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PHL
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Texas Department of Health

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Radiation Control
(512) 834-6688

Roy L. Hogan
Deputy Commissioner for Administration

March 26, 1997

Paul H. Lohaus, Deputy Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C., 20555-0001

Dear Mr. Lohaus:

Staff members of the Texas Department of Health (TDH), Bureau of Radiation Control have reviewed the final rulemaking plan regarding a proposed rule which will allow the exempt distribution of capsules containing one microcurie of C-14 Urea to any person for diagnostic testing. We offer the following comments for consideration.

In response to the first question, although this will set a precedent for in vivo use of radioactive material under an exemption, the risks from use of this regulatory structure appear to be very low. Therefore, we agree with the staff recommendation of the U.S. Nuclear Regulatory Commission.

As for the second question, we are not aware of any other regulations that might be of concern if the capsules are authorized under an exempt distribution license, with a Division 1 level of compatibility for the users. However, we have forwarded the final rulemaking plan to the Texas Board of Pharmacy and to the TDH Drugs and Medical Devices Division.

We appreciate the opportunity to provide comments. If you have any questions or need further information, please contact me at (512)834-6688 or E-mail address rratliff@brc1.tdh.state.tx.us.

Sincerely,

Ruth E. McBurney for

Richard A. Ratliff, P.E., Chief
Bureau of Radiation Control

SP-A-4
SP-AG-27

TEXAS DEPARTMENT OF HEALTH

BUREAU OF RADIATION CONTROL
1100 West 49th Street
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STANDARDS

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DIVISION: BRC

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COMMENTS: COMMENT RULEMAKING PLAN-10 CFR PARTS 30 & 32 C-14
UREA H. PULORI DIAGNOSTIC TEST

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