
Princeton, NJ 08540

Attention: Anthony Narisetty
Senior Manager, US Biosimilar RA Team

Dear Anthony Narisetty:

Please refer to your supplemental biologics license application (sBLA) dated and received June 7, 2023, and your amendments, submitted under section 351(k) of the Public Health Service (PHS) Act for Hyrimoz (adalimumab-adaz) injection.

This Category F Prior Approval supplemental biologics license application seeks licensure of Hyrimoz (adalimumab-adaz) injection for subcutaneous use as interchangeable with US-licensed Humira (adalimumab) injection for subcutaneous use as follows:

- Hyrimoz 40 mg/0.8 mL in a prefilled syringe (PFS) as interchangeable with US-Humira 40 mg/0.8 mL in a PFS.
- Hyrimoz 20 mg/0.4 mL in a PFS as interchangeable with US-Humira 20 mg/0.4 mL in a PFS.
- Hyrimoz 10 mg/0.2 mL in a PFS as interchangeable with US-Humira 10 mg/0.2 mL in a PFS.
- Hyrimoz 80 mg/0.8 mL in a PFS as interchangeable with US-Humira 80 mg/0.8 mL in a PFS.
- Hyrimoz 40 mg/0.4 mL in a PFS as interchangeable with US-Humira 40 mg/0.4 mL in a PFS.
- Hyrimoz 20 mg/0.2 mL in a PFS as interchangeable with US-Humira 20 mg/0.2 mL in a PFS.
- Hyrimoz 10 mg/0.1 mL in a PFS as interchangeable with US-Humira 10 mg/0.1 mL in a PFS.

Hyrimoz is licensed as biosimilar to US-licensed Humira for the following indications:

- Rheumatoid Arthritis (RA): reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA.

- Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.
- Psoriatic Arthritis (PsA): reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
- Ankylosing Spondylitis (AS): reducing signs and symptoms in adult patients with active AS.
- Crohn's Disease (CD): treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- Ulcerative Colitis (UC): treatment of moderately to severely active ulcerative colitis in adult patients.
- Plaque Psoriasis (Ps): treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
- Hidradenitis Suppurativa (HS): treatment of moderate to severe hidradenitis suppurativa in adult patients.
- Uveitis (UV): treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

For administrative purposes, we have split S-019 into the following supplements:

- BLA 761071/S-019 – Hyrimoz (adalimumab-adaz) 40 mg/0.8 mL, 20 mg/0.4 mL, 10 mg/0.2 mL, 80 mg/0.8 mL, 20 mg/0.2 mL, and 10 mg/0.1 mL in a PFS.
- (b) (4)

The subject of this correspondence is BLA 761071/S-019. (b) (4)

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.

FIRST INTERCHANGEABLE EXCLUSIVITY

Section 351(k)(6) of the PHS Act provides:

> The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies

on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)

(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken and the term "first interchangeable biosimilar biological product" means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product.

Hyrimoz (adalimumab-adaz) injection, 80 mg/0.8 mL, 20 mg/0.2 mL, and 10 mg/0.1 mL for subcutaneous use are the first products relying on their respective reference products to receive a determination of interchangeability for any condition of use. Therefore, with this approval, these products qualify as first interchangeable biosimilar biological products for purposes of section 351(k)(6) of the PHS Act. The expiration date of any first interchangeable exclusivity has yet to be determined.

Submit a general correspondence to this 351(k) BLA informing the Agency of the date of any final court decision (as defined in section 351(k)(6) of the PHS Act) on all patents in suit in any action implicating this BLA instituted under section 351(l)(6) of the PHS Act, or

the date of dismissal with or without prejudice of any action implicating this BLA instituted under section 351(l)(6), within 30 days of such date or within 30 days of this approval if such date occurred prior to approval. If any action implicating this BLA instituted under section 351(l)(6) is still ongoing at the time of this approval, submit a general correspondence informing the Agency of this within 30 days of this approval. Submit a duplicate copy of the correspondence(s) via email to PurpleBook@fda.hhs.gov.

WAIVER OF HIGHLIGHTS 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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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).

[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.

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We remind you that postmarketing requirement 3506-3 in the October 30, 2018 approval letter is still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

Your products are Part 3 combination products (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, call Sadaf Nabavian, Sr. Regulatory Project Manager, at 301-796-2777.

Sincerely,

{See appended electronic signature page}

Raj Nair, MD
Director (Acting)
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling

- Prescribing Information
- Medication Guide (revised September 2023)
- Instructions for Use (revised March 2023)

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/

RAJ NAIR
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