CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-372/SE1-003

Correspondence

Nycomed Amersham

Nycomed Amersham Imaging

October 12, 2001

Patricia Love, M.D., MBA, Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products (HFD-160)
Office of Drug Evaluation III
Center for Drug Evaluation and Research
Document Control Room
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

DUPLICATE
N-000-44

RE: NDA 20-372 MYOVIEW™ (Kit for the preparation of Technetium ^{99m}Tc Tetrofosmin for Injection)

6 Month Report on Postmarketing Studies

Dear Dr. Love,

Reference is made to the February 20, 2001 Final Rule (Delay of Effective Date) regarding submission of "Postmarketing Studies for Approved Human Drug and Biological Products; Status Reports". Reference is also made to the April, 2001 Draft Guidance for Industry entitled "Reports on the Status of Postmarketing Studies-Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997". In compliance with the Final Rule, enclosed please find a 6-month report on postmarketing studies for the subject NDA.

This correspondence is being submitted in triplicate and includes a signed FDA 2252 form. We understand that this correspondence and all information contained herein unless indicated otherwise by Nycomed Amersham is CONFIDENTIAL. Please address any questions to Stefan Ochalski at (609)-514-6843 or Fred Longenecker, Director, Regulatory Affairs at (609)-514-6573.

Sincerely,

Stefan J. Ochalski, MBA
Senior Manager
Regulatory Affairs

18 pages redacted from this section of the approval package consisted of draft labeling