



NDA 201277/S-032

SUPPLEMENT APPROVAL

Bayer Healthcare Pharmaceuticals Inc.
Attention: Diane-Fleur Kadio Atta, PharmD, MBA
Senior Manager, Regulatory Affairs
100 Bayer Boulevard, P.O. Box 0915
Whippany, NJ 07981-1544

Dear Dr. Kadio Atta:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 30, 2026, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gadavist (gadobutrol injection).

This “Changes Being Effectuated” supplemental new drug application provides for updates to the Prescribing Information and the prefilled syringes carton and container labeling as follows:

1. Updates to the Full Prescribing Information– Section 16, "How Supplied/Storage and Handling" to include plastic prefilled syringe information.
2. Addition of carton and container labeling for 7.5 mL, 10 mL, and 15 mL plastic prefilled syringes.

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, and Medication Guide) with the addition of any labeling changes in pending “Changes Being Effectuated” (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>.

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 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 and carton and container labels submitted on June 11, 2026, 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 201277/S-032.**” Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, contact Shazma Aftab, PharmD, Regulatory Business Process Manager, at (301) 796 - 3138 or shazma.aftab@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Brock Roughton, PhD
Supervisor
Division of Product Quality Assessment XI
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling
Content of Labeling



Brock
Roughton

Digitally signed by Brock Roughton

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