DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22090/S-011

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals, Inc.
Attention: Dolores Fliss, BS, MSA
Associate Director, Global Regulatory Affairs-Contrast Agents
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981- 0915

Dear Ms. Fliss:

Please refer to your Supplemental New Drug Application (sNDA) dated December 19, 2013, received May 29, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Eovist® (Gadoxetate Disodium) single dose, rubber stoppered vials, 10mL single–dose vials filled with 10 mL.

We acknowledge receipt of your amendment(s) dated June 10, 2014; September 17, 2014; March 4, 2015; March 12, 2015 and March 26, 2015.

This "Prior Approval" supplemental new drug application proposes to add the clinical findings from an observational study in pediatric age group greater than 2 months to 18 years in section 8.4 of the package insert in fulfillment of a PMR from July 2008 approval letter.

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 text.

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 package insert), 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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).

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.

We note that you have fulfilled PMR 1324-2, the pediatric study requirement for ages greater than 2 months to 18 years, for this application as stated in FDA Fulfillment letter dated November 25, 2014.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)

We reference your submission dated November 27, 2013, Final Report for PMR 1324-2 and your interim report/ submission dated March 4, 2015, reporting on the following postmarketing requirement:

1324-1 Deferred pediatric study under PREA for use in magnetic resonance imaging (MRI) of the liver in pediatric patients ages 0 to 2 months with known or suspected hepatobiliary pathology. This study will obtain evaluable safety and imaging data from at least 10 subjects, however, due to the anticipated rarity of these clinical conditions in this pediatric population, progress towards recruitment will be assessed at one year after study start and the targeted number of patients may require adjustment. Any adjustment in the sample size will be supplied in a protocol amendment that contains supportive information and a request for FDA concurrence. Descriptive statistics will summarize safety and efficacy outcomes. Efficacy determination will be based upon extrapolation from studies in other patient populations.

Protocol Submission: November, 2011
Study Start: May, 2012
Final Report Submission: May, 2014

We note the FDA granted deferral extension of the Final Report Submission date to the following:

New Final Report Submission: December, 2015

We have reviewed your submissions and conclude that the above requirement was fulfilled.

This completes all of your postmarketing requirements acknowledged in our July 3, 2008, letter.

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Alberta Davis-Warren, Regulatory Project Manager, at (301) 796-3908.

Sincerely,

{See appended electronic signature page}

Libero Marzella, MD, PhD
Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LIBERO L MARZELLA
03/27/2015