CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020351/S01/S03

Trade Name: VISIPAQUE INJECTION PARENTERAL 270 mgI/mL AND 320 mgI/mL

Generic Name: IODIXANOL

Sponsor: NYCOMED, INC.

Approval Date: 10/10/97

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APPLICATION: 020351/S01/S03

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Pharmacology Review(s)				
Statistical Review(s)				
Microbiology Review(s)				
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Biopharmaceutics Review(s)				
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Application Number: 020351/S01/S03

APPROVAL LETTER

DEPARTMENT OF HEAL... & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-351/S-001,S-003

OCT 10 1997

Nycomed Inc.
466 Devon Park Drive
P.O. Box 6630
Wayne, PA 19087-8630

Attention: Michael Angioli
Senior Manager, Corporate Quality and Regulatory Affairs

Dear Mr. Angioli:

Please refer to your supplemental new drug application dated March 26, 1996, received March 27, 1996, and your supplemental new drug application dated October 10, 1996, received October 11, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VISIPAQUE (iodixanol) Injection parenteral 270 mgI/ml and 320 mgI/ml.

We acknowledge receipt of your submissions dated September 20, 1996; and January 17, and 28, May 8, June 4, and August 11, 1997. The User Fee goal date for the application received October 11, 1996, is October 11, 1997.

The supplemental application dated March 26, 1996, provides for labeling editorial changes. The supplemental application dated October 10, 1996, provides for the expansion of the existing indications to the pediatric population.

We have completed the review of these supplemental applications including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the attached labeling dated October 10, 1997. Accordingly, the supplemental applications are approved effective on the date of this letter. These revisions are terms of the supplemental NDA approval.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 20-351. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Catalina Ferre-Hockensmith, Consumer Safety Officer, at (301) 443-3500.

Sincerely yours,

/S/

Patricia Y. Love, M.D., M.B.A.
Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-351
HFD-160/Div. files
HFD-160/CSO/cfh
HFD-160/ej/sc/el/rk/mw/ms/dl/ymc
HFD-002/ORM (with labeling)
HFD-103/Office Director
HFD-101/L.Carter
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFD-560/OTC (with labeling - for OTC Drug Products Only)

APPEARS THIS WAY
ON ORIGINAL

HFI-20/Press Office (with labeling)

Drafted by: cfh/September 30, 1997/n20351.ap
Initialed by:
final:

APPEARS THIS WAY
ON ORIGINAL

APPROVAL (AP)

/S/ 10/10/97

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.