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*APPLICATION NUMBER:*

**022454Orig1s000**

**OFFICE DIRECTOR MEMO**

**Office Director Memorandum**

NDA #: 22-454

Drug Name: DaTscan (Ioflupane I 123)

Sponsor: GE Healthcare

Memo Date: 1-12-11

Subject: Office Director Memo for New Drug Application

As noted in the Division Director memo, this is the third cycle for this application. I will not go into detail about past history, but will focus on the current review cycle. The date of submission for this cycle is November 16, 2010 with a PDUFA date of January 14, 2011. DaTscan is a radiopharmaceutical indicated for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected Parkinson's syndromes. GE healthcare received a complete response letter on December 22, 2009 in which the major deficiency related to the need to incorporate Controlled Substance text in the package insert. The drug is a derivative of cocaine and, as such, requires DEA scheduling. During the second review cycle, GE healthcare did not want to have Controlled Substance labeling which led to the complete response letter. The company has had a change of opinion, and now agrees that Controlled Substance labeling can be included in the drug product labeling (b) (5)

In the December 22, 2009 letter, two post-marketing issues were identified and the company has responded in this submission. The two issues were as follows:

1) to conduct a clinical trial that assesses the agreement between DaTscan imaging results and diagnostic outcomes among non-Caucasian and Caucasian patients. The trial will be designated and conducted in a manner that allows a comparison of the results between the non-Caucasian and Caucasian patients.

2) to conduct a clinical trial that assesses the impact of dopaminergic drugs upon DaTscan results. In addition to any other drugs, levodopa and carbidopa effect should be studied in this trial.

The company has provided a protocol to IND 101,016 for a clinical trial to evaluate the imaging results and diagnostic outcomes between non-Caucasian and Caucasian patients. The medical reviewer has found this protocol to be satisfactory and the company has provided dates for completion of the study. A post-marketing commitment remains for this issue. With regard to the second issue, the clinical pharmacology reviewer found the submission to be adequate and provided sufficient information so that this issue is resolved and is no longer a post-marketing commitment.

I recommend approval of the application.

Charles J. Ganley, M.D. \_\_\_\_\_  
Director, Office of Drug Evaluation IV

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CHARLES J GANLEY  
01/12/2011