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Dated: April 12, 2000.

Jill Long Thompson,

Under Secretary, Rural Development.

[FR Doc. 00-10140 Filed 4-21-00; 8:45 am]

BILLING CODE 3410-15-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

[Docket No. PRM-32-05]

Metabolic Solutions: Denial of Petition for Rulemaking

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM-32-05) submitted by Metabolic Solutions. The petitioner requested that the NRC extend the regulatory distribution exemption for 1 microcurie of carbon-14 (C-14) urea to include a product being developed by its company. The product is the Erythromycin Breath Test (EBT) which uses a 111-kilobecquerel (kBq) (3-microcurie) dose of C-14 erythromycin.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Rulemakings and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website (<http://ruleforum.llnl.gov>). This site provides the capability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher (301) 415-5905 (e-mail: cag@nrc.gov).

Copies of any comments received may be examined at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC.

FOR FURTHER INFORMATION, CONTACT: James Smith, telephone (301) 415-6459, e-mail: jas4@nrc.gov, of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

The Petition

On May 4, 1999 (64 FR 23796), NRC noticed receipt and requested comment on the PRM filed by Metabolic Solutions Inc. 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.

The C-14 EBT measures the activity, in-vivo, of an important liver enzyme that is the most abundant drug-metabolizing enzyme in the body. This test is currently used to determine the safety of new drugs during clinical trials; as such, it is used only as a research tool. The petitioner states that the doses associated with this test are comparable to the doses for the C-14 urea test which is exempt from the requirement for licensing pursuant to 10 CFR 30.21 (a).

Public Comments on the Petition

The notice of receipt of the PRM invited interested persons to submit comments. The two public comments received in response to the notice, from the University of Nebraska Medical Center and Johns Hopkins Medical Institutions, were in support of the petition. The two comments generally noted the low doses associated with the test and the possible economic benefit in reducing the expense of clinical trials through elimination of the need for a byproduct materials license.

Reasons for Denial

A denial is consistent with the Commission's previous decision on the C-14 urea tests to require that research be performed under a specific license (62 FR 63634), since this product is to be used only in research use. The doses are not the limiting factor for extending the distribution exemption to this test. The previous decision was based upon restrictions of such use under the common rule entitled "Federal Policy for the Protection of Human Subjects; Notices and Rules" (56 FR 28002). Although the NRC did not adopt the common rule, our intention is to follow the essential requirements of the rule, which have been adopted into 10 CFR 35.6, "Provisions for Research Involving Human Subjects." Specifically, 10 CFR 35.6 requires a licensee that 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 for exemptions for research involving minimal risk, the Commission determined that such

research use should not be exempt from 10 CFR 35.6.

Dated at Rockville, Maryland, this 5th day of April, 2000.

For the U.S. Nuclear Regulatory Commission.

William D. Travers

Executive Director for Operations.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-SW-66-AD]

Airworthiness Directives; Eurocopter Deutschland GMBH Model BO-105A, BO-105C, BO-105 C-2, BO-105 CB-2, BO-105 CB-4, BO-105S, BO-105 CS-2, BO-105 CBS-2, BO-105 CBS-4, and BO-105LS A-1 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the superseding of an existing airworthiness directive (AD) for Eurocopter Deutschland GMBH (ECD) Model BO-105A, BO-105C, BO-105 C-2, BO-105 CB-2, BO-105 CB-4, BO-105S, BO-105 CS-2, BO-105 CBS-2, BO-105 CBS-4, and BO-105LS A-1 helicopters. That AD currently requires creating a component log card or equivalent record and determining the calendar age and number of flights on each tension-torsion (TT) strap. That AD also requires inspecting and removing, as necessary, certain unairworthy TT straps. This action would establish a life limit for certain main rotor TT straps. This proposal is prompted by a need to establish a life limit for certain TT straps because of an accident in which a main rotor blade (blade) separated from an ECD Model MBB-BK 117 helicopter due to fatigue failure of a TT strap. The same part-numbered TT strap is used on the ECD Model BO-105 helicopters. The actions specified by this AD are intended to prevent fatigue failure of the TT strap, loss of a blade, and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before June 23, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 99-SW-66-