


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.

18 November, 1999

Dear Mr. Bhachu,


Per our telephone conversation of this date the following is respectfully submitted:

Mills Biopharmaceuticals, Lead Safe Label (3.25" x 1.5"). Label material supplied by Weber, 711 W. Algonquin Rd., Arlington Heights, IL. 60005-4457 is attached.

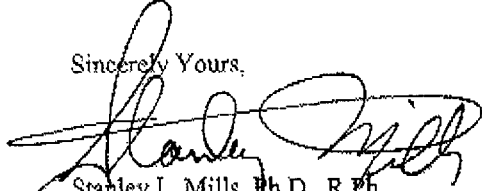
ProstaSeed		Model 125SL
I-125 Source		
Mills Biopharmaceuticals, Inc. OKC, OK		 Caution Radioactive Material
Total activity:	MBq	CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription. Read package insert.
Total #:		
Apparent activity range:	MBq	
Assay date:	12:00 CST	
Lot #:		
0018121		

See

Mills Biopharmaceuticals Inc., Vial Label (1.87" x 1.12"). Label material supplied by Weber, 711 W. Algonquin Rd., Arlington Heights, IL. 60005-4457 is attached.

ProstaSeed		Model 125SL
Mills Biopharmaceutical, Inc. OKC, OK		I-125 Source
		 Caution Radioactive Material
Total activity:	MBq	CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription. Read package insert.
Total #:		
Apparent activity range:	MBq	
Assay date:	12:00 CST	
Lot #:		
0018122		

Sincerely Yours,


Stanley L. Mills, Ph.D., R.Ph.
President and CEO
Mills Pharmaceuticals, Inc.
120 N.E. 26th Street
Oklahoma City, Oklahoma 73105
405-525-3141
405-525-3143 FAX

Weber® Marking Systems, Inc.

711 W. Algonquin Road · Arlington Heights, IL 80005-4457
Phone 847/364-8500

Product Information

Pressure-Sensitive Label Materials

Ultraplate EF Silver and White

- GENERAL DESCRIPTION**
- High-gloss film designed for durable nameplate applications
- FACESHEET**
- 2-mil gloss polyester
 - Designed to accept thermal-transfer imprinting
 - Ultimate abrasion resistance
 - Remains stable outdoors
- ADHESIVE**
- High performance permanent acrylic
 - High degree of initial tack and ultimate bond strength
 - Adheres to aluminum, painted metal, steel, plastic, polypropylene, polyethylene, polyvinyl chloride
 - Application temperature range: 50°F to 302°F
 - Use temperature range: -40°F to 302°F
- LINER**
- 3.1 mil high-strength, silicone-coated
 - Suitable for fanfolded or rolled configurations
 - 50 lbs/ream ± 10% (500 - 24" x 36")
- VARIABLE PRINTING**
- Compatible with Zebra, Sato, and Datamax thermal-transfer printers
 - Not compatible with dot matrix printing
 - Not compatible with laser printing
 - Not compatible with automatic applying equipment
 - For thermal-transfer imprinting utilize the Ultraplate II ribbon. For non-UL applications, the Duraprint II may be used.
 - For outdoor UL applications, only blue or black UV flexo ink may be used
- APPLICATIONS**
- Nameplates • Serial plates • Rating plates • Bin/shelf identification • Property asset management
- UL RECOGNITION**
- | <u>Printer Technology</u> | <u>Required Components</u> | <u>File Number</u> |
|----------------------------------|---|--------------------|
| • Zebra, Sato & Datamax printers | • Ultraplate II ribbon
• Ultraplate EF label
• Zebra, Sato & Datamax printers | • UL-MH18091 |
- SHELF LIFE**
- 1 year at 75°F and 50% R.H.

Mills Biopharmaceuticals Inc.
Bracktherapy Seeds.

We are in the process of reviewing your application for the I-125 Bracktherapy Seeds. However, in order to continue our review, we need the following information:

1. Request for Exemption from Bending and Tensile Tests

The primary purpose of the bend test is to measure the integrity or ductility or both, of the metal surfaces. As a rule, the criteria for acceptance will be the absence of any cracking or surface separation (not originating at the edges of the specimen). The secondary purpose is to characterize composition and properties to ensure consistency in the starting material used directly or as modified by forging, forming, and welding in the manufacture of the medical device.

Please provide estimated maximum forces to be applied or that the sources may be subjected to during manufacture, receiving, handling, loading, and insertion of the sources. Please describe the details of the delivery systems for the seeds.

In lieu of the bending and tensile test, you may establish the integrity of the source by the application of analytical techniques.

2. Request for Lower Test Temperature

In order to gauge the margin of safety, please provide what is the maximum test temperature that the source can withstand. What is the maximum temperature allowed during the source welding process? Are there any intrinsic and extrinsic hot or cold spots set up by the source and spherical seed configuration?

3. Accident conditions

Please demonstrate that during accident conditions such as fire and explosion that the radiation releases will not expose any individual to doses in excess of the regulatory doses. (see NUREG 1556 Vol. 3, Section 10.5)

MSH
99-10-12

TRANSMISSION REPORT

10.12.1999 11:27

301 415 5369

DATE TIME	DURATION	REMOTE ID	MODE	PAGES	RESULT
10.12 11:26	00'42"	253143	ECM	2	O.K.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

FAXED FROM

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
Telephone: 301-415-7197 Fax: 301-415-5369

DATE: October 12, 1999

1. NAME: DR. STANLEY L. MILLS

FAX #: 405-525-3143 . VERIFY _____

2. NAME: _____

FAX# _____ VERIFY _____

3. NAME: _____

FAX #: _____ VERIFY _____

4. NAME: _____

FAX# _____ VERIFY _____

NUMBER OF PAGES INCLUDING COVER SHEET 2

FROM: UTAGAR J. BHACHU

PHONE: (301) 415-7894 MAIL STOP: 8F27