NOVO LABORATORIES INC.

59 DANBURY ROAD P.O. BOX D WILTON, Connecticut 06897-0820 (203) 762-2401

December 17, 1985

RECEIVED
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U.S.N.R.C.
I.C. FEE MGMT. BRANCH

Ms. Judy Joustra
U.S. Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, Pennsylvania 19406

Dear Ms. Joustra:

As we discussed by telephone on November 25-26, 1985 and I clarified in conversations with Mr. J. Miller (NRC, King of Prussia) and Ms. G. Jackson (NRC, Washington, D.C.), December 16, 1985 please find attached:

1. Information to amend our current license 06-17718-01 to allow not only current R&D uses of by product material, but also processing and distribution of Radioimmunoassay (RIA) Test Kits containing I^{125} to licensed operators.

2. A check in the amount of $460.00 for fees.

Our current license with amendments reflects classification within the old category 3K. Pursuant to discussions with Ms. Jackson this classification was changed by NRC to 3M. In view of our current business direction, Novo requests that our license be amended to the 3B category to allow processing and distribution/sales of in vitro RIA Test Kits for R&D purposes to NRC/agreement State licensed operations (hospitals, laboratories and health care professionals). It is Novo's understanding that 3B classification will also allow marketing the kits to licensed intermediates (laboratory, hospital supply houses) for eventual sale to licensed R&D end users.

Currently Novo kits are only intended for in vitro testing within the Research and Development environment. However, in the future, and upon approval of the appropriate federal agencies, Novo intends to market RIA Test Kits for in vitro human diagnostic purposes. In advance of that time we will seek amendment to our license reflecting this extension of activity.

8604150292 860205
REG1 LIC30
06-17718-01 PDR

Applicant Jan 3I
Check No. 004435
Amount/Fee Category $460 (3B)
Type of Fee APP fee
Date Check Rec'd 1/3/86
Received By dk

Inasmuch as these products represent important technologies for medical research in the United States we would appreciate your efforts to expedite our request for amendment.

If you require any additional information or clarification please call my Wilton office (203) 762-2401 Ext. 121.

Thank you,

Gregory B. Bidou, CIH
Industrial Hygienist
Dept. of Regulatory Affairs

GBB:MSG
Encls.

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Item 1, sec. b - check this section
license number 06-17718-01

Item 2 - Delete: Ext. 163 and Add: Ext. 121.

Item 3 - Delete: J.R. Fordham, Ph.D., Manager, Regulatory Affairs (203) 762-2401 Ext. 163 and Add: G.B. Bidou, M.S., C.I.H. Industrial Hygienist, Regulatory Affairs (203) 762-2401 Ext. 121.

Item 6 - line b - Delete: Karen L. Lourd, B.S. and Add: Robert J. Malley, Manager, Novo BioLabs.

line c - Delete: Ann M. Palmer, M.S. and Add: Robert L. Starnes, Ph.D., Group Leader.

Item 7 - Delete: Robert L. Starnes, Ph.D., Group Leader and Add: Gregory B. Bidou, M.S., C.I.H., Industrial Hygienist

Item 8 - Licensed Material - Sec. A - line 4 - Add: I^{125}
Sec. B - line 4 - Add: prepackaged radiolabeled research biochemicals
Sec. C - line 4 - Add: Not applicable
line 4 - 6 millicurie/Max storage
45 microcurie/kit Max.

Section E - line 3 - storage, processing (relabeling) and distribution/sales of <u>in vitro</u> RIA Test Kits for R&D applications to NRC/agreement State licensed operations (hospitals, laboratories and health care professionals). Sales to licensed laboratory supply companies for resale to licensed R&D operations.

Item 10 - Radiation Detection Instruments - Delete: line 1, parts a, b, c, d, e, and f (liquid scintillation counter no longer in service).

Item 11 - Calibration of Instruments - Delete: part b (no longer applicable)

Item 12 - Personnel Monitoring Devices - Delete: Section A, part 1, Film Badge (No active use or potential exposure). Experimentation involving I^{125} is not currently being conducted. Add: to section A, part 3, Others. None necessary for prepackaged biochemicals inasmuch as there will be no potential for exposure as they will not be worked with or opened on site.

Item 13 - Facilities and Equipment - Add: All prepackaged materials will be transferred to a laboratory cold storage room where controlled access will be assured. A designated area has been isolated for locked storage. Access will be by key with keys assigned to: the Manager of Novo BioLabs, the Radiation Safety Officer (RSO), and the Customer Service representative responsible for inventory control.

Each prepackaged radiolabeled unit has an integral lead shield surrounding the vials containing source material. Each prepackaged unit will be tagged with an appropriate label. The over pack will also be appropriately labeled.

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SUPPLEMENTAL SHEET NRC FORM 313I 10 CFR 30

Item 15 - Radiation Protection Program - Add: 10. Physical Handling of Radio labeled kits at Novo Laboratories.

A. Arrival
Periodic, consolidated shipments of materials will arrive at Novo Laboratories from parent company located in Denmark.

1. Shipping cartons will be opened and inspected by the Customer Service Representative or Director upon arrival and prepackaged materials logged into inventory. Subsequently, prepackaged materials will be placed in the controlled access storage area.

B. When order(s) received, appropriate invoices/shipping papers will be processed. Shipping will be handled as follows:

1. The Customer Service Representative or Director unlocks the storage area, selects the appropriate materials, deducts the amount from the inventory log and delivers the materials to the Shipping Department.

2. The Shipping Department overpacks the prepackaged materials, attaches the shipping and radioisotope safety warning label prior to shipping via overnight express courier service.

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SUPPLEMENTAL SHEET NRC FORM 313I 10 CFR 30

Item 16 & 17 - Formal Training in Radiation Safety and Experience

Delete: 3 and Add as new 3: Gregory B. Bidou, (B.S.) Zoology - Colorado State University.

(X) Medical Technologist (ASCP) - Weld County General Hospital

(XX) M.S. Environmental Health/Industrial Hygiene - Colorado State University.

(X) Formal course work and supervised experience in RIA thyroid function testing within clinical laboratory (I^{125})

(XX) Formal course work - (1975-77) Colorado State University, Dept. of Radiation Biology - included principals and practices of radiation protection; radioactivity measurement, standardization and monitoring techniques and instrumentation. Course work also involved mathematics and calibrations basic to the use and measurement of radioactivity, in-depth study of radiation health aspects with particular emphasis on industrial non-military uses of materials.

Formal course work in Personal Protective Equipment and laboratory decontamination procedures (Respiratory protection - Los Alamos Scientific Labs.)

Experience -

1. Medical Clinical Laboratory diagnostic materials 4 yrs: 25 microcuries, binding studies.

2. Clinical diagnostic x-ray imaging - 3 yrs.

Delete: 4 and Add as new 4: Robert J. Malley, Jr.

Title: Director, Novo BioLabs (a wholly owned on-site subsidiary of Novo Laboratories, Inc.)

Academic Background: B.Sc. - Microbiology Southern Illinois University (b)(6)

Applicable Academic Coursework: Radio-Biochemistry Medicinal Biochemistry

Employment Experience: Radio Labeling of Proteins (Enzymes) - 1.5 years

Present Function: General Management responsibilities for a business unit distributing RADIOIMMUNOASSAYS (RIA) for research use.

Item 18 - Section a - License Fee Required - pursuant to discussions with Ms. G. Jackson find enclosure of check in the amount of $460.00.

Section a - Part 1 - License Fee Category - 3B

Section a - Part 2 - License Fee Enclosed $460.00

Section b - Certifying Official (signature)

G. B. Bidou

Section c - Name - Gregory B. Bidou, CIH

Section d - Title - Industrial Hygienist

Section e - Date - December 19, 1985

03013216
03620 12/87

EXPEDITE

verbal OK
1/7/86

SWEEN: William D. 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 1

1. APPLICATION ATTACHED

Applicant/Licensee: Novo Laboratories, Inc

Application Dated: 12/17/85

Control No.: 104824

License No.: 06-17718-01

2. FEE ATTACHED

Amount: $460.00

Check No.: 004435

3. COMMENTS

Signed Brenda Pilatchek

Date 12/30/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: ~~3M~~ 3B ← changing to ($460) - app fee

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

Amendment ↘

Renewal

License

Signed G Jackson

Date 1/7/86

GION I FORM 213
ARCH 1983)