

From: Pamela Henderson
To: Michael.vala@bms.com
Date: 9/20/01 9:47AM
Subject: Letter dated July 18, 2001

29-00139-02, 030-05222, 130308

These questions concern your letter dated July 18, 2001.

In order for us to add the use of radioactive drugs containing H-3 and C-14 for metabolic studies, provide the information specified in 32.72(a)(3).

Confirm that you will only prepare and distribute radioactive drugs which the U.S. Food and Drug Administration (FDA) has accepted an Investigational New Drug (IND) application; and which contain only microcurie quantities of hydrogen-3 or carbon-14.

Please confirm that you will satisfy the labeling requirements in 32.72(a)(4) and the instrumentation and measurement requirements in 32.72(c)(1) and (2).

Please note that should Part 32 authorization to manufacture, prepare and transfer certain radioactive drugs containing H-3 or C-14 material for medical use (10 CFR 32.72) be added to your broad-scope license (-02), your -02 license will become a Part 32 license, in addition to a Part 33 (broad scope) licensee. As a Part 32 licensee, you will not require an exemption from 33.17(a)(4) which addresses the activities conducted under the broad scope portion of your license and not the Part 32 authorization. Please note that only the manufacture, preparation or transfer of radioactive drugs containing H-3 or C-14 for non-commercial medical research use (metabolism studies) may be added to your license. Any radioactive drugs for commercial transfer will require that you apply for and receive a **separate** Part 32 manufacturing and distribution license.

You requested that we add 750 millicuries of Tc99m for the New Brunswick facility. Please confirm that you are not using generators (Mo99) to obtain the Tc99m.

In items 9.F. and G of your current license, interim storage is stated. Please confirm that you are not utilizing interim storage at this time. If you want to submit an interim waste storage plan for our review, to enable you to begin interim waste storage should waste disposal facilities close, it must contain all the information in Information Notice 90-09 (Please do not refer to any previously submitted material). If approved, the plan would be added to your license. However, it could not be activated until such time as radioactive waste disposal facilities become unavailable. Otherwise, you may apply for an amendment and submit an interim waste storage plan at such time as radioactive waste disposal facilities become unavailable.

Regarding your request to change the authorized use condition for I-131 under 9.B. to "Storage for decay;" Please note that decay-in-storage is authorized by condition 21 of your current license. Thus, it need not be listed as an authorized use in item 9 of your license.

Please submit a written reply to my attention at the Region I Office and refer to Mail Control No. 130090. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-6952. You may send your response by facsimile: (610) 337-5269. If you choose to send your response by fax, you do not need to also send us your response by mail.

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