NDA 050718/S-060

SUPPLEMENT APPROVAL

Baxter Healthcare Corp
Attention: Jenifer Avenatti
Associate Director, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, IL 60073

Dear Ms. Avenatti:

Please refer to your Supplemental New Drug Application (sNDA) dated November 5, 2021, and received November 8, 2021, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DOXIL (doxorubicin hydrochloride liposome injection).

This "Changes Being Effected" supplemental new drug application provides for changes to the drug product labeling as specified in the Agency's Supplement Request Letter dated September 20, 2021.

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 agreed-upon labeling and with minor editorial revisions listed below and reflected in the enclosed labeling.

A. Dosage and Administration Section, Doxil and Doxorubicin Hydrochloride Liposome Injection Full PI
    a. We recommend adding an "s" to the word "minute" in the fourth bullet under the Management of Suspected Extravasation section, as follows: "15 minutes".

B. How Supplied/Storage and Handling Section, Doxil PI
    a. We recommend adding a space between the words "not" and "freeze" in the following storage instructions: "Do not_freeze".

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 listed, 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 SPL files using eLIST may be found in the guidance for industry *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 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 MS Word format, that includes the changes with the revisions listed 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

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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 050718/S-060.**" Approval of this submission by FDA is not required before the labeling is used.

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 Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, B1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
Date: 5/06/2022 07:41:54PM
GUID: 502d0913000029f375128b0de8c50020