NDA 012041/S-052

APPROVAL LETTER

Bristol-Myers Squibb Company
Attention: Maria Wagner, PhD
Director, Global Regulatory Sciences
P.O. Box 5326
Princeton, NJ 08543-5326

Dear Dr. Wagner:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 19, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kenalog-10 Injection (triamcinolone acetonide injectable suspension, USP).

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

- Updates to the United States Prescribing Information (USPI) for Kenalog-10 Injection (triamcinolone acetonide injectable suspension, USP) to define and clarify agglomeration of the drug product and to include an excursion range in accordance with an 02/16/2024 update made to the Company Core Data Sheet (CCDS).
- Updates to the drug product storage conditions in Module 3.2.P.8 (Stability) and to the USPI and carton labeling. Proposed changes include:
  - the addition of the instruction “Do not refrigerate” to the USPI to align with text included on the approved carton labeling.
  - the addition of a temperature excursion limit for the drug product to both the USPI and carton labeling.
  - an update to the instructions in the USPI for in-use storage conditions of the drug product after opening the multi-dose vial presentation of Kenalog-10 Injection (triamcinolone acetonide injectable suspension, USP).

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 the enclosed labeling (text for the prescribing 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/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 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 012041/S-052.**" 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 21 CFR 314.80 and 314.81.

If you have any questions, please contact Stephanie Ngan at Stephanie.Ngan@fda.hhs.gov or (240) 402-5932.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Supervisor, Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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