

April 24, 2000

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the subcommittee is a copy of a Federal Register notice denying a petition for rulemaking (PRM-32-05) filed by Metabolic Solutions, Inc. The petition requested that the U.S. Nuclear Regulatory Commission (NRC) extend the regulatory distribution exemption for 37 kilobecquerel (kBq) (1 microcurie) of carbon-14 (C-14) urea to include the Erythromycin Breath Test (EBT), which uses a 111-kBq (3-microcurie) dose of C-14 erythromycin.

On May 4, 1999 (64 FR 23796) the NRC noticed receipt and requested comment on the PRM filed by Metabolic Solutions. The comment period closed on July 20, 1999. Notice of receipt of the Metabolic Solutions PRM resulted in the NRC receiving comment letters from two medical universities in support of the petition.

Although the NRC did not adopt the common rule entitled "Federal Policy for the Protection of Human Subjects; Notices and Rules" (56 FR 28002), our intention is to follow the essential requirements, which have been adopted into 10 CFR 35.6, "Provisions for Research Involving Human Subjects." Specifically, 10 CFR 35.6 requires a licensee who conducts research involving human research subjects to obtain informed consent and obtain approval by an Institutional Review Board. Because the common rule did not allow exemption for research involving minimal risk, the Commission determined that such research use should not be exempt from 10 CFR 35.6. Therefore, the NRC is denying the Petitioner's request.

The Commission will publish the denial in the Federal Register.

Sincerely,

/RA/

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: Federal Register Notice

cc: Senator Bob Graham

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Enclosure: Federal Register Notice

cc: Senator Bob Graham
DISTRIBUTION: IMNS TICKET 7507

IDENTICAL LTR SENT TO The Honorable Dan Schaefer, House of Representatives

cc: Rep. Ralph Hall

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DATE	2/3/00	2/3/00	3/13/00	02/01/00	3/28/00	4/24/00	2/22/00

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The Honorable Joe Barton, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of
Representatives
Washington, DC 20510

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Dennis K. Rathbun, Director
Office of Congressional Affairs

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cc: Representative Rick Boucher