

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
831 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
811 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 06-13053-01
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Miles Laboratories, Inc.
Miles Pharmaceuticals Division
400 Morgan Lane
West Haven, CT 06516

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Miles Laboratories, Inc.
Miles Pharmaceuticals Division
400 Morgan Lane
West Haven, CT 06516

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ralph M. Galustian

TELEPHONE NUMBER

(203) 937-2000

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and, c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. See Item 7 (Attached)

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3K AMOUNT ENCLOSED \$ 120.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 82 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Ralph M. Galustian

Vice President, Operations

07/13/87

14. VOLUNTARY ECONOMIC DATA

A. ANNUAL RECEIPTS

< \$250K	\$1M—3.5M
\$250K—500K	\$3.5M—7M
\$500K—750K	\$7M—10M
\$750K—1M	> \$10M

B. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

C. NUMBER OF BEDS

9. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)

☐ YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

BB04140413 B70903

REG1 LIC30

06-13053-01

DCD

APPROVED BY

DATE

AMOUNT RECEIVED

CHECK NUMBER

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

ITEM 7

Training and Experience

Roger A. Celesk, Ph.D. (Radiation Safety Officer)

Type of Training	Where Trained	Duration of Training	Nature of Training
a. Principles and practices of radiation protection	National Institutes of Health Bethesda, MD	2 1/2 years	Formal Course Work and/or Job-Related
	University of Dayton Dayton, OH	3 1/2 Years	Same as above
b. Radioactivity measurement standardization and monitoring techniques and instruments	Same as above	Same as above	Same as above
c. Mathematics and calculations basic to the use and measurement of radioactivity	Same as above	Same as above	Same as above
d. Biological effects of radiation	Same as above	Same as above	Same as above

ITEM 7 (Cont'd)

Experience with Radiation

Roger A. Celesk, Ph.D.

<u>Isotope</u>	<u>Maximum Amount</u>	<u>Where Experienced Was Gained</u>	<u>Duration of Experience</u>	<u>Type of Use</u>
^3H	10 mCi	NIH and University of Dayton	6 Years	Microbiological Research, labeling of bacterial cells
^{14}C	10 mCi			

Present Position: Research Scientist
 Product Development - Microbiology
 Miles Pharmaceuticals, Division of
 Miles Laboratories, Inc.
 West Haven, CT 06516

ITEM 7 (Cont'd)

Training and Experience

Norman J. Robiliard, Ph.D.

Type of Training	Where Trained	Duration of Training	Nature of Training
a. Principles and practices of radiation protection	University of Massachusetts	3 Years	Training films, seminars, Job Experience
b. Radioactivity measurement standardization and monitoring techniques and instruments	Same as above	Same as above	Same as above
c. Mathematics and calculations basic to the use and measurement of radioactivity	Same as above	Same as above	Same as above
d. Biological effects of radiation	Same as above	Same as above	Same as above

ITEM 7 (Cont'd)

Experience with Radiation

Norman J. Robillard, Ph.D.

<u>Isotope</u>	<u>Maximum Amount</u>	<u>Where Experienced Was Gained</u>	<u>Duration of Experience</u>	<u>Type of Use</u>
32 P	1 mCi	University of MA Tufts University Boston	3 Years 2 Years	Southern Hybridization

Present Position: Research Scientist
 Product Development - Microbiology
 Miles Pharmaceuticals, Division of
 Miles Laboratories, Inc.
 West Haven, CT 06516

ITEM 7 (Cont'd)

Training and Experience

George J. Krcl, Ph.D

Type of Training	Where Trained	Duration of Training	Nature of Training
a. Principles and practices of radiation protection	University of Rochester	6 Mos.	Formal Course Work or Job-Related
b. Radioactivity measurement standardization and monitoring techniques and instruments	Same as above	6 Mos.	Same as above
c. Mathematics and calculations basic to the use and measurement of radioactivity.	Same as above	6 Mos.	Same as above
d. Biological effects of radiation	Same as Above	6 Mos.	Same as Above

ITEM 7 (Cont'd)

Experience with Radiation

George J. Krol, Ph.D.

<u>Isotope</u>	<u>Maximum Amount</u>	<u>Where Experienced Was Gained</u>	<u>Duration of Experience</u>	<u>Type of Use</u>
^{90}Sr ^{14}C	1 uCi 2 mCi	Univ. of Rochester Rochester, NY	6 Mos.	90 Environmental contamination. Synthesis of ^{14}C labelled compounds
^{14}C ^3H	2 mCi 10 mCi	Hoffman-LaRoche Nutley, NJ	2 Years	Detection and identification of drug metabolites

Present Position: Staff Scientist
Pharmaceutical Development Services
Miles Pharmaceutical, Division of
Miles Laboratories, Inc.
West Haven, CT 06516

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03620
9/89

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

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Miles Laboratories, Inc.

Application Dated: 7-13-87

Control No.: 107568

License No.: 06-13053-01

2. FEE ATTACHED

Amount: \$120⁰⁰

Check No.: 99-47417

3. COMMENTS

Signed M. Wersinger

Date 7-24-87

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3M \$120

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal

License

Signed A. Kimberley

Date 7/28/87