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APPLICATION NUMBER:

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RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	August 4, 2009
To:	Rafel (Dwaine) Rieves, M.D., Director Division of Medical Imaging and Hematology Products (DMIHP)
Through:	Claudia Karwoski, Pharm.D., Director Division of Risk Management (DRISK) Office of Surveillance and Epidemiology (OSE)
From:	Kathryn O'Connell, MD, PhD, Medical Officer (DRISK) Mary Dempsey, Risk Management Coordinator (DRISK)
Subject:	Review of Risk Management Plan
Drug Name(s):	DaTSCAN™ (123I-ioflupane)
Submission Number:	Original NDA
Application Type/Number:	NDA 22-454
Applicant/sponsor:	GE Healthcare
OSE RCM #:	2009-1114

1 INTRODUCTION

This memorandum responds to a Division of Medical Imaging and Hematology Products (DMIHP) request that the Office of Surveillance and Epidemiology (OSE) review and comment on the DaTSCAN™ (123I-ioflupane) Risk Management Plan. The plan was included in the New Drug Application (NDA 22-454) submission dated March 6, 2009.

DaTSCAN™ (123I-ioflupane) is a radiopharmaceutical imaging agent with the following proposed indication: "for detecting loss of functional nigrostriatal dopaminergic neurons by single photon emission computed tomography (SPECT) imaging in patients presenting with symptoms or signs suggestive of dopaminergic neurodegeneration." The product was approved for marketing in Europe in 2000 and is currently licensed in over 32 countries. Over (b) (4) patients have received the product.

2 MATERIAL REVIEWED

The following materials were reviewed:

- Proposed Risk Management Plan in NDA 22-454 Section 1.6 pages 1 and 2. (March 6, 2009)
- FDA Briefing Document for planned August 11, 2009 Advisory Committee meeting

3 RESULTS OF REVIEW

FDA's review of the clinical and supportive data is ongoing, but based on trial data and extensive post-marketing experience, neither the sponsor nor the review division have identified safety concerns for this product. The Advisory Committtee is being convened to address whether the data support the proposed indication, and whether the clinical utility of DaTSCAN is self-evident, since it was not directly assessed in clinical studies. In other words, FDA is seeking advice on whether there is "added value" of using this diagnostic product compared to clinical diagnosis.

The sponsor has proposed post-marketing risk management consisting of labeling and routine pharmacovigilance.

4 CONCLUSION

Based on the information reviewed and discussion with the clinical reviewer in DMIHP, we agree with the sponsor that labeling (which we have not reviewed) and routine pharmacovigilance suffice for this product and that a REMS is not needed. If on-going review identifies unexpected safety concerns for possible risk mitigation, please re-consult us.

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/s/

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08/21/2009

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08/24/2009