June 15, 2001

Dr. Stanley Mills
Mills Biopharmaceuticals, Inc.
120 NE 26th St.
Oklahoma City, OK 73105

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON MODEL Pd-103 SEEDS

Dear Dr. Mills:

This letter is in response to your application dated April 30, 2001, requesting an amendment of your Registration Certificate No. NR-1081-S-101-S to add two models of palladium-103 seeds. We are in the process of evaluating your request. In order to continue our evaluation, we need additional information attached in the Enclosure.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions, please contact me at (301) 415-7904 or Dr. Seung J. Lee at (301) 415-5787.

Sincerely,
/RA/

John Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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Enclosure

Request For Additional Information

Please provide additional information to supplement what you have included in your application dated April 30, 2001, regarding the following issues.

1. Engineering Design:

   1.1 Please clarify the physical dimensions both for the I-125 seeds and for the Pd-103 seeds. Specifically, Registration Certificate No. NR-1081-S-101-S, dated December 1, 1999, authorized I-125 seeds to be manufactured with the external dimensions of 4.9 mm in length and 0.96 mm in diameter with a wall thickness of 0.06 mm. The application states these dimensions as 4.5 mm, 0.8 mm, and 0.05 mm respectively. Please confirm that (a) the dimensions of the I-125 seeds will change to the latter values, and (b) both the I-125 and the Pd-103 seeds will be manufactured with the latter dimensions.

   1.2 Please clarify the number of seeds both in the I-125 and the Pd-103 models. The Registration Certificate No. NR-1081-S-101-S, dated December 1, 1999, authorized the use of three to five I-125 seeds. Your application stated that "all models have five silver seeds." Please clarify the discrepancy. If you always use five seeds, but some of the seeds are inert for spacing purposes within the capsule, please state so.

   1.3 Please clarify the maximum activity for the Model 125SH I-125 seeds. The Registration Certificate No. NR-1081-S-101-S, dated December 1, 1999, authorized a maximum activity of 5.55 GBq (150 millicuries). You have also committed to such a maximum value in your letter dated October 1, 1999. However, the application shows a maximum activity of 5.55 GBq (150 millicuries) + 10%. Do you intend to increase the maximum activity with 10% for I-125? If so, please provide information that the design is sufficient for such an activity regarding capsule design, capsule testing, and radiation protection.

   1.4 Please confirm that the maximum activity for the Palladium Model 103SH is 185 MBq (5 millicuries) + 10%.

2. FDA Approval: Please provide a copy of FDA Form 510(k) or pre-market approval from FDA for the Pd-103 models. Please note that without FDA approval, NRC cannot issue a registration certificate for the Pd-103 seeds.

3. Labeling: Please confirm that the label materials and the placement of labels are identical to those for the I-125 models.

4. Conditions of Use:

   4.1 Please state the working life for the sources, i.e. the length of time that the

Pd-103 sources may be used. Please provide information similar to what you have provided for the I-125 seeds in your letter dated October 1, 1999.

4.2 Please specify the maximum temperature and pressure for sterilization or autoclaving.

5. Prototype Testing: Please describe the prototype tests that you have conducted on your Pd-103 models and provide the test results. If no prototype tests were conducted, please specify in detail the operational experience, including failures or leaks, with your I-125 models and explain why the operational experience is applicable to the Pd-103 models.

6. Quality Assurance: The application showed that the leak testing period is to be reduced from 18 hours to 4 hours. Please delineate the rationale for the change and provide data that support the change.

7. Instructions to Users: Please provide a user manual or instructions that includes the Pd-103 models.