

## MATERIALS LICENSE

Amendment No. 04

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

OFFICIAL RECORD COPY

## Licensee

1. Novartis Pharmaceuticals Corporation  
Building 404
2. 59 Route 10  
East Hanover, New Jersey 07936-1080

In accordance with letter dated  
February 10, 1997,

3. License Number 29-08978-04 is amended in  
its entirety to read as follows:

4. Expiration Date March 31, 2004

5. Docket or  
Reference No. 030-31037

6. Byproduct, Source, and/or  
Special Nuclear Material

7. Chemical and/or Physical  
Form

8. Maximum Amount that Licensee  
May Possess at Any One Time  
Under This License

A. Cesium 137

A. Sealed source  
(J.L. Shepherd  
Model 6810)

A. 2500 curies

## 9. Authorized use

A. For possession and storage in J.L. Shepherd Mark I, Model 68 Irradiator.

## CONDITIONS

10. Licensed material shall be stored only at 59 Route 10, East Hanover, New Jersey.
11. The Radiation Safety Officer for this license is David S. Hwang, CSP.
12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
13.
  - A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
  - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
  - C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
  - D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

29-08978-04

Docket or Reference Number

030-31037

Amendment No. 04

E. Sealed sources and detector cells need not be leak tested if:

- (i) they contain only hydrogen-3; or
- (ii) they contain only a radioactive gas; or
- (iii) the half-life of the isotope is 30 days or less; or
- (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
- (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

15. A. Written instructions for the use of the J. L. Shepherd and Associates, Mark I Irradiator, shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material.

B. Any changes in these instructions shall have the prior approval of the U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

29-08978-04

Docket or Reference Number

030-31037

Amendment No. 04

16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated February 27, 1989
- B. Letter dated February 22, 1994
- C. Letter dated July 25, 1996
- D. Letter dated January 3, 1997
- E. Letter dated February 10, 1997

For the U.S. Nuclear Regulatory Commission

**ORIGINAL SIGNED BY:**

By **JAMES M. BONDICK**

Nuclear Materials Safety Branch

Region I

King of Prussia, Pennsylvania 19406

MAY - 6 1997

Date \_\_\_\_\_

MAY - 6 1997

Daniel Hauser, Ph.D.  
Head, PDPM Operations U.S.  
Novartis Pharmaceuticals Corporation  
Building 404  
59 Route 10  
East Hanover, NJ 07936-1080

Dear Dr. Hauser:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Note that the curriculum vitae for Mr. Hwang submitted with your application contains private information. Documents submitted in support of licensing actions are available to the public under the Freedom of Information Act. In the future, do not submit private information for individuals, such as home address, home phone number, or date of birth in support of a licensing action, unless this information is specifically requested.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

**ORIGINAL SIGNED BY:  
JAMES M. BONDICK**

James M. Bondick  
Health Physicist  
Division of Nuclear Materials Safety

License No. 29-08978-04  
Docket No. 030-31037  
Control No. 124292

Enclosure:  
Amendment No. 04

D. Hauser, Ph.D.  
Novartis Pharmaceuticals Corporation

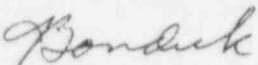
-2-

DOCUMENT NAME: R:\WPS\MLTR\L2908978.04

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	JBondick/jmb <i>JB</i>						
DATE	02/25/97	02/ /97	02/ /97	02/ /97	02/ /97	02/ /97	02/ /97

OFFICIAL RECORD COPY

<b>TELEPHONE CONVERSATION RECORD</b>		<b>Date:</b> 2/25/97	<b>Time:</b> 2pm
<b>Mail Control Nos.:</b> 124291 and 124292	<b>License Nos.:</b> 29-08978.02 and 29-08978.04	<b>Docket Nos.:</b> 030-05357 and 030-31037	
<b>Person Called:</b> Daniel Hauser, Ph.D.	<b>Organization:</b> Novartis Pharmaceuticals Corporation	<b>Telephone Number:</b> 203-503-8300	
<b>Person Calling:</b> J. Bondick	<b>Organization:</b> NRC	<b>Telephone Number:</b> 6951	
<b>Subject:</b> Clarification exact licensee name and specific building.			
<p><b>Summary:</b> The -02 and -04 licenses list two different building numbers. Called Dr. Hauser to clarify this discrepancy. He had Mr. David Hwang call with the information. 1) the name of the company is Novartis PHARMACEUTICALS(Plural) Corporation, 2) to simplify the mailing, they want the building listed on the license as building 404 for both licenses, rather than 404/509 on the -02 license and 404/154 on the -04 license. Mr. Hwang also stated that he will be sending in another license application.</p>			
<b>Action Required/Taken:</b> Note to file of -02 and -04 licenses			
<b>Signature:</b> J. Bondick 		<b>Date:</b> 2/25/97	





Novartis Pharmaceuticals Corporation  
59 Route 10  
East Hanover, NJ 07936-1080

Tel 201 503 8300

February 10, 1997

Certified # P 199 697 061

Mr. John D. Kinneman  
U.S. Nuclear Regulatory Commission  
Region 1  
Nuclear Materials Safety and Safeguards Branch  
475 Allendale Road  
King of Prussia, PA 19406-1415

030-05357 / 030-31037

Re: License Nos. 29-08978-02 and 29-08978-04

Dear Mr. Kinneman,

This letter is to inform you that Mr. Carmine Sodano, the Radiation Protection Officer from Novartis Pharmaceuticals Corporation, East Hanover facility, NRC Licenses Nos. 29-08978-02 and 29-08978-04 officially retired from services on January 31, 1997 and will no longer perform the duties of the Radiation Protection Officer for these licenses.

This letter serves as a request to amend the above licenses for a name change of the Radiation Safety Officer. As published in the Proposed Rules of the Federal Register / Volume 61, No. 221/ under 10 CFR 33.17 (c), we are officially notifying you, in writing, within 30 days, that we have appointed Mr. David Hwang as the new Radiation Safety Officer for Novartis Pharmaceuticals Corporation. We have attached his qualifications as requested. Mr. Hwang will be responsible for implementing the radiation safety program by ensuring that the radiation safety activities are being performed in accordance with the approved procedures and regulatory requirements for the daily operation of these licenses.

Additionally, as previously discussed, we will be submitting a new license application for a broad scope type A, to cover multi-sites in order to unify the old Ciba-Geigy and Sandoz programs. We have a target date of April, 1997 to submit the new license application to the NRC.

Enclosed is a check for \$660.00, the fee required to amend the above licenses.

Thank you for your attention and forthcoming reply to this matter.

Daniel Hauser, Ph.D.  
Head, PDPM Operations U.S.

1 2 4 2 9 2

FEB 20 1997

OFFICIAL RECORD COPY

ML 10

**David Steven Hwang, CSP**

***work address:***

Novartis Pharmaceutical Corporation  
556 Morris Ave.,  
Summit, NJ 07901  
(908) 277-2361

***home address:***

**PROFESSIONAL ORGANIZATIONS & CERTIFICATION:**

- President, NJ Health Physics Society (1996 - present).
- Board of Certified Safety Professional (BCSP) - Comprehensive practice 1995.
- Executive Council, NJ Health Physics Society (1990 - present).
- President, Radiological & Environmental Health Technologies Inc.
- American Society of Safety Engineers (National and NJ Chapters).
- Member, Mid-Atlantic Biological Safety Association.
- Member, American Nuclear Society.
- Plenary Member, National Health Physics Society.
- Consultant, City of Summit, Office of Emergency Management.
- Consultant, Union County, Division of Emergency Management, Department of Public Safety.

**Experience:**

**Ciba-Geigy Corporation, Pharmaceuticals Division, Summit, NJ.**  
***January 1992 - December 1996***

**Senior Health Physicist / Environmental Health & Safety Coordinator**

- Coordination and supervision of all operational Health Physics program consistent with the new 10 CFR 20 requirements.
- Personnel monitoring and dose equivalent calculations.
- Coordination and supervision of the health physics Radiochemistry Laboratory.
- Developed and implemented the Low-level radioactive waste minimization plan.
- OSHA, Fire protection, and Emergency response management.
- Workman's compensation and injury/illness review programs including legal and regulatory affairs.
- Biological safety program development and implementation.
- Coordination of Chemical and Systems Safety hazard analysis.
- International and Domestic transportation of hazardous materials.
- Non-ionizing radiation (rf, EMF, UV, and etc.) safety program development and implementation including LASERS.
- Implementation and coordination of regulatory safety training programs.
- Laboratory and contractor safety administration.
- Implementation of Pollution Prevention programs in the laboratory environment.



**Princeton University - Plasma Physics Laboratory, Princeton NJ.**  
**February 1987 - January 1992**

**Sr. Health Physicist, Head of Tritium Operations (faculty and staff)** (September 1991 - January 1992).

- Management of the tritium facilities relating to radiological protection (meteorological tower, special nuclear material accounting, waste solidification, and customer support for 1000 employees).
- Design and engineering of the HVAC system for effluent monitoring in compliance with regulations.
- Oversight of tritium recovery, processing, and decontamination facilities.
- Oversight of employee exposure monitoring and bioassay calculations.

**Sr. Health Physicist, Head of Field Operations (faculty and staff)** (October 1988 - December 1991).

- Implementation and coordination of ALARA engineering programs.
- Internal and external personnel monitoring and dose equivalent calculations.
- Supervision and training of seven health physics technicians.
- Neutron dosimetry and activation product profiles.
- Maintenance and coordination of all radiation and contamination surveys.

**Health Physicist (faculty and staff)** (February 1987- October 1988).

- Investigation and hazard analysis involving radiation incidents and exposures.
- Assistant Laser Safety Officer.
- Environmental Monitoring (gamma spectroscopy, effluent monitoring, and radiochemical analysis).
- Environmental regulatory compliance (RCRA, EPA, TOSCA, SARA, and etc.).
- Supervision of five safety technicians to adequately support 1000 employees.

**Schering-Plough Corporation, Pharmaceuticals Division, Bloomfield NJ.**  
**January 1986-January 1987**

**Assistant Radiation Safety Officer**

- Provided technical radiation safety consultations to 500 Research Scientist.
- Coordination of laboratory contamination surveys, and personnel monitoring.
- Calibration and maintenance of radiation detection instrumentation and efficiency determinations.
- Oversight of radiochemical analysis laboratory including sample analysis.

**Rutgers University, New Brunswick, Piscataway, and Newark Campuses.**  
**March 1985 - January 1986**

**Radiation and Environmental Health and Safety Intern**

- Provided basic health physics and industrial hygiene consultations to faculty and staff of Rutgers University.

## EDUCATION:

Rutgers - The State University, Cook College, New Brunswick, NJ.

Bachelor of Science (BS), Environmental Sciences.

Specialization: Radiation and Nuclear Sciences.

Rutgers - The State University

Masters of Science (MS) Program (Radiological Sciences) - enrolled.

Executive Masters in Business Administration (EMBA) Candidate - Sponsored by Ciba Corporation.

- Biosafety in Microbiological and Biomedical Laboratories- Center for disease Control, Atlanta, GA.
- Non-ionizing Radiation Safety Officers Course - Lorrel/Narda Microwave systems, Haupaugh, NY.
- Tap-Root Accident and Incident Investigation Review Course - Summit, NJ.
- Laser Safety Officers Course - Rockwell Laser Industries, Orlando, FL.
- Nuclear Materials Management and Safeguards Systems (NMMSS), Denver, CO.
- ALARA for Design and Operations Engineers - Oak Ridge National Laboratory, Oak Ridge, TN.
- Radioactive waste characterization and designation Course - Westinghouse Hanford Co., Brookhaven National Laboratory, Brookhaven, NY.
- Waste Treatment and Handling course - Lawrence Livermore National Laboratory, Monta Ray, CA.
- Advanced Tritium Safe Handling Course - Canadian Fusion Fuels Technology, Toronto, Canada.
- Tritium Safe Handling Course - Los Alamos National Laboratory (TSTA), Los Alamos, NM.

## PUBLICATIONS:

- "TFTR Radiation Contour and Shielding Efficiency Measurements During D-D Plasma Operations," presented at the 11th Topical Meeting on the Technology of Fusion Energy, American Nuclear Society, New Orleans, LA, June 1994 (co-author).
- "Deuterium-Deuterium Radiation Shielding Measurements in support of the Tokamak Fusion Test Reactors Deuterium-Tritium Operations," presented at the 37th Annual Meeting of the Health Physics Society, Columbus, Ohio, June 1992 (author).
- "Radiological Investigation Report, Van Dyk Research Corporation," Prepared for Flavio-Sciences, Inc., submitted to the NJDEP for approval, May, 1991 (author).
- "Radiological Assessment of the Princeton-Pennsylvania Accelerator for Final Decontamination and Decommissioning," presented at the 35th Annual Meeting of the Health Physics Society, Anaheim, CA, June 1990 (co-author).

## SPECIAL SKILLS:

Semi-professional soccer player (Portuguese first division NY-MET league).

Computer programming

## REFERENCES:

Furnished upon request

## LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH  
DIVISION OF ACCOUNTING AND FINANCE  
OFFICE OF THE CONTROLLER  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001NOVARTIS PHARMACEUTICAL CORPORATION  
ATTN: DANIEL HAUSER, PH.D.  
HEAD, PDPM OPERATIONS U.S.  
59 ROUTE 10  
EAST HANOVER, NJ 07936-1080

## TYPE OF ACTION

- ☐ NEW LICENSE  
☐ RENEWAL OF LICENSE  
☒ AMENDMENT TO LICENSE

## REQUESTED DATE

2-10-97

## LICENSE NUMBER

29-08978-04

## CONTROL NUMBER

124292

## I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3P	\$	\$	\$ 300.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	300.00
PAYMENT RECEIVED	\$	0.00
AMOUNT DUE	\$	300.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

SIGNATURE - LICENSE FEE ANALYST

LFDCB

LFDCB

BRENDA BROWN 301-415-6055

BBB  
3/5/97

## II. FEE NOT REQUIRED

☐ Enclosed is Check No. \_\_\_\_\_ which accompanied your request. The fee is not required because:

☐ We received your Check No. \_\_\_\_\_ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated \_\_\_\_\_, Control No. \_\_\_\_\_.

☐ Your request was combined, prior to review, with your request, Control No. \_\_\_\_\_.

## III. CHECK RETURNED

☐ Enclosed is Check No. \_\_\_\_\_ which was returned to us by the bank for:

☐ INSUFFICIENT FUNDS

☐ ACCOUNT CLOSED

☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

## IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. \_\_\_\_\_, Amendment No. \_\_\_\_\_, issued on \_\_\_\_\_.

\_\_\_\_\_ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section I of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section I of this form.

## Distribution:

Region I LPAB R/F

Pending OC/DAF R/F

BBrown OC/DAF S/F (LF-3.2.7)

DATE

3-5-97

```

: PROGRAM CODE: 03510
: STATUS CODE: 0
: FEE CATEGORY: 3P
: EXP. DATE: 20040331
: FEE COMMENTS: STORAGE ONLY EFF 3/31
: DECOM FIN ASSUR REQD: N
: .....

```

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

A. REGION

APPLICANT/LICENSEE: NOVARTIS PHARMACEUTICAL CORPORATION  
RECEIVED DATE: 970220  
DOCKET NO: 3031037  
CONTROL NO.: 124292  
LICENSE NO.: 29-08978-04  
ACTION TYPE: AMENDMENT

AMOUNT: \_\_\_\_\_  
CHECK NO.: \_\_\_\_\_

Ref. 124291.

H. A. Perkins  
2/24/93

1. FEE CATEGORY AND AMOUNT: 3P \$300

3. OTHER

[illegible]

Log MAI  
 Remitter \_\_\_\_\_  
 Check No. 2018245  
 Amount \$300  
 Fee Cat. 3P  
 Type of Ans  
 Date Check 9/25/97  
 Date Completed 9/25/97  
 By BB

} Also see 124291

1997 FEB 26 AM 9:46