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USNRC

'99 MAY 28 A11:59

OFFICE OF THE
RULEMAKING
ADJUDICATIONS STAFF

May 21, 1999

DOCKET NUMBER

PETITION RULE PRM 32-5
(64FR23796)

Secretary

U.S. NUCLEAR REGULATORY COMMISSION
Washington DC 20555

ATTN: Rulemakings and Adjudications Staff

Dear Secretary:

This is to provide my support for the petition by Metabolic Solutions, Inc. (10 CFR Part32, Docket No. PRM-32-5).

The C14 erythromycin breath test has a great deal of potential, in view of the central role the cytochrome P450 process plays in the body and in pharmacology. My particular interest as a transplant surgeon involves metabolism particularly of the key drugs FK506 and cyclosporine, along with other related drugs that impact on these.

Although not technically able to comment on the dosimetry and risks per se, it does seem that this tracer level process, which would not be likely to be used in extraordinary numbers of patients in the near future, less than 10^6 total tests, spread around the country, would be unlikely to produce an increase in these levels of any significant degree. Given that, I would emphasize that the potential importance of this test would seem to me warrants the agency agreeing to the petition.

Thank you for your attention to this.

Sincerely,

James F. Burdick, M.D.
Professor of Surgery

cc: Martin A Baker, Metabolic Solutions, Inc.

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