

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-066**

**PROPRIETARY NAME REVIEW(S)**

**MEMORANDUM****Division of Medication Errors and Technical Support  
Office of Surveillance and Epidemiology  
(HFD-420; White Oak Bldg. 22, Mail Stop 4447)  
Center for Drug Evaluation and Research**

**TO:** Rafel Rieves, M.D.  
Acting Director, Division of Medical Imaging and Hematology Products

**THROUGH:** Linda Y. Kim-Jung, Pharm.D., Team Leader  
Denise Toyer, Pharm.D., Deputy Director  
Carol Holquist, R.Ph., Director  
Division of Medication Errors and Technical Support, HFD-420

**FROM:** Todd Bridges, R.Ph., Safety Evaluator  
Division of Medication Errors and Technical Support, HFD-420

**DATE:** March 9, 2007

**SUBJECT:** DMETS Label Review  
Drug: Omniscan  
(Gadodiamide Injection)  
287 mg/mL  
NDA #: 22-066  
Sponsor: GE Healthcare

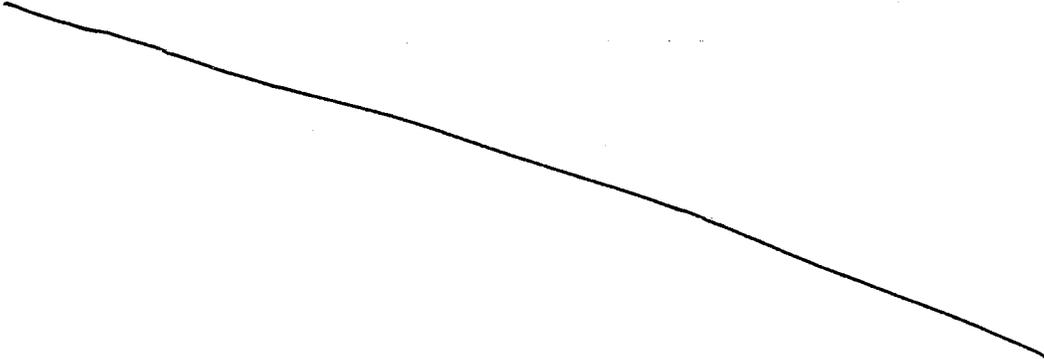
**OSE REVIEW #:** 2007-179

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This memorandum is in response to a February 12, 2007, request from the Division of Medical Imaging and Hematology Products (HFD-160) for a review of the pharmacy bulk container labels of Omniscan.

OSE review 05-0142 and 05-0142-1 (dated March 16, 2006) pertained to safety concerns with Omniscan and other contrast agents. Recommendations made in the aforementioned review will not be restated in this review but will be discussed during an upcoming meeting between DMETS and the Division, which will occur as soon as scheduling permits.

Upon review of the pharmacy bulk package labels of Omniscan, DMETS has identified the following areas of improvement, in the interest of minimizing user error and maximizing patient safety.

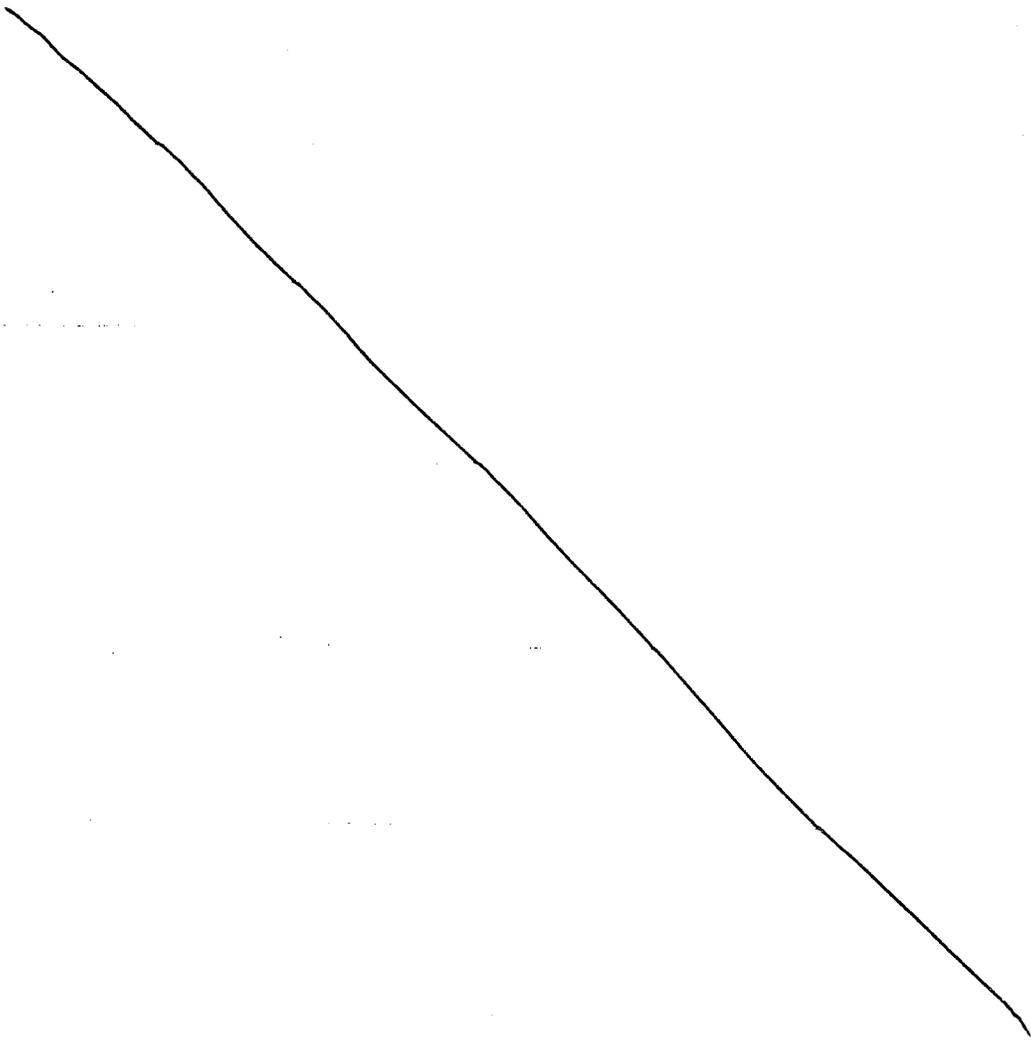


1   Page(s) Withheld

       Trade Secret / Confidential

  ✓   Draft Labeling

       Deliberative Process



DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Sam Chan, OSE Project Manager, at 301-796-2283.

APPEARS THIS WAY ON ORIGINAL

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/s/

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Todd Bridges  
3/22/2007 05:17:50 PM  
DRUG SAFETY OFFICE REVIEWER

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