COPY

Stanley L. Mills, Ph.D.
Mills Biopharmaceuticals Incorporated

United States Nuclear Regulatory Commission
Materials Safety Branch
Division of Industrial and Medical Nuclear Safety
Two White Flint North
11545 Rockville Pike
North Bethesda, MD 50852

1 April, 1999

Dear Sir/Madam,

Attached is an **Application for Sealed Source and Device Evaluation and Registration**. I have enclosed one copy and a 3.5 inch disk in WordPerfect format of the Application. One of the files included in the disk is a draft of the Certificate which is included in the application. I hope this will assist you in your review and approval process. Please contact me by phone if you have any questions regarding this application.

Please consider this application for expedited review based upon the following considerations. There is a current shortage world wide for I-125 Brachytherapy seeds resulting in delays in treatment for a number of cancers. Current manufacturers, Nycomed Amersham and North American Scientific, are unable to supply the current demand. In addition, Mills Biopharmaceuticals is a small company and this application constitutes our first product. I believe the FDA 510(k) approval will occur very soon and a long delay in your evaluation process will place this company in a commercial hardship. I appreciate any consideration you can give regarding this request.

Sincerely,

Stanley L. Mills, Ph.D., R.Ph.
President and CEO

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Oklahoma City, Oklahoma
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FAX TRANSMITTAL

☒ *For your information, no response necessary*

☐ *Please respond/reply as soon as possible*

TO: **Mr. Ujagar S. Bhachu** **Mail Stop – 8F27**

COMPANY: **U. S. Nuclear Regulatory Commission**

FROM: **Dr. Stanley L. Mills**

DATE:

This is a fax transmission consisting of page(s). If all pages were not received or you received this fax in error please contact this office immediately.

MESSAGE: Please confirm receipt of this fax.

Thank you

Mills

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