September 23, 1999

Dr. Stanely L. Mills, President
Mills Biopharmaceuticals, Inc.
120 N.E. 26th Street
Oklahoma City, Oklahoma 73105

Dear Dr. Mills:

We have reviewed your application dated August 2, 1999, requesting Sealed Sources and Devices Evaluation and registration of I -125, Therapeutic Seed Source. In reviewing the application information, we find the application is lacking significant amounts of information for us to reach a decision. Therefore, we request that you address the issues outlined in the attached Enclosure.

Please respond within 30 days of the date of this letter and be certain to address all the areas of concern cited herein. If you would like to discuss any of the issues identified in this letter or have any questions, please contact me at (301)415-7894.

Sincerely,

original signed by:

Ujagar S. Bhachu, PEng. CEng., Mechanical Engineer
Materials Safety and Inspection Branch,
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards.

Enclosure: As stated
cc. w/encl: S. Kimberly, LFDCB

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Mills Biopharmaceutical, Inc. Enclosure

1. Engineering and Design

1.1 Please verify and confirm that Maximum Activity including the tolerances is 150 mCi. Page 1 of the draft registration certificate provided with your application indicates a maximum activity for model 125SH as 150 mCi. and Page 1 of your application states the Maximum activity for the same model as 150 mCi. + 10%. The check list and page 6, of your application, states the maximum activity as 150 mCi. ± 10%.

1.2 The description and the tabulated dimensions and sketch dimensions for the titanium tube do not match. Please verify all dimensions and tolerances' consistency in the text and resubmit the sketch with the correct dimensions.

1.3 The text gives the dimensions as diameter and the sketch gives tube dimensions as a width. Please have these apparent discrepancies corrected.

1.4 Please provide titanium, A-40 (commercially pure) chemical compositing, physical properties and details stating the grade and unique acceptance criteria.

2.0 **Prototype Testing**

2.1 Your sources do not qualify as tubes hence the tests performed on these sources are inadequate. The maximum overall length of your source is 4.90 mm and the maximum diameter is 0.95 mm. By definition tubes are those sources that: (1) are not intended for direct implantation, (2) have an outside diameter of at least 1.9 mm, and (3) have a length to diameter ratio less than 10. Any source that does not meet all these three requirements shall be classified and tested as a needle. (See Section 2.0 of ANSI N44.1-1973).

2.2 Your temperature test specification of 250°C∓ 20°C, indicated on page 2 of your application, is way too low. The recommended standard test temperature is 800°C ∓ 20°C. (See Section 4.2.1. of ANSI N 44.1-1973). Please provide the rational for adopting a lower test temperature. Also, please state the temperature of the test water used.

2.2 Please provide the values of the radiation measurements taken after the tests to support the integrity of the source. Please also provide the calibration data and the type of equipment used to observe the radiation readings.

3. Working Life Of Sources

Please state the working life of the sources. By working life we mean the physical life of the sources and not half life of the source.

4. Leak Testing

Page 5 , Item 2 last sentence should be modified to read, ".... 0.005 microcurie of removable contamination."

5. QA Manual

5.1 Pages 1 & 7 of the manual makes a reference and compliance to 10 CFR Part 21, Subpart 820. This is an incorrect reference. Please resubmit pages of the QA Manual with correct reference.

6. Storage and Shipping Containers:

6.1 Please provide diagrams and details of labels for storage containers and packages for shipping. Please confirm that the labels will meet the requirements of 10 CFR 32.74, 20.1901 and 20.1904.