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DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, DC 20310

REPLY TO
ATTENTION OF
DASG-PSP-E

13 June 1983

'83 JUN 15 P3:07

US Nuclear Regulatory Commission
Division of Fuel Cycle and Material Safety
Materials Licensing Branch
Washington, DC 20555

Dear Sirs:

I refer to my letter of 4 February 1983 and my telephone conversations on 18 March 1983 and 10 June with Mr. Jim Myers and Mrs. Patricia Vaca, respectively of your office. The Department of the Army was issued IND #12,605 for the subject protocol. Lieutenant Colonel Peter W. Blue, Fitzsimons Army Medical Center, (FAMC) Aurora, Colorado is authorized under the IND to enter patients into studies utilizing NP-59. Request your reconsider your decision, and amend the FAMC license per my request of 23 February 1983.

Dr. Blue's inclusion on the IND may be verified with Mr. Niel Abel, FDA, telephone number 443-4260. If you need any additional information on this matter please contact me at 697-2796.

Sincerely,

Frank E McDermott

FRANK E. MCDERMOTT
Colonel, MSC
Radiological Hygiene Consultant

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DEPARTMENT OF THE AI Y
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20310

41 - Dme
Radiol.

REPLY TO ATTENTION OF
SGRD-HR

30 DEC 1980

SUBJECT: "Intravenous Administration of 131-I-6-B Iodomethylnorcholesterol (NP-59) for Adrenal Evaluation and Imaging," Submitted by LTC Peter W. Blue, MC, FAMC

Commander
Fitzsimons Army Medical Center
ATTN: C, Department of Clinical Investigation
Aurora, CO 80045

1. The subject protocol was previously approved by The Surgeon General for implementation at Letterman Army Medical Center, Brooke Army Medical Center, and William Beaumont Army Medical Center. The studies are being conducted under Department of Army IND #12,605, with LTC Robert J. Lull, MC, LAMC, as the principal investigator. The protocol submitted by LTC Blue with the same subject is therefore administratively approved for implementation at FAMC.

2. As specified in FD Form 1573, only LTC Blue or someone under his direct supervision is authorized to enter patients into the study.

3. If there are any questions concerning this matter, please contact the Human Use Review Office at AUTOVON 343-2165.

FOR THE SURGEON GENERAL:

Marian F. Barlow (LT, MSC)

ROGER A. BENNETT
LTC, MSC
Chief, Human Use Review Office

CF:
LTC Lull, LAMC

1516

X-2751 Fitzsimons

THE UNIVERSITY OF MICHIGAN
MEDICAL SCHOOL
ANN ARBOR, MICHIGAN 48109

DEPARTMENT OF INTERNAL MEDICINE
Division of Nuclear Medicine

3828

August 13, 1982

Dear Customer:

The University of Michigan Nuclear Pharmacy has recently had their NP-59 files reviewed by the University's Radiation Control Services. They have found the following deficiency in your licensing which must be corrected before the Nuclear Pharmacy will be allowed to ship any NP-59 (I-131 iodomethylnorcholesterol) to your Institution. Please respond immediately to ensure uninterrupted service.

☐ License number _____ expired: _____

Please send a complete copy of new license or extension.

☒ Your group license number 05-00046-13 does not include authority to possess NP-59. See attached letter (a similar letter was sent in January 1982). Please send us NRC or State Amendment to receive NP-59.

☐ We have no license in our files for your institutioon.

☐ Other: _____

_____

_____

Mail all information to: Nuclear Pharmacy
W5628 Main Hospital
University of Michigan Medical Center
1405 East Ann Street
Ann Arbor, Michigan 48109

If you have any questions, call Nancy Wirth or Dennis Swanson at (313) 763-0147.

TERMS AND CONDITIONS

1. Transportation Costs: Materials are sold F.O.B. destination. UMNP will arrange shipment by air common ground carrier to the buyer. Transportation costs are included in the price of the radiopharmaceutical and will not be listed separately on the invoice.

2. Payment Terms: Terms are net, thirty days from date of invoice.

3. Order Information: Buyer's purchase order shall specify the name of desired material, quantity desired, shipping date desired, Buyer's purchase order number and name of authorized purchaser. Such orders shall be addressed to or telephoned into the University of Michigan Nuclear Pharmacy, University Hospital - W5628, Ann Arbor, Michigan, 48109, Telephone: (313) 763-0147. All orders should be received by UMNP by the Tuesday preceding the scheduled shipment date.

4. Returned Goods Policy: All sales are final, and no materials may be returned for credit unless they do not meet the specifications cited herein.

5. Licensing Information: The Buyer must possess appropriate NRC or Agreement State Licenses necessary for the procurement of the radioactive material specified in #3 above. A copy of this license, together with all amendments, must accompany the return of this agreement. It is the responsibility of the Buyer to notify the UMNP upon renewal or revocation of said license.

   The Nuclear Pharmacy, University of Michigan, currently ships NP-59 to outside investigators as per a "transfer between approved NRC licensees" under the authority of the NRC Broad License issued to the University of Michigan. In other words, the Nuclear Pharmacy does not possess its own NRC "Distribution License" as found with other commercial manufacturers.

   In view of the above, if you obtain and store radiopharmaceuticals under the authority of an NRC Group License, you must amend this license to indicate that you will be obtaining NP-59 from the University of Michigan Nuclear Pharmacy. This amendment can be achieved by writing a letter directly to the NRC indicating your desire to purchase NP-59 and your NRC Group License Number.

   If you operate under the authority of NRC Broad License, amendments to this license are not necessary providing you have the appropriate human use/ radioisotope committee approval of your institution.

6. Pharmaceutical Use of Radioactive Materials: ^{131}I-6β-Iodomethylnorcholesterol (NP-59) is initially offered by the UMNP with a radiopharmaceutical quality suitable for human use, however the UMNP does not act as the clinical sponsor for this agent. If the Buyer intends to use NP-59 in humans, he must comply with Food and Drug Administration requirements by obtaining his own Notice of Claimed Investigational Exemption for a New Drug (I.N.D.) and/or other such authorization as deemed necessary for his particular project. NOTE: As stipulated in this I.N.D. application (Form 1571, 5.) it is a responsibility of the Buyer (as the sponsor of this agent) to verify the final suitability of