MAR 01 1984

FCML:PCV
(16016)
030-20858

Mr. Steven R. Lefevre, President
Centra-Pharm, Inc.
2937 Switzer Road
Columbus, OH 43219

Gentlemen:

This is in reference to your October 10, 1983 application for a new nuclear pharmacy license and to our February 24, 1984 telephone conversations with you and with Mr. Chris Wagner of Nuclear Medicine Associates. From our February 24, 1984 telephone conversation, we understand that your organization was not able to incorporate in the State of Ohio under the name "Centra-Pharm, Inc." but that you have incorporated under another name and that, under the new name, your organization has a license application pending with the Ohio Board of Pharmacy. We also understand that you have made at least one change in your facility (i.e., the location of the exhaust vent in your "Hot Lab Area") and that at least one of the spaces on one side of your facility is now occupied. Although Item 5 of your application appears to indicate that Nuclear Medicine Associates will be providing some radiation safety assistance to you beyond assistance with the preparation of the application for a new license, Mr. Wagner of Nuclear Medicine Associates did not have this understanding.

To clarify these matters and other points identified during our review of your application, we need the following additional information.

1. As indicated above, we understand that your organization has incorporated under a name other than "Centra-Pharm, Inc." If our understanding is correct, please:

   a. Specify the new name of your organization.

   b. Verify that all commitments made in the October 10, 1983 application filed by Centra-Pharm, Inc. are binding on the organization named in response to Item 1.a. above.

   c. Verify that all procedures, instructions and other documents prepared in support of the October 10, 1983 license application that specify the name "Centra-Pharm, Inc." will be changed to reflect the name of the organization listed in response to Item 1.a. above.

   You should be sure that your response to this letter is signed by a person authorized by the organization named in response to Item 1.a. above to make commitments to NRC on behalf of that organization.

2. Nuclear pharmacy licenses are issued using a format similar to that shown in Enclosure 1. This format has been designed to give nuclear pharmacies a reasonable amount of flexibility, yet limit the possession of certain critical radionuclides (e.g., iodine-131) so that radiological contingency plans are not needed. Enclosure 2 explains NRC's criteria for selection of licensees needing radiological contingency plans.

   Please provide us with a marked copy of Enclosure 1 to specify the possession limits that you desire for the various items. Note that, when your license is issued, it will not contain a specific entry for depleted uranium. Depleted uranium that is used as shielding on Union Carbide's high activity Mo-99/Tc-99m generators is also a shipping container and you as the recipient are exempt from licensing in accordance with the provisions of 10 CFR 40.13(c)(c), copy enclosed.

3. When your license is issued, we will name specific individuals as users in Condition 12.A. of the license and will require that "at least one individual named in Condition 12.A. shall be physically present at the authorized place of use whenever licensed material is being used." After your license is issued and the NRC staff has had the opportunity to inspect your program and has seen the qualifications of additional personnel that you propose as authorized users, we could reconsider your request to select users in the manner described in Item 8 of your application or in some alternative manner proposed at a later date.

   Please be advised that George Hinkle is not specifically named as a user on License No. 34-00293-02 that is issued to Ohio State University. This license authorizes the University's committee to select users. In order for us to consider Mr. Hinkle as an authorized user, we need:

   a. The number of a nuclear pharmacy license, issued by NRC, on which Mr. Hinkle was or is specifically named as an authorized user, OR

   b. A copy of a nuclear pharmacy license, issued by an Agreement State, on which Mr. Hinkle was or is specifically named as a user, OR

   c. Documentation of Mr. Hinkle's training and experience. This documentation should be sufficient to show that Mr. Hinkle's training and experience meet or exceed the criteria described in Appendix B of the enclosed draft guide. Please use forms similar to Figures 1 and 2 in Appendix B for documenting Mr. Hinkle's training and experience.

   If you wish to propose authorized users in addition to those specified in your October 10, 1983 application, please provide for each proposed user the same type of information as we have requested for Mr. Hinkle.

4. Mr. Lefevre is identified as the president of your organization and the day-to-day radiation safety officer. Please specify the percentage of time that Mr. Lefevre will devote to his radiation safety duties. For additional guidance, see Item 7.b., pages 6 and 7, of Enclosure 4.

5. As we discussed in our Feburary 24, 1984 telephone conversation, NRC is very interested in a description of the site of the nuclear pharmacy. You indicated that, although your application stated that the spaces on either side of the nuclear pharmacy were vacant at the time you filed your application, one space is now occupied by a courier service and that the other was occupied for a time by a machine shop, but is now vacant. We need up-to-date information about the identification and location of other tenants, more information about the characteristics of the neighborhood in which you are located, confirmation that operation of a nuclear pharmacy does not conflict with local codes and zoning laws, a description of arrangements you have made with the fire department and a description of fire protection methods that you will use if you request a possession limit of 1 Curie or more of iodine-131.

   Please provide the information requested in Item 9.a.(1), (2), (5), (6), and (7) on pages 9-10 of Enclosure 4.

6. The description of your facility did not provide all of the information we need in order to ensure that you have adequate facilities and equipment. Specifically, we need information on the following:

   a. In our February 24, 1984 telephone conversation, you indicated that you had changed the location of the exhaust vent in your "Hot Lab Area." Please provide a revised drawing to show the new location of the exhaust vent and to show any other changes made in your design since the submission of your license application.

   b. As we understand your application, packages of radioactive materials that are delivered after normal working hours are placed at Position 4 on the drawing on page 7 of Item 11. We are concerned that the drivers (presumably non-radiation workers) for the courier services who deliver packages would have access to the waste storage area (Position 8 on the same diagram) and that radioactive wastes are not secured from unauthorized removal from Position 8. Please explain what changes will be made to control access to Position 8 and to secure the radioactive wastes from unauthorized removal.

   c. You are located in a multi-tenant building and it will be necessary for you to perform certain surveys to demonstrate compliance with NRC's regulations; e.g., 10 CFR 20.105(b)(1) and (2) with respect to radiation levels in unrestricted areas along common walls with other tenants. Outline the access agreement(s) you have with tenants in the adjacent spaces to allow you to perform surveys or describe an alternative monitoring procedure (e.g., posting of film badges at specified intervals along common walls).

   d. In your application, you have indicated that iodine-131 would stored and opened in a hood at Position 11 on the drawing on page 7 of Item 11. In order to maintain concentrations of radioactive materials in effluent releases as low as is reasonably achievable, most licensees use a charcoal filtration system to remove a large

percentage of volatile iodine-131. Please describe the filtration system used in conjunction with your hood that will minimize releases of radioactive iodine to the environment and specify the percentage of radioiodine that this system can be expected to remove from environmental effluents.

7. The August 26, 1983, letter attached to your October 10, 1983 application requests authorization to dispose of certain records subsequent an NRC inspection. We do not believe that it is appropriate to allow you to maintain these records just until the time of an NRC inspection because of possible disputes over whether specific records were reviewed in any given inspection. However, we believe that 2 years is the minimum time that records of dose calibrator accuracy, constancy and linearity checks, survey meter calibration records, instrument calibration and quality assurance records and records of training for occupational and nonoccupational personnel should be maintained. Please advise us whether you wish to revise your request and maintain the records identified above for at least 2 years.

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8. Your package receipt procedures (i.e., page 2 of Item 13) and your emergency procedures (i.e., page 1 of Item 16) do not provide detailed information on how to contact designated individuals. We need a commitment from you that each of these procedures will contain up-to-date information on how to contact the designated individuals. Please provide this commitment to us.

9. Item 14 of your application pertains to procedures for safely opening packages and we need the following additional information on this subject.

   a. Page 1 of Item 14 states that the specified procedures will be carried out for all (emphasis added) packages, yet the August 26, 1983 cover letter attached to your October 10, 1983 application states that the procedures are "not applicable to prepackaged in vitro kits except that radiation labels will be obliterated." Section 20.205(d) of 10 CFR Part 20 (copy enclosed) requires licensees to have procedures for safely opening all packages and does not provide an exemption for any package. Please revise your response to Item 14 to state clearly that your procedures apply to all packages including those containing prepackaged in vitro kits.

   b. We note that Item 14 is very similar to an appendix in Regulatory Guide 10.8 (Revision 1) that was developed for medical licensees, rather than nuclear pharmacies. The footnote on page 1 of Item 14 implies that the nuclear pharmacy will have a physician's written requisition for all special orders (e.g., therapy doses) by the time that the special order is received by the nuclear pharmacy. If this is your intention, please verify this fact. If this is not your intention, please clarify.

10. With regard to your request for authorization to collect radioactive wastes from your customers:

a. We believe that Section I.A. on page 2 of Item 18 does not list correctly all of the possible contents of the radioactive wastes that you may be picking up. You did not mention xenon-133 nor iodine-131 used to treat thyroid carcinoma (i.e., in Group V). It is not clear to what Group III wastes you are referring (e.g., Mo-99/Tc-99m generators?). We assume that returned radioactive wastes may contain any radionuclide that you were authorized to distribute. Please verify that our assumption is correct or provide clarifying information.

b. You should provide to your customers additional instructions to ensure that they, as the shippers of radioactive wastes, will be complying with all applicable DOT regulations. Please submit a copy of these additional instructions.

11. Please clarify your description of the equipment used to make thyroid uptake measurements. On page 1 of Item 9 you identified a Nucleus, Inc. Model 2560 well detector and on page 1 of Item 19 it appears that you will be using a Nucleus, Inc. Model 256D multichannel analyzer to make thyroid uptake measurements. A well detector is not an appropriate instrument with which to measure thyroid uptake; rather a collimated thyroid uptake probe is appropriate. Please describe in greater detail the exact equipment used to make thyroid uptake measurements.

12. Certain aspects of your area survey procedures need clarification. It is not clear under what circumstances areas of Tc-99m spills will not be cleaned. It is also not clear that higher than normal radiation levels will be investigated to determine their cause and steps taken to reduce these values. See Item 10.k. on pages 29-31 of Enclosure 4. Please revise your survey procedures to incorporate as requirements points 3, 7 and 8 on page 30 of Enclosure 4.

13. With regard to your activities as a nuclear pharmacy:

a. Please submit a copy of the pharmacy license issued to your organization by the State of Ohio.

b. Confirm that your activities will be limited to the preparation of radiopharmaceuticals for delivery on prescription basis to physicians in the Columbus area or provide clarifying information that demonstrates that your operation fulfills the requirements of 10 CFR 32.72(a)(2)(ii).

14. Please submit actual color samples of all labels that will be used with your products and specify where each label will be placed. See Item 10.m. on page 33 of Enclosure 4 for additional guidance.

15. For each radionuclide that you wish to distribute:

a. State the maximum activity that will be placed in each type of container (e.g., vial, syringe).

b. Describe the type and thickness of shielding that you will provide for each type of container.

c. Indicate the maximum radiation levels to be expected at the surface of each shielded container when filled with the maximum activity.

See Item 10.n. on page 34 of Enclosure 4 for additional guidance.

16. Based on past experience with nuclear pharmacy operations, we believe that these licensees need an independent audit program to ensure continuing compliance with NRC regulations and the terms and conditions of the NRC license. Accordingly, please:

a. Describe the type, extent, and frequency of the audits to be conducted of your operations.

b. Specify the name and describe the training and experience of the individual who will conduct the audits.

c. Describe the basis for the auditor's ability and authority to mandate needed changes.

For further guidance on these matters, see Item 10.p. on page 35 of Enclosure 4.

17. With respect to your request for authorization to redistribute sealed calibration and reference sources:

a. We need to know to whom you wish to redistribute these sources. Do you wish to redistribute these sources to Group medical licensees only or also to other specific licensees?

b. We need confirmation that you will obtain these sources from a manufacturer licensed pursuant to 10 CFR 32.74 or under equivalent Agreement State regulations.

c. We need confirmation that the manufacturer's packaging and labeling will be unaltered and that you will ensure that the sealed calibration and reference sources that you redistribute will be accompanied by the calibration certificate and the leaflet or a brochure supplied by the manufacturer that provides instructions for handling and storage of the sealed sources.

Please provide this information to us.

18. With respect to your request for authorization to redistribute in vitro kits to specific licensees:

a. We need confirmation that you will be obtaining only prepackaged in vitro kits as described in 10 CFR 31.11 for redistribution to specific licensees.

b. We need confirmation from you that labels, leaflets or brochures accompanying the kits do not reference general licensees, exempt quantities or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).

c. We need confirmation from you that labeling of these kits will conform to the requirements of 10 CFR 20.203.

Please provide this information to us.

The following does not require a response from you. As you have indicated in Item 15 of your application, you must be sure to comply with all DOT regulations. Your procedures in Item 15 do not specifically mention tests for removable contamination as required by 49 CFR 173.443. You should review your procedures and DOT regulations and revise your procedures, as needed, to ensure compliance with all applicable DOT regulations. Enclosure 5 may be of assistance to you in this regard.

We will continue our review of your request upon receipt of this information. Please reply in duplicate and reference Control No. 16016. If you have any questions on these matters, please contact us at (301)427-4232.

Sincerely,

Patricia C. Vacca
Material Licensing Branch
Division of Fuel Cylce and
Material Safety

Enclosures:
1. Sample Nuclear Pharmacy License
2. NUREG-0767
3. 10 CFR Parts 20, 32, and 40
4. Draft Nuclear Pharmacy Guide (dated February 22, 1984)
5. A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (Revised 1983)

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