



NDA 208143/S-013

**APPROVAL LETTER**

Bracco Diagnostics Inc  
Attention: Jo Anna Monteferrante  
259 Prospect Plains Rd  
Building H  
Monroe Township, NJ 08831-3820

Dear Ms. Monteferrante:

Please refer to your Supplemental New Drug Application (sNDA) dated September 15, 2021, received September 15, 2021, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tagitol V (barium sulfate) Oral Suspension.

*We also refer to our approval letter dated March 10, 2022, which contained the following errors:*

- 1. The revised date on the first page of labeling displayed “Revised: 12/2021” at the conclusion of the Highlights of Prescribing Information. The correct date is 03/2022.*
- 2. The revised date on the last page of the package insert displayed “rev. 01/22” The correct date is 03/22.*
- 3. The revised date on the carton and container labeling displayed “rev. 01/22” The correct date is 03/22.*

*This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 10, 2022, the date of the original approval letter.*

This “Changes Being Effected in 30 days” supplemental new drug application provides for:

Alternative container/closure system; (b) (4)

**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 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>.

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 208143/S-013.**” 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, contact Lana Rossiter, Regulatory Business Process Manager, at [Lana.Rossiter@fda.hss.gov](mailto:Lana.Rossiter@fda.hss.gov) or (301) 796 - 6823.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, PhD  
Branch Chief, Branch 1  
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



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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