



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
631 PARK AVENUE  
KING OF PRUSSIA, PENNSYLVANIA 19406

REAGENT KIT DISTRIBUTION APPROVAL  
CADEMA MEDICAL PRODUCTS, INC.  
569 NORTH STREET  
P.O. BOX 250  
MIDDLETOWN, NEW YORK 10940

Approval No. 31-20841-01MA  
Docket No. 030-21252

1. The reagent kits listed below are approved for distribution by Cadema Medical Products, Inc., to persons licensed pursuant to Section 35.14 and Section 35.100, Group III, of 10 CFR Part 35, or under equivalent licenses of Agreement States.

| <u>Kit Trade Names</u>   | <u>Radiopharmaceutical Prepared From Kit</u>  |
|--|---|
| A. Cadema Medical Products, Inc. Lymph-Scan Kit (IND 13, 717)              | A. Tc 99m labeled antimony trisulfide colloid |
| B. BNL Red Blood Cell Kit (IND 12,003)                                     | B. Tc 99m labeled red blood cells             |
| C. Cadema Medical Products, Inc. DTPA Kit (IND 24, 406)                    | C. Tc 99m labeled pentetate                   |
| D. Cadema Medical Products, Inc. Aubumin Colloid Kit (Tcm AC) (IND 22,683) | D. Tc 99m labeled albumin colloid             |

2. Cadema Medical Products, Inc. is authorized to distribute the reagent kits listed in Item 1 above from 569 North Street, Middletown, New York.
3. Any proposed changes in packaging, shielding, labeling, or the package insert shall be submitted to the U. S. Nuclear Regulatory Commission for review.
4. Cadema Medical Products, Inc., shall notify the U. S. Nuclear Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or the withdrawal of a "New Drug Application" (NDA) for any reagent kit listed in Item 1 of this approval.

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5. The reagent kits listed above shall be manufactured, packaged, labeled and distribution in accordance with statements, representations, and procedures contained in application dated April 15, 1985 and letter dated June 12, 1985.
6. This approval shall expire on June 30, 1990.

Date

JUN 26 1985

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Jenny M. Johansen

By

Nuclear Materials Safety and  
Safeguards Branch, Region I  
King of Prussia, Pennsylvania 19406