DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 14 1989

Office of Nuclear Material Safety and Safeguards
Division of Industrial and Medical Nuclear Safety
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Richard E. Cunningham
Director

Dear Mr. Cunningham:

This is in response to your June 24, 1988 inquiry to Dr. Temple regarding the use of radiopharmaceutical drug products in human subjects that are not the subject of investigational new drug applications (INDs) or approved new drug applications (NDAs). Your request that we comment on FDA's drug regulations concerning the subject was prompted by a letter to you dated April 25, 1988 from Dr. Gerard C. Wong of the California Department of Health Services. In addition, you requested that we comment on the authority of various local committees to approve the use of such radiopharmaceuticals prior to their clinical use in diagnosis or therapy.

In general, the Federal Food, Drug, and Cosmetic Act (the Act) requires that any new drug, as defined by Section 201(p) of the Act, (including diagnostic or therapeutic radiopharmaceuticals), must either be the subject of an approved NDA before it may be commercially marketed or it must be the subject of an IND authorized by the agency before clinical investigation may be carried out. However, there are certain circumstances to which the requirement does not apply, namely:

1. Radioactive drugs for certain research uses (21 CFR 361.1).

   These are prescription drugs which a Radioactive Drug Research Committee (RDRC) can authorize to be used in "basic research" under the specific requirements set forth in 21 CFR 361.1. Such drugs are not regarded to be new drugs under the conditions specified by the investigator's protocol and approved for basic research by the RDRC. The types of basic research specified in the regulation include studies of metabolism, human physiology, pathophysiology or biochemistry. Imaging or localized counting used for determining biodistribution or pharmacokinetics can also be regarded as satisfying the basic research requirement. The types of clinical trials not permitted under this regulation are not specified but clinical studies intended to collect drug

safety and effectiveness data are not permitted under this mechanism. The agency has considered the evaluation of a drug as a clinical tool, including comparison with other agents, as part of a clinical trial and subject to the investigational new drug (IND) requirements of 21 CFR Part 312.

The radiation dose limitation contemplated in 21 CFR 361.1 is that which has been established by the Nuclear Regulatory Commission (NRC) for basic occupational radiation protection (10 CFR 20.101 and 20.102). Levels below this, the agency presumes, could fulfill the criteria for a drug to be considered not a new drug if all other portions of the regulations are met. That is the sole purpose of the limit.

2. The compounding of such drugs on the basis of a valid prescription under the practice of medicine/pharmacy in accordance with FDA's policy guide on nuclear pharmacies.

For many years radiopharmacists have obtained radiochemicals to prepare in-house formulations of both approved and non-approved radiopharmaceuticals for human administration under what FDA regards as the practice of medicine and/or pharmacy. The agency has not sought to regulate under the new drug provisions of the Act the practice of pharmacy where a radiopharmacist acts under a prescription order from a physician for a specified patient. Traditional compounding of a radiopharmaceutical intended for clinical use only within an institution with which a radiopharmacist is affiliated becomes the practice of medicine and/or pharmacy which are properly regulated by state and local authorities. The FDA issued a policy statement in May 1984 to clarify the practice of medicine/pharmacy issue as it pertains to the preparation of radiopharmaceuticals by nuclear pharmacies. A copy of this statement is enclosed for your information.

3. Products excluded from the definition of "radioactive drug" under 310.3(n).

There are a limited number of radiopharmaceuticals that are regarded generally by nuclear medicine experts to be safe for their intended purpose which as a matter of regulatory discretion are not regulated by the agency as new drugs. These are naturally occurring radionuclides which are used in trace (microcurie) amounts to tag body constituents such as potassium

containing salts, amino acids or other body metabolites. Such radiopharmaceuticals may be either compounded in-house or obtained through commercial channels.

The user of investigational radiopharmaceutical drugs (categories 1 and 3 above) must, however, obtain the approval of appropriate in-house committees according to FDA regulations. We have briefly discussed the limited authority of the RDRC (category I) to approve certain metabolic or pharmacokinetic studies considered to be basic research functions. Please refer to 21 CFR 361.1 for detailed information. FDA regulations do not specifically address Radiation Safety Committees which function as the result of the NRC regulations. FDA regulations do provide for public or private institutions to establish Institutional Review Boards (IRBs) with the responsibility to approve and review, both initially and periodically, clinical investigations regulated by the FDA. The IRB is charged with the responsibility to assure the protection of the rights and safety of human subjects.

4. Finally, there is an additional category of prescription drugs currently being marketed without FDA approval which are not exempt from the new drug provisions of the Act. These drugs are being reviewed in accordance with Compliance Policy Guide (CPG) 7132c.02 (copy enclosed). Through this guide the agency will eventually require all marketed prescription drugs to have FDA approval. We are unaware of any radiopharmaceuticals that are included in the drugs defined by this CPG; if there are, this CPG would apply.

We hope that the above will clarify our position regarding your inquiry. If you need further information or assistance, please contact our Division of Oncology and Radiopharmaceutical Drug Products at 443-4250.

Sincerely yours,

Paula Botstein MD

Paula Botstein, M.D.
Deputy Director (Medical Affairs)
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Administrative Code, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any conditions specified in this license.

1. *Licensee* Los Angeles County Harbor UCLA Medical Center, Environmental Health and Safety Office 2. *Address* 1000 West Carson Street Torrance, CA 90509 *Attention:* Jack Patrick, Ph.D. Radiation Safety Officer	3. *License No.* 0359-70 is hereby amended in its entirety. *Amendment No.* 73 4. *Expiration date* February 19, 1995 5. *Inspection agency* Los Angeles County Department of Health Services

6. Nuclide	7. Form	8. Possession Limit
A. Hydrogen 3	A. Any	A. Not to exceed 20 curies.
B. Any nuclide with atomic numbers 3-83 inclusive	B. Any	B. Not to exceed 5 curies for any one radionuclide, total not to exceed 12 curies.
C. Any nuclide with atomic numbers 3-83 inclusive	C. Sealed sources manufactured and distributed in accordance with a license issued by the U. S. Nuclear Regulatory Commission or Agreement States	C. Total not to exceed 1.5 curies.
D. Any nuclide with atomic numbers 84-105 inclusive except: (1) Special Nuclear Material (2) Source Material	D. Any	D. Total not to exceed 100 millicuries.
E. Any nuclide with atomic numbers 84-105 except: (1) Special Nuclear Material (2) Source Material	E. Sealed sources manufactured and distributed in accordance with a license issued by the U. S. Nuclear Regulatory Commission or Agreement States	E. Total not to exceed 500 millicuries.

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Radiologic Health Section
744 P Street, Sacramento, CA 95814

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6. Nuclide (cont.)	7. Form (cont.)	8. Possession Limit (cont.)
F. Source material	F. Any	F. Not to exceed 350 lbs.
G. Carbon 14	G. Any	G. Not to exceed 10 curies.
H. Cesium 137	H. Sealed source (J. L. Shepherd Model 6810 or ORNL Model A0096)	H. 1 source not to exceed 1,150 curies.
I. Any radionuclide listed in Group 1, 2, 3, 4, or 5 of the Department's form RH2010-R, "Well Established Medical Uses", or listed under an NDA approved by the FDA	I. Any radiopharmaceutical listed in Groups 1 through 5 of the Department's form RH2010-R or listed under an NDA approved by the FDA	I. One curie for each radionuclide except 5 curies each for Technetium 99m and Molybdenum 99. Total possession limit not to exceed 15 curies.
J. Any radionuclide listed in Group 6 of the Department's form RH2010-R, "Well Established Medical Uses", or approved by the FDA	J. Sealed or solid sources, manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or a specific license issued by an Agreement State pursuant to equivalent state regulations (except for sources manufactured prior to August 16, 1974)	J. Not to exceed 200 millicuries for any one source. Total possession limit not to exceed 5 curies.
K. Any radionuclide with atomic numbers 3-83 inclusive	K. Sealed sources, manufactured, labeled, packaged, and distributed in accordance with a specific license issued to the manufacturer by the U. S. Nuclear Regulatory Commission or an Agreement State	K. Not to exceed 15 millicuries per source. Total possession limit not to exceed 500 millicuries.

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6. Nuclide (cont.)	7. Form (cont.)	8. Possession Limit (cont.)
L. Any radionuclide as specified in an IND which has been accepted by the USFDA	L. Any radiopharmaceutical as specified in an IND which has been accepted in writing by the USFDA	L. Not to exceed 200 millicuries of Iodine 131 and not to exceed 500 millicuries for any other radionuclide. Total possession limit not to exceed 5 curies.
M. Any radionuclide with atomic numbers 1-83 inclusive	M. RIA kits, manufactured, labeled, packaged, and distributed in accordance with a specific license issued to the manufacturer by the U. S. Nuclear Regulatory Commission or an Agreement State	M. Total possession limit not to exceed 500 millicuries.

9. Authorized Use

A. and B. To be used for research and development as defined in 17 CCR 30100 (ad), instructional purposes, and research studies in humans, as defined in 21 CFR Section 361.1 and as approved by a Food and Drug Administration Radioactive Drug Research Committee under the provisions of 21 CFR Part 361.

C., D., E., and G. To be used for research and development as defined in 17 CCR 30100 (ad) and instructional purposes. Radioactive materials shall not be used in or on humans.

F. To be used for shielding, collimation, and field-shaping in beam therapy machines.

H. To be used in a J. L. Shepherd irradiator Model 143-45 for irradiation of materials.

I. To be used for nuclear medicine and/or therapy procedures. Radiopharmaceuticals approved for human use under an NDA by the USFDA and not listed on form RH 2010-R may be used in accordance with the package insert relative to "indications" and "doses". Radiopharmaceuticals listed in Groups 1 through 5 of form RH 2010-R may be used only as noted below or as specifically approved by the Harbor UCLA Radiation Safety Committee.

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Group 1 - To be used for diagnostic studies involving measurement of uptake, dilution, or excretion but not involving imaging.

Group 2 - To be used for diagnostic studies involving imaging, including the use of Xenon 127 and/or Xenon 133 gas.

Group 3 - Use of reagent kits including Mo/Tc-99m, Os-191/Ir-191m, Sn-113/In-113m, and Rb/Kr-81m generators for preparation of radiopharmaceuticals listed in Group 2.

Group 4 - To be used for internal therapy not usually requiring hospitalization.

Group 5 - To be used for internal therapy usually requiring hospitalization for purposes of radiation safety.

J. To be used only for treatment of cancer or for ophthalmic treatment. Use of sealed sources in remote afterloading devices is not authorized by this Subitem.

K. To be used as marker sources or for testing and calibration of instruments.

L. To be used for diagnostic or therapeutic studies conducted in strict accordance with manufacturer-sponsored or physician-sponsored IND(s) which have been accepted in writing by the USFDA and have been approved by the Harbor UCLA Radiation Safety Committee.

M. To be used for in-vitro clinical testing only.

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10. Radioactive material shall be used only at the following locations:

    (a) 1000 West Carson Street, Torrance, California (including the Research and Education Institute).

11. In accordance with Section 6103 of the California Government Code, this license is not subject to payment of an annual license fee.

12. All uses of radioactive material under this license shall be conducted in accordance with the user's application to and modifying requirements of the Harbor UCLA Medical Center Radiation Safety Committee. The review of intramural applications shall include findings with respect to matters specified in Section 30194 of the California Radiation Control Regulations (CRCR), and if human uses is at issue, Section 30195 (b) of the CRCR. Documentation of these findings shall be maintained for review by the Department or its authorized representatives.

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13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(a) The letter dated July 23, 1987, signed by Edward J. Foley, with the following attachments:

(1) Application for renewal of Broad Scope-Type A dated July 23, 1987, signed by Edward Foley.

(2) Radiation Safety Manual dated June 30, 1987.

(3) Appendices B through G.

(b) The application (form RH-2000) with attachments dated July 23, 1987, signed by Edward J. Foley.

(c) The letter dated February 26, 1982, signed by J. W. Patrick, Ph.D. (regarding waste compaction).

(d) The letter dated July 24, 1987, signed by Ismael Mena, M.D.

(e) The letter dated November 10, 1988, signed by Jack Patrick, Ph.D.

14. (a) The radiation safety officer in this program shall be Jack Patrick, Ph.D.

(b) The chairperson of the radiation safety committee shall be Ismael Mena, M.D.

(c) The custodians of sealed sources <u>for</u> <u>medical</u> <u>therapy</u> shall be Jack Patrick, Ph.D., or M. Herman, Ph.D.

15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Section 30275 (c) of the California Radiation Control Regulations.

16. Except for alpha sources, the periodic leak test required by Condition 15 does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

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17. Analytical tests for leakage and/or contamination of sealed sources shall be performed by qualified individuals designated by the radiation safety officer.

18. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services.

    (a) The radiation safety officer.

    (b) Qualified individuals designated by the radiation safety officer.

19. Records of leak test results shall be kept in units of microcuries and maintained for inspection. Records may be disposed of following Department inspection. Any leak test revealing the presence of 0.005 microcurie or more of removable radioactive material shall be reported to the Department of Health Services, Radiologic Health Branch, 744 P Street, P. O. Box 942732, Sacramento, CA 94234-7320, within five days of the test. This report shall include a description of the defective source or device, the results of the test, and the corrective action taken.

20. Notwithstanding the periodic leak test required by Section 30275 (c), any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

21. The licensee is authorized to calibrate radiation detection instruments (for personal use). Each calibration of a radiation detection instrument shall include not less than 2 points other than zero (separated by 50 percent of full scale) for each scale of the instrument certified by the licensee.

22. The licensee is authorized to hold radioactive materials with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

    (a) Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    (c) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

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23. The licensee is authorized to use a radioactive waste compactor for compacting radioactive waste under the following limitations:

(a) Compacting of radioactive waste is prohibited if the radioactive waste contains:

(1) Unsealed radioactive material other than contaminated articles;

(2) Alpha emitters other than source material;

(3) Strontium 90; or

(4) Radioactive material in liquid form.

(b) The radioactive waste compactor shall be used in accordance with statements, representations, and procedures as described in Condition 13 (c) of this license except as specifically provided otherwise by this license.

(c) The licensee shall test areas near the compactor considered most likely to be contaminated for removable contamination at intervals not less frequently than weekly, or if used less frequently than weekly, after each use. Results of such tests shall be maintained available for inspection. If removable contamination exceeds 2,000 disintegrations per minute per 100 square centimeters, the licensee shall immediately decontaminate the area.

24. The licensee is authorized to dispose of liquid scintillation media and animal carcasses as nonradioactive hazardous chemical/biological waste for Hydrogen 3 and Carbon 14 in concentrations less than 0.05 microcuries per gram (averaged over the weight of the entire animal).

25. Except as otherwise specifically provided by this license, radioactive pharmaceuticals to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is registered with the U. S. Food and Drug Administration in accordance with Section 510 of the Federal Food, Drug, and Cosmetic Act, or licensed as a radiopharmacy with the California Board of Pharmacy, and who guarantees the pharmaceutical quality of each product.

26. Except as otherwise specifically provided by this license, radioactive biologicals (including human serum albumin) to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is licensed for the preparation and distribution of such products by the Division of Biologics Standards of the National Institutes of Health, pursuant to Part 73 of the Public Health Service Regulations, or by the Bureau of Biologics, U. S. Food and Drug Administration, or from a radiopharmacy licensed with the California Board of Pharmacy.

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27. Radioactive materials prepared, processed, or modified by the licensee shall not be administered to humans except as specifically authorized by this license.

28. Technetium 99m, Iridium 191m, and Indium 133 generators approved by the Department may be used as sources of radioactive materials for use in preparations to be administered to humans, provided the generators are used in strict accordance with the manufacturer's instructions.

29. Where users or their assistants are engaged in elution of generators and/or preparation of labeled pharmaceuticals from kits, the exposures to the fingers or hands of these individuals shall be monitored, using appropriate dosimeters.

30. Technetium 99m labeled pharmaceuticals prepared by the licensee by aseptic addition of pertechnetate to sterile, pyrogen-free reagents procured in the form of kits which have been approved by the Department, may be administered to humans provided all instructions and recommendations contained in the manufacturer's package insert information are strictly followed, and provided the radioassay of the final product is determined with an overall error not exceeding ten percent.

31. Counting equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in vitro assay samples shall be calibrated and tested sufficiently often to ensure the medical validity and reliability of data obtained. The stability of the equipment shall be checked at least once on each day of use, using appropriate standards or reference sources.

32. The licensee shall not use radioactive material in the form of gas or aerosol in such a manner as to produce an airborne concentration exceeding the appropriate limit specified in Section 30266 or 30269 of the California Radiation Control Regulations.

33. Where clinical test studies of a new radiopharmaceutical product are authorized by this license, the responsible physician shall observe all subjects for any significant reactions, and shall prepare and maintain reports of such reactions, and of the clinical efficacy of each study. Copies of all such reports shall be provided to the sponsoring firm supplying the product within 30 days of completion of the clinical test series. Any adverse reactions shall be reported immediately to the Department of Health Services.

34. The licensee shall not routinely use doses exceeding those specified in the Department's "Routine Uses" list unless: (a) a nonroutine authorization for use of a different dose range is included in the license, or (b) a "Notice of Intent" has been filed with the Department.

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35. No clinical trial authorized in Subitem L of Items 6 through 9 of this license shall be initiated prior to the investigator's receipt and review of the following:

    (a) Necessary informational material, including a description of prior investigations and experience with the agent, a protocol for performance of the study, a copy of the proposed package insert information including any hazards or contraindications, investigators' case report forms, and patient dosimetry calculations.

    (b) Written certification by the sponsor that the relevant IND has been accepted as of a specified date by the U. S. Food and Drug Administration and that that agency has no objection to initiation of the investigation.

    (c) Written certification by the sponsor that a copy of the relevant IND and of the U. S. Food and Drug Administration letter of acceptance has been filed with the State Department of Health Services.

36. No clinical trial authorized in Subitem L of Items 6 through 9 of this license shall be initiated prior to the date specified in the U. S. Food and Drug Administration letter of acceptance of the relevant IND (ordinarily 30 days following the date of the letter).

37. Physicians participating in clinical trials shall obtain the informed consent of all human subjects of such investigations in accordance with the requirements of Section 130.37 of the Federal Food and Drug Regulations. (A copy of these requirements is available upon request from the Radiologic Health Branch.)

38. The licensee shall give prompt notification to the Radiologic Health Branch, as well as to the sponsor, of any serious problems encountered with, or adverse reactions attributable to, any investigational radiopharmaceutical.

39. The expression "IND" as used in this license shall be interpreted to mean only a Notice of Claimed Investigational Exemption for a New Drug, prepared in the format designated "Form FD 1571", as described in Section 130.3 of Part 130 of Title 21 (Food and Drugs) of the Code of Federal Regulations.

40. The licensee shall maintain an orderly file of all documentation required by the conditions of the Subitem L authorization and shall make it available to representatives of the Department upon request.

41. Treatment and management of patients receiving therapeutic quantities of unsealed radioactive materials shall be in accordance with guidance contained in Chapter 4, NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received

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Therapeutic Amounts of Radionuclides" (NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, Maryland 20814).

42. Treatment and management of patients undergoing brachytherapy shall be in accordance with guidance contained in Chapter 5, "Safety Precautions in Clinical Application", NCRP Report No. 40, Protection Against Radiation From Brachytherapy Sources (NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, Maryland 20814).

43. If there is reason to suspect that a medical radium source may be leaking or contaminated, it shall be tested before further use, by a method acceptable to the Department of Health Services, and a report of the test results and the action taken shall be submitted within 30 days to the Radiologic Health Branch.

44. Notwithstanding the six-month test interval requirement of Section 30275 of the California Radiation Control Regulations, medical cesium sources (3M Company Models 6500 - 6507 or old Model 6D6C, and Isotope Products Model 67-800 or 67-820 series) possessed under this license may be tested for leakage and/or contamination at three-year intervals, provided that the test method used has been specifically authorized by the Department of Health Services. The licensee shall maintain records of such tests for inspection by the Department or its authorized representative.

45. Except for plutonium contained in a medical device designed for individual human application, no plutonium, regardless of form, shall be transported in an aircraft unless contained in packages the design of which the NRC has specifically approved for transport of plutonium by air.

46. Bioassays shall be performed within 72 hours for persons preparing and/or administering therapeutic quantities of Iodine [illegible], in liquid form.

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by

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