

COOK®

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August 11, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Citizen Petition

Dear Sir or Madam:

Cook Imaging requests the commissioner of Food and Drugs to allow Cook Imaging Corporation to submit a supplement to Iopamidol Injection, ANDA #74-881, in a dosage form which is not identical to the listed drug, Isovue Injection. Cook Imaging has documented the request on the enclosed Citizen Petition.

Cook Imaging would appreciate an expedited review and reply to the Citizen Petition. Cook Imaging Corporation considers the filing of this application to be confidential and requests that FDA not make knowledge of this submission public or disclose any information contained within without written permission of Cook Imaging Corporation.

If you have any questions regarding this application, please feel free to contact me via telephone at 800-353-0887 or facsimile at 812-332-3079.

Best Regards,



Kelly Davis
Regulatory Affairs Associate

OOP-1452

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Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Citizen Petition

The undersigned submits this petition under Chapter 314.93 of the Code of Federal Regulations to request the Commissioner of Food and Drugs to allow Cook Imaging Corporation to submit a supplement to the abbreviated new drug application for Iopamidol Injection in a dosage form which is not identical to the listed drug, Isovue Injection.

A. Action requested

Cook Imaging Corporation requests approval to submit a supplement to the abbreviated new drug application for Iopamidol Injection in a dosage form which is not identical to the listed drug, Isovue Injection.

B. Statement of grounds

Iopamidol – M is a diagnostic, non-ionic radiopaque contrast media for intrathecal administration. Iopamidol is currently approved for manufacture at Cook Imaging in 50, 100 and 200 mL vial sizes in 200, 250, 300 and 370 mgI/mL strengths. Intentions are to manufacture Iopamidol-M (15 mL fill volume) in a 20 mL syringe in 200 and 300

mgI/mL strengths. The 20 mL syringe is composed of the same USP Type I borosilicate glass as the approved 50, 100 and 200 mL vials. The 20 mL syringe will use the currently approved 4405/50 gray butyl stopper.

Cook Imaging has obtained 25 months stability (Upright/Inverted) at 25° to 30°C and 40°C/75% RH for the Iopamidol - M 20 mL syringe.

The stability data follows the same profile as the currently approved 50, 100 and 200 mL vial sizes:

The stability data follows the same profile as the currently approved 50, 100 and 200 mL vial sizes (ANDA No. 74-881):

1. No out of specification results were observed in the Iopamidol-M Injection, 200 and 300 mgI/mL, stability data. Similar stability trends were observed between Iopamidol-M Injection, 200 and 300 mgI/mL, and Iopamidol Injection, 200 and 300 mgI/mL.
2. No stability lot of Iopamidol-M Injection in either dosage form has shown evidence of instability in the form of degradation or pH shift.

C. Environmental impact

Cook Imaging Corporation claims a categorical exclusion as permitted according to 21 CFR 25.24 (c) (1). Iopamidol will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and data are available to the agency which do not establish that, at the expected level of exposure, the substance may be toxic to organisms in the environment.

Cook Imaging complies with all Federal, State and Local regulations regarding air, wastewater, solid waste and hazardous waste emissions.

D. Economic impact

Information regarding the economic impact of this petition has not been requested by the Commissioner.

Cook Imaging Corporation will provide economic impact information upon request by the Commissioner.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.



Jennifer A. Walls, Regulatory Affairs Manager

Cook Imaging Corporation

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