NDA 020220/S-055 and NDA 021425/S-037

SUPPLEMENT APPROVAL

Bayer Healthcare Pharmaceuticals Inc
Attention: Megan Socaciu
Director, Global Regulatory Affairs
100 Bayer Blvd. P.O. Box 915
Whippany, NJ 07981

Dear Ms. Socaciu:

Please refer to your supplemental New Drug Application(s) (sNDA) pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 020220/S-055	Ultravist (iopromide) Injection	December 15, 2022	December 15, 2022
NDA 021425/S-037	Ultravist (iopromide) Injection Imaging Bulk Package	December 15, 2022	December 15, 2022

These Prior Approval supplemental new drug applications provide for labeling changes as specified in the Agency's supplement request letter dated 09/20/2022.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 these supplemental applications, 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 020220/S-055.**" 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 Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}
Signed For:
Ramesh Raghavachari, PhD
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality

Center for Drug Evaluation and Research

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

Rohit Kolhatkar

Digitally signed by Rohit Kolhatkar
Date: 6/15/2023 02:50:53PM
GUID: 57bf531500b52a2eccd5395bec77ebc2
Comments: Approving for Ramesh Raghavachari