

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

216016Orig1s000

216017Orig1s000

***Trade Name:* Iomervu Injection, 250, 300, 350, 400 mg Iodine/mL**

***Generic or Proper Name:* (iomeprol)**

***Sponsor:* BRACCO DIAGNOSTICS, INC.**

***Approval Date:* November 27, 2024**

***Indication:* Provides for the use of Iomervu (iomeprol) injection as a radiographic contrast agent indicated for:**

Intra-arterial Procedures

- Cerebral arteriography, including intra-arterial digital subtraction angiography (IA-DSA), in adults and pediatric patients
- Visceral and peripheral arteriography and aortography, including IA-DSA, in adults and pediatric patients
- Coronary arteriography and cardiac ventriculography in adults
- Radiographic evaluation of cardiac chambers and related arteries in pediatric patients

Intravenous Procedures

- Computed tomography (CT) of the head and body in adults and pediatric patients
- CT angiography of intracranial, visceral, and lower extremity arteries in adults and pediatric patients
- Coronary CT angiography in adults and pediatric patients
- CT urography in adults and pediatric patients

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APPROVAL LETTER



NDA 216016 & 216017

NDA APPROVAL

Bracco Diagnostics Inc
Attention: Cheryl Dicks, MSc., RAC
259 Prospect Plains Road
Building H
Monroe Township, NJ 08831

Dear Cheryl Dicks:

Please refer to your new drug applications (NDA) dated November 30, 2023, and December 14, 2023, received November 30, 2023, and December 14, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Iomervu (iomeprol) injection.

These NDAs provide for the use of Iomervu (iomeprol) injection as a radiographic contrast agent indicated for:

Intra-arterial Procedures

- Cerebral arteriography, including intra-arterial digital subtraction angiography (IA-DSA), in adults and pediatric patients
- Visceral and peripheral arteriography and aortography, including IA-DSA, in adults and pediatric patients
- Coronary arteriography and cardiac ventriculography in adults
- Radiographic evaluation of cardiac chambers and related arteries in pediatric patients

Intravenous Procedures

- Computed tomography (CT) of the head and body in adults and pediatric patients
- CT angiography of intracranial, visceral, and lower extremity arteries in adults and pediatric patients
- Coronary CT angiography in adults and pediatric patients
- CT urography in adults and pediatric patients

APPROVAL & LABELING

We have completed our review of this 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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling text for the Prescribing Information, 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*.²

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 216016 & 216017.**” Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for lomervu (iomeprol) injection shall be 24 months from the date of manufacture when stored at 25°C/60%RH in the carton protected from light.

ADVISORY COMMITTEE

Your application for lomervu was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

PMC 4661-1 (NDA 216017)
PMC 4662-1 (NDA 216016)

Quality CMC Study for Environmental Assessment

The timetable you submitted on May 10, 2024, states that you will conduct this study according to the following schedule:

Final Report Submission: 01/25

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

POST APPROVAL FEEDBACK MEETING

New molecular entities qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, contact Frank Lutterodt, Regulatory Project Manager, at 301-796-4251.

Sincerely,

{See appended electronic signature page}

Alexander Gorovets, M.D.
Deputy Director
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALEXANDER GOROVETS
11/27/2024 11:37:40 PM