

JUN 26 1985

License No. 31-20841-01MA  
Docket No. 030-21252  
Control No. 03754

Cadema Medical Products, Inc.  
ATTN: Maurice E. Bordonì, President  
569 North Street  
P. O. Box 250  
Middletown, New York 10940

Gentlemen:

Please find enclosed your NRC material license.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5239, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

In order to avoid further delays in marketing your kits we have decided to issue your approval. We note, however, that your 10 CFR 32.73(a)(5)(ii) statement needs correction to read:

"The Reagent Kit is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to Section 35.14 and 35.100 Group III of 10 CFR 35 or under equivalent license of Agreement States."

Your statements as shown in your June 12, 1985 letter have left out the words by persons licensed and or under equivalent licenses of Agreement States.

Additionally, we note that the DTPA Kit's finished drug label for vial and vial shield in your application and letter were artwork mock-ups, not the actual color labels. Please submit as soon as possible the color labels in order that we may assure that the radiation warning part of the label meets the color requirements in 10 CFR 20.203. Refer to Control No. 03754 when submitting the above and the corrected package inserts shown in your June 12, 1985 letter.

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Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:  
Jenny M. Johansen

Jenny M. Johansen, M.S.  
Nuclear Materials Safety Section B  
Division of Radiation Safety  
and Safeguards

Enclosures:

1. License No. 31-20841-01MA
2. Requirements for Materials Licensees
3. NRC Forms 3 and 313
4. 10 CFR Parts 2, 32, 35 and 170

RI:DRSS *[Signature]* RI:DRSS  
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