



BLA 761058/S-014

SUPPLEMENT APPROVAL

Boehringer Ingelheim Pharmaceuticals Inc
Attention: Christopher Dougherty
Director Regulatory Affairs
900 Ridgebury Rd
Ridgefield, CT 06877

Dear Mr. Dougherty:

Please refer to your supplemental biologics license application (sBLA) dated and received April 4, 2022, and your amendment, submitted under section 351(k) of the Public Health Service Act for Cyltezo (adalimumab-adbm) injection.

This Prior Approval sBLA provides for revisions to the 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL prefilled syringe carton labeling, including a statement "citrate free" on the principal display panel.

APPROVAL & LABELING

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

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](http://www.fda.gov)¹, that is identical to the enclosed labeling (text for the prescribing information) and include the labeling changes proposed in any pending "Changes Being Effectuated" (CBE) supplements.

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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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 Effectuated" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

CARTON AND CONTAINER LABELS

We acknowledge your July 18, 2022, submission containing final printed carton and container labeling.

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).

If you have any questions, call Melinda Bauerlien, Senior Regulatory Business Process Manager, at (301) 796 - 0906.

Sincerely,

{See appended electronic signature page}

Susan Kirshner, Ph.D.
Director
Division of Biotechnology Review and Research III
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



Susan
Kirshner

Digitally signed by Susan Kirshner

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