DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-711/S-001 **SUPPLEMENT APPROVAL**

Lantheus Medical Imaging
Attention: Mary E. Taylor, MPH
Vice President Global Regulatory Affairs
331 Treble Cover Road
North Billerica, MA 01862

Dear Ms. Taylor:

Please refer to your supplemental new drug application dated April 17, 2009, received April 17, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VASOVIST® (gadofosveset trisodium) Injection.

We acknowledge receipt of your submissions dated May 19, June 10, July 10 and 15, October 14 and 16, and November 11, 2009.

This "Prior Approval" supplemental new drug application provides for a change in the proprietary name of the product from VASOVIST® to Ablavar.

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 text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 21-711/S-001."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on

heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for approved NDA 21-711/S-001." Approval of this submission by FDA is not required before the labeling is used.

PROPRIETARY NAME

The proposed proprietary name, Ablavar, was found acceptable on July 17, 2009.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A)).

We reiterate the postmarketing requirement for your product, as described in our approval letter of December 22, 2008. As described in that letter, you are required to conduct the following:

1. A clinical trial to collect clinical data sufficient to assess the magnitude of risk for the development of NSF (nephrogenic systemic fibrosis) with your product among patients with moderate (GFR < 60 mL/min/1.73m^2) to severe renal insufficiency.

The timetable cited in our December 22, 2008, letter stated that you will conduct this clinical trial according to the following timetable:

Protocol Submission:	June, 2009
Trial Start Date:	September, 2009
Final Report Submission:	September, 2014

We acknowledge submission of the protocol to your IND on October 8, 2009 with a cross-reference letter to this NDA. Because this protocol submission date differs from that specified in timetable listed in the December 22, 2008, approval letter, we consider the status of this postmarketing requirement to be delayed, and this status has been posted on the FDA Postmarketing Requirement and Commitments website:

http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm.

On November 11, 2009, you submitted a proposed, revised timetable that differs from the timetable listed above and cited in our December 22, 2008, letter. We remind you that an applicant's failure to comply with the approved timetable, periodic report submissions, and other requirements of section 505(o)(3)(E)(ii) will be considered a violation of that subsection unless the applicant demonstrates good cause for the noncompliance. Under section 505(o)(3)(E)(ii) of the Act, FDA will determine what constitutes good cause.

Submit all final reports to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate:

- **REQUIRED POSTMARKETING PROTOCOL UNDER 505(o)**
- **REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o)**
- **REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o)**

PROMOTIONAL MATERIALS

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 James Moore, Regulatory Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

Rafel Rieves, M.D.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure(s)
Content of Labeling
Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21711	SUPPL-1	LANTHEUS MEDICAL IMAGING INC	VASOVIST(GADOFOSVESET TRISODIUM)0.25MMO1

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

/s/

JAMES W MOORE
01/11/2010

RAFEL D RIEVES
01/11/2010