NDA 050778/S-029

APPROVAL LETTER

Pfizer Inc
Attention: William Vogt
Director, Pfizer Global Regulatory Sciences
66 Hudson Boulevard East
New York, NY 10001

Dear William Vogt:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 3, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ellence (epirubicin hydrochloride injection).

We acknowledge receipt of your amendment dated September 5, 2024, which constituted a complete response to our March 1, 2024, action letter.

This Prior Approval supplemental new drug application provides for the following:

- Addition of an alternate manufacturer, (b) (4) for epirubicin hydrochloride drug substance as referenced under DMF (b) (4)
- Addition of (b) (4) as an alternative site for the manufacture of the drug product.

APPROVAL & LABELING

We have completed our review of this supplemental application, 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 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, except with the revisions indicated, the enclosed labeling (text for the perscribing 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.

Information on submitting PL files using eLI T 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 UCM07 3 .pdf.

The PL will be accessible via 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 [1 CFR 314.50(l)(1)(i)] in M S Word format, that includes the changes with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

CARTON AND CONTAINER LABELS

ubmit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on eptember 5, 0 4, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 050778/S-029.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 1 CFR 314.80 and 314.81. n

If you have any questions, contact Utkarsh Desai, Regulatory Business Process Manager, at Utkarsh.Desai@fda.hhs.gov or (301) 7 6 8114.

incerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
upervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

- Content of Labeling
- Carton and Container Labeling

Ramesh U Raghava ha

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