

L+L= 20841

030-21252

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April 23, 1985

U. S. Regulatory Commission, Region I
Nuclear Material Section B
631 Park Avenue
King of Prussia, PA 19406

Gentlemen:

Pursuant to Section 32.73 of 10 CFR Part 32, Cadema Medical Products, Inc., requests NRC authorization to distribute to NRC's "group medical licensees" reagent kits that will be used when combined with byproduct material, Technetium Tc-99m, for the following indications:

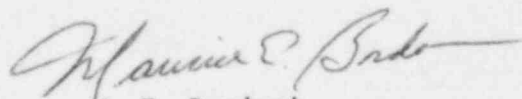
- A. Antimony Trisulfide Colloid Reagent Kit (ASC) for Lymphoscintigraphy.
- B. Red Blood Cell Reagent Kit, (RBC) for heart imaging.
- C. Pentatate Sodium Reagent (DTPA) for brain, renal, and aerosol (lung ventilation) imaging.
- D. Microalbumin Colloid Reagent Kit (TcmaC) for liver, spleen, and bone marrow imaging.

Each reagent kit described in A through D above is to be manufactured, labeled, and packaged in accordance with FDA regulations under a "Notice of Claimed Investigational Exemption for a New Drug." (IND)

Attached as Appendices 1 through 4 is information from the submitted IND's for each reagent kit.

Also included are signed applications in duplicate as well as the \$700.00 fee required under paragraph 170. 12(a) of 10 CFR Part 170.

Very truly yours,


M. E. Bordoni
President

MEB/pmw
Enclosures

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