MAY 11 1982

MEMORANDUM FOR: Bernard Singer, Chief, Material Certification and Procedures Branch, NMSS

FROM: William O. Miller, Chief, License Fee Management Branch, ADM

SUBJECT: FEE CATEGORY FOR DISTRIBUTION APPROVALS

In the proposed fee schedule transmitted by R. E. Cunningham's March 26, 1982 memorandum to Daniel Donoghue, no fee category was established for the review of medical approvals (MA's), copy attached. Currently, fees are not assessed for these approvals.

Would your office please provide us with the staff-hour requirements for new medical approvals, and renewals and amendments thereto. Since the proposed fee schedule is due to the Commission shortly, we would appreciate your response to this request by c.o.b., Wednesday, May 12, 1982.

We appreciate your assistance in this matter.

Original Signed by
Wm. O. Miller

William O. Miller, Chief
License Fee Management Branch
Office of Administration

Enclosure:
Copy of medical approval for
3M Company

DISTRIBUTION:
License Fee File
CJHolloway, LFMB
ASCabell, LFMB
GJackson, LFMB
LFMB R/F (2)

LFMB:ADM	LFMB:ADM	FMB:ADM				
ASCabell:bs	CJHolloway	WOMiller				
5/11/82	5/11/82	5/10/82				

NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

REAGENT KIT DISTRIBUTION APPROVAL

MINNESOTA MINING AND MANUFACTURING COMPANY

3M CENTER

SAINT PAUL, MINNESOTA 55101

Approval No. 22-00057-56MA
Amendment No. 05

accordance with application dated August 1, 1980, Approval No. 22-00057-56MA amended in its entirety to read as follows:

The reagent kit(s) listed below are approved for distribution by Minnesota Mining and Manufacturing Company, to persons licensed pursuant to Section 35.14 and Section 35.100, Group III, of 10 CFR 35, or under equivalent licenses of Agreement States.

Kit Trade Name	Radiopharmaceutical Prepared From Kit
A. 3M Instant Microspheres (NDA 17-832/S-001)	A. Technetium 99m labeled albumin microspheres

The reagent kit(s) listed above shall be manufactured, packaged, labeled, and distributed in accordance with statements, representations, and procedures contained in application dated August 1, 1980 and letter dated August 31, 1981.

Any proposed changes in packaging, shielding, labeling, or the package insert shall be submitted to the U. S. Nuclear Regulatory Commission for review.

The Minnesota Mining and Manufacturing Company is authorized to distribute the reagent kit(s) listed in Item 1 above from the Twin City Army Ammunitions Plant, Building 590, New Brighton, Minnesota.

The Minnesota Mining and Manufacturing Company shall notify the U. S. Nuclear Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or the withdrawal of a "New Drug Application" (NDA) for any reagent kit listed in Item 1 of this approval.

This approval shall expire on September 30, 1986.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

PW 9/29/81

Material Licensing Branch
Division of Fuel Cycle and Material Safety

SEP 29 1981

[redacted]

701