

MATERIALS LICENSE

Amendment No. 08

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, 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.

<p>Licensee</p> <p>1. Novo Nordisk Bioindustrials, Inc.</p> <p>2. 33 Turner Road P.O. Box 1907 Danbury, Connecticut 06813-1907</p>	<p>In accordance with letter dated March 26, 1991, 3. License number 06-17718-01 is amended in its entirety to read as follows:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3 B. Carbon 14 C. Iodine 125 D. Iodine 125</p>	<p>4. Expiration date December 31, 1992</p> <p>5. Docket or Reference No. 030-13216</p> <p>7. Chemical and/or physical form</p> <p>A. Any B. Any C. Any D. Prepackaged Test Kits.</p> <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 10 millicuries B. 20 millicuries C. 1 millicurie D. 12 millicuries</p>

9. Authorized use

A. through C. Research and development as defined in 10 CFR 30.4.

D. For the receipt, possession, storage and processing in vitro radioimmunoassay test kits for distribution to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

CONDITIONS

10. Licensed material shall be used only at 33 Turner Road, Danbury, Connecticut.
11. A. Licensed material shall be used by, or under the supervision of, Joseph R. Fordham, Ph.D. or Carrie L. Hoffman.
- B. The Radiation Safety Officer for this license is Joseph R. Fordham, Ph.D.

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 6
FOIA-2008-0015

9201290289/910626
REG1 LIC30
MATLSLICENSING PDR

C/S

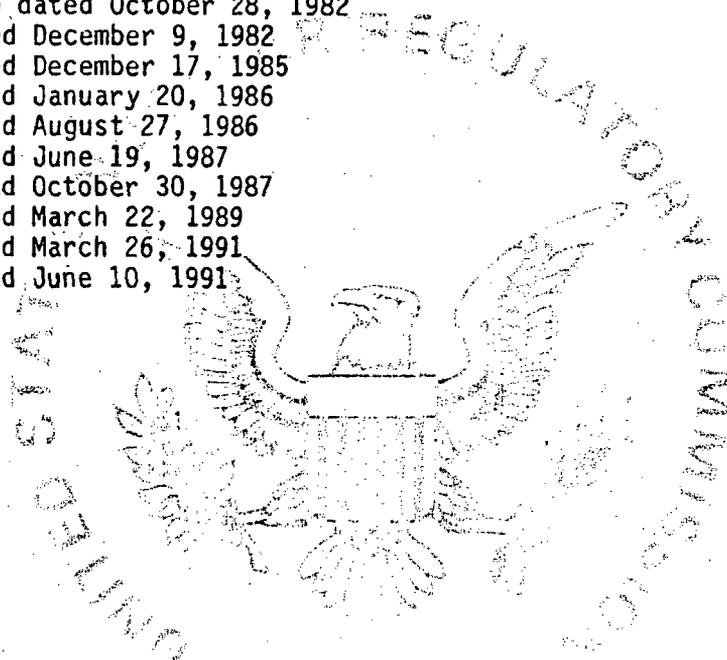
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number	06-17718-01
Docket or Reference number	030-13216
Amendment No. 08	

(Continued) CONDITIONS

12. 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 October 28, 1982
- B. Letter dated December 9, 1982
- C. Letter dated December 17, 1985
- D. Letter dated January 20, 1986
- E. Letter dated August 27, 1986
- F. Letter dated June 19, 1987
- G. Letter dated October 30, 1987
- H. Letter dated March 22, 1989
- I. Letter dated March 26, 1991
- J. Letter dated June 10, 1991



For the U.S. Nuclear Regulatory Commission

Original Signed By:

By John D. Kinneman

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

Date JUN 26 1991

JUN 26 1991

License No. 06-17718-01
Docket No. 030-13216
Control No. 114486

Novo Nordisk Bioindustrials, Incorporated
ATTN: Joseph R. Fordham
Director of Regulatory Affairs
33 Turner Road
P.O. Box 1907
Danbury, Connecticut 06813-1907

Dear Mr. Fordham:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

RECEIVED
DIVISION OF ACCOUNTING
91 JUL -5 AM 11:00
U.S. NUCLEAR ENERGY
COMMISSION

Novo Nordisk Bioindustrial, Inc.

2

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:

John D. Kinneman

John D. Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

Enclosures:

1. Amendment No. 08
2. Requirements for Materials Licensees

DRSS:RI
M.Roberts/bh
mer
06/14/91

[Signature]
DRSS:RI
Kinneman
06/16/91

OFFICIAL RECORD COPY

ML 06-17718-01/LTR - 0002.0.0
06/18/91

June 10, 1991

Mark C. Roberts, CHP
Health Physicist
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406

RE: NRC Material License No. 06-17718-01

Dear Mr. Roberts:

Thank you for your fax of June 7, 1991 requesting additional information on the name change from Novo Laboratories, Inc. to Novo Nordisk Bioindustrials, Inc..

As noted in our March 26, 1991 letter to amend the above license the above name change does not reflect a change in ownership of the company. Formerly Novo Laboratories, Inc. was a wholly owned subsidiary of Novo Industri A/S. Novo Nordisk A/S was formed in 1989 by a merger of the two Danish companies, Novo Industri A/S (established in 1925) and Nordisk Gentofte A/S (established in 1923). Novo Nordisk A/S is one of the world's leading biotechnology companies. It is a major force in insulin manufacture and diabetes treatment and is the world's largest producer of industrial enzymes. The company also manufactures and markets a number of other pharmaceutical and bioindustrial products. The company employs over 8,700 people world-wide.

The President and Chief Executive Officer of Novo Nordisk A/S is Mads Ovlisen, who was formerly President and CEO of Novo Industri A/S. The management philosophy of the company has not changed as the result of the merger. Personnel from Nordisk Gentofte A/S and Novo Industri A/S were essentially integrated to form Novo Nordisk A/S.

Novo Laboratories, Inc. changed its name to Novo Nordisk Bioindustrials, Inc. to reflect the merger and more accurately describe our business which focuses on the marketing of industrial enzymes and biopesticides in the U. S. and Canada. The organization, facilities, equipment and personnel of Novo Laboratories, Inc. were not affected by the name change to Novo Nordisk Bioindustrials, Inc..



Novo Nordisk

Novo Nordisk
Bioindustrials, Inc.

33 Turner Road
P.O. Box 1907
Danbury, CT 06813-1907

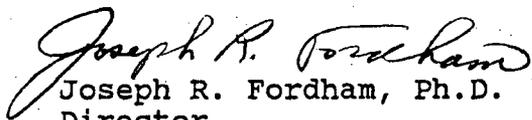
Tel. 203-790-2600
FAX 203-790-2748

91 JUN 12 P2:18
RECEIVED-REGDNY 1

We affirm that Novo Nordisk Bioindustrials, Inc. agrees to abide by all commitments and representations made to the Nuclear Regulatory Commission by Novo Laboratories, Inc..

Please do not hesitate to contact our office here in Danbury if you have need of additional information. I certify that the information furnished herewith is true and correct.

Sincerely,

A handwritten signature in cursive script that reads "Joseph R. Fordham".

Joseph R. Fordham, Ph.D.
Director
Regulatory Affairs

JRF

CONVERSATION RECORD

TIME 1:30

DATE 6-7-91

TYPE VISIT CONFERENCE TELEPHONE INCOMING OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

Carrie Hoffmann

ORGANIZATION (Office, dept., bureau, etc.)

NOVO NORDISK BION INDUSTRIES

TELEPHONE NO.

203-790-2600

ROUTING	
NAME/SYMBOL	INT

SUBJECT

Deficiency phone call - License # 06-17718-01
Mail Contact # 114486

SUMMARY

Requested information concerning name change of company. Std. ~~Def.~~ Def. paragraph # _____ was faxed to Dr Fordham (Rso licensee) and discussed w/ Ms Hoffmann. Requested that licensee confirm that the new company would abide by terms and conditions agreed to by the old company.

ACTION REQUIRED

Continue action upon receipt of the requested information

NAME OF PERSON DOCUMENTING CONVERSATION

MARK ROMERO

SIGNATURE

MC R

DATE

6-7-91

ACTION TAKEN

SIGNATURE

TITLE

DATE

030-13216

Novo Nordisk



Novo Nordisk Bioindustrials, Inc.

33 Turner Road
P.O. Box 1907
Danbury, CT 06813-1907

Tel. 203-790-2600
FAX 203-790-2748

March 26, 1991

United States Nuclear Regulatory Commission
Region 1
Licensing Section
475 Allendale Road
King of Prussia, Pennsylvania 19406

RE: NRC Material License No. 06-17718-01

We wish to amend the above license to reflect changes in our operation. The following needs to be changed.

- 1. Name of licensee - Change to: Novo Nordisk Bioindustrials, Inc.

This does not reflect a change in ownership of the company. Our parent company, Novo Industri A/S, of Copenhagen, Denmark merged with another Danish Pharmaceutical Company and the name of the company was changed to Novo Nordisk A/S. For consistency sake, the name of Novo Laboratories was changed to the above.

- 2. Address change - Change to:

33 Turner Road
P. O. Box 1907
Danbury, CT 06813-1907

This does not reflect a change in the location of our place or business. It is the result of a change in the postal zip codes initiated by the Post Office.

- 3. Condition 11 A. The names of Carol M. Beck, Ph.D., Robert J. Malley, Robert L. Starnes, Ph.D., and Rose Lance should all be removed as persons authorized to use or supervise the use of the licensed material.

We request that the following persons be added as being authorized to use or supervise the use of the licensed material: Joseph R. Fordham, Ph.D., and Carrie L. Hoffman.

Remitter	
Check No.	5982
Amnt	440
Fee Category	3B
Type of Fee	AMD
Date Check Rec'd.	5/24/91
Date Completed	

U.S. NUCLEAR REGULATORY COMMISSION

91 APR 23 AM 1:17

RECEIVED
DIVISION OF ACCOUNTING

OFFICIAL RECORD COPY

ML 10

114486

APR 03 1991

The background of these people as relates to the handling of licensed material is:

Joseph R. Fordham

B.S. Chemistry, Holy Cross College, (b)(6) M.S.
Biochemistry, Purdue University, 1963; Ph.D.
Biochemistry, Purdue University, 1966.

Satisfactorily completed courses in Health Physics and Radioisotope Techniques at Purdue in 1960.

Used C-14, H-3 and P-32 isotope labeling techniques extensively in Ph.D. Dissertation Research at Purdue (1963-65).

Used C-14 and H-3 labeling techniques while employed as a Senior Research Scientist at Joseph E. Seagram & Sons, Louisville, KY, 1965-69.

Conducted research utilizing C-14 and H-3 labeling techniques while employed as an Assistant Professor and Associate Professor at the University of Kentucky, 1969-77. Served as Department of Nutrition and Food Science liaison to the University of Kentucky Radiation Safety Officer, 1969-77.

Employed at Novo Laboratories, Inc. as Manager, Regulatory Affairs, 1982-88 and as Director, Regulatory Affairs, 1988-present. He was and is responsible, in these capacities, for the maintenance of the NRC Materials License. We request that he be added to our license in the capacity of Radiation Safety Officer.

Carrie L. Hoffman

B. S. Medical Technology, Univ. Conn., (b)(6) Graduate courses in microbiology, University of Bridgeport and Quinnipiac College. National Certification Agency for Clinical Laboratory Scientists, certified and American Society of Clinical Pathology, registered, 1984.

While employed as a medical technologist, Danbury Hospital, Danbury, CT had instruction in the use of radio-labeled in vitro test kits.

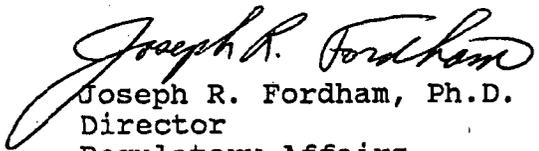
Employed at Novo Laboratories, Inc. as Assistant Researcher, 1985-88, Associate Researcher, 1988-90 and as a Sales Specialist by Novo BioLabs, since Feb., 1990. Her present position includes sales and marketing of radio immuno (I-125) assay kits. Although she does not actually manipulate radiolabeled material other than in the form of packaged kits, she does from time to time re-

box and/or display product for customers. Therefore, we request that she be added to our license.

4. Condition 11 B. As noted above we request that the license be amended to include Joseph R. Fordham, Ph.D. as Radiation Safety Officer.

Please do not hesitate to contact our office here in Danbury if you have need of additional information. I certify that the information furnished herewith is true and correct.

Sincerely,


Joseph R. Fordham, Ph.D.
Director
Regulatory Affairs

JRF

21 MAR 73 6123

RF

Novo Nordisk Bioindustrials, Inc.
ATTN: Joseph R. Fordham, Ph.D.
Director, Regulatory Affairs
33 Turner Road
P.O. Box 1907
Danbury, CT 06813-1907

APR 29 1991

Gentlemen:

This refers to your letter dated March 26, 1991, for an amendment to Materials License 06-17718-01.

Your request is subject to an amendment fee of \$440 as specified in fee Category 3B of §170.31, 10 CFR 170, which went into effect July 2, 1990. A copy of the May 23, 1990, Federal Register notice regarding the revision to the Commission's fee regulations is enclosed. Payment of the \$440 fee should be made to the U.S. Nuclear Regulatory Commission and mailed to the following address:

U.S. Nuclear Regulatory Commission
ATTN: Sandra Kimberley
License Fee and Debt Collection
Branch, OC/DAF
Mail Stop MNBB 4503
Washington, DC 20555

Your application will be processed by the Region I Licensing staff located at 475 Allendale Road, King of Prussia, Pennsylvania 19406. The fee, however, is required prior to issuance of the amendment. When submitting the fee, please refer to CONTROL NUMBER 114486.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application and will void this action.

Sincerely,

/s/

Sandra Kimberley
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

Enclosure:
May 23, 1990, Federal Register notice

cc: Region I

DISTRIBUTION:
Pending Fee File
OC/DAF R/F
LFDCB R/F (2)
DW/LBRI/Novo

OFFICE: OC/LFDCB
SURNAME: SKimberley:jv
DATE: 4/27/91

OC/LFDCB
GJackson
4/27/91

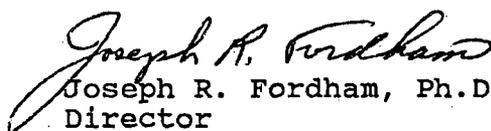
May 10, 1991

U. S. Nuclear Regulatory Commission
ATTN: Sandra Kimberly
License Fee and Debt Collection
Branch, OC/DAF
Mail Stop MNBB 4503
Washington, DC 20555

RE: CONTROL NUMBER 114486

Enclosed is a check for \$440.00 for an amendment to
Materials License 06-17718-01.

Sincerely,


Joseph R. Fordham, Ph.D.
Director
Regulatory Affairs

JRF
attachment



Novo Nordisk

**Novo Nordisk
Bioindustrials, Inc.**

33 Turner Road
P.O. Box 1907
Danbury, CT 06813-1907

Tel. 203-790-2600
FAX 203-790-2748

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

:
:
:
:
:
PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: 3B
EXP. DATE: 19921231
FEE COMMENTS: EFF. 2/5/86
:.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: NOVO NORDISK BIOINDUSTRIALS, INC.
RECEIVED DATE: 910403
DOCKET NO: 3013216
CONTROL NO.: 114486
LICENSE NO.: 06-17718-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: -----
CHECK NO.: -----

3. COMMENTS

SIGNED _____
DATE _____

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED)

1. FEE CATEGORY AND AMOUNT: 3B ----- 440

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED _____
DATE 5/27/91

COVER SHEET FOR CORRESPONDENCE
USE THIS COVER SHEET TO PROTECT ORIGINALS OF
MULTI-PAGE CORRESPONDENCE