2. We already provide some services to aquaculture industries. We provide laboratory diagnostic services, endorse export health certificates for aquatic animals and aquatic animal products, and license vaccines and biologic reagents for use in aquatic animals. We also control damage done by wild birds and other animals to farmed aquatic animals. Should we expand the range of our services? If we expand our services to aquaculture industries, what new or additional services should we consider providing?

3. We currently regulate the importation of livestock and poultry and livestock and poultry products. These regulations are designed to prevent diseases and pests of livestock and poultry from being introduced into the United States. Should we consider adopting regulations to prevent the introduction of diseases and pests of aquatic animal species? If so, should the regulations be similar to those we have for livestock and poultry? If not, how should the regulations be different?

4. We work closely with industry and State representatives to administer many of our current disease control programs. For example, we work with industry and State representatives to control and eradicate brucellosis, tuberculosis, and other livestock diseases. If we develop any regulatory programs for aquatic animal species, what form should our cooperation take?

5. We currently regulate the interstate movement of livestock and poultry and livestock and poultry products. These regulations are designed to prevent diseases and pests of livestock and poultry from being spread within the United States. Currently, we administer several voluntary programs designed to help producers control and eliminate certain diseases in their livestock. The goal of these programs is to eliminate sources of infection, while helping producers improve their stock. For example, we have a program covering scrapie in sheep and goats called the Voluntary Scrapie Flock Certification Program. Should we consider adopting regulations to prevent the interstate spread of diseases and pests of any aquatic species? If we were to adopt regulations covering interstate movement of any aquatic animal species, should we include voluntary programs to help producers control and eliminate certain diseases? If so, what species and diseases should be covered? What should we include in such programs?

How Should We Conduct Rulemaking?

Developing a new regulatory program can be very complicated. It is important that we establish reasonable goals and adopt workable programs to achieve them. We will need to collect reliable information on the costs and benefits of any program. Public participation and input in the rulemaking process is vital to success.

In the rulemaking process, we can either draft proposed regulations ourselves or use negotiated rulemaking to develop the proposals. In negotiated rulemaking, an agency brings together the groups that are interested in or would be affected by proposed regulations. Working together, agency employees and representatives of interested and affected groups negotiate the text of a draft proposed rule.

Whether we draft a proposed rule ourselves, or use negotiated rulemaking, later steps in the rulemaking process would be the same. We would publish any proposed rule in the **Federal Register**, including an analysis of the costs and benefits, and invite the public to submit comments. After reviewing all the comments we receive, we would decide upon what further action to take.

Therefore, we are asking for comments from interested persons regarding the desirability of using a negotiated rulemaking process should we decide to proceed with rulemaking affecting farm-raised fin fish or other aquatic animals.

Authority: 5 U.S.C. 5542; 7 U.S.C. 147b; 21 U.S.C. 111–114a, 114b–114c, 114h, 115, 117–130, 134, 134(a)–134(h), 135a, 136, and 136a; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 28 day of April 1999.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–11130 Filed 5–3–99; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

[Docket No. PRM–32–5]

Metabolic Solutions, Inc.; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking dated March 5, 1999, filed by Metabolic Solutions, Inc. (petitioner). The petition has been docketed by the Commission and has been assigned Docket No. PRM–32–5. The petitioner is requesting that the NRC regulations be amended to extend a regulatory distribution exemption to the petitioner's product, an ''Erythromycin Breath Test.'' That test uses a three-microcurie dose of carbon-14 (C14)-erythromycin to measure the rate of drug metabolism in the human liver. Current NRC regulations permit distribution of radioactive drug capsules that contain one microcurie of C14-urea to persons exempt from licensing. Dose regulations also permit any person exempt from the requirements of a license to use the capsules for diagnostic tests in humans. The petitioner believes that exempting the C14-erythromycin from regulatory control would make the breath test more widely available and reduce the costs of clinical trials without increasing the radiation risk to the public.

DATES: Submit comments by July 20, 1999. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

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

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

For a copy of the petition, write: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). This site provides the availability 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).

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301–415–7162 or Toll Free: 1–800–368–5642 or E-mail: *DLM1@NRC.GOV*.

SUPPLEMENTARY INFORMATION:

Background

On December 2, 1997 (62 FR 63634), the NRC published a final rule in the **Federal Register** that permitted the

distribution of radioactive drug capsules that contain one microcurie of carbon-14 (C14)-urea to persons exempt from licensing. The rule added 10 CFR 30.21 entitled, ''Radioactive drug: Capsules containing carbon-14 urea for ''in vivo'' diagnostic use for humans,'' and 10 CFR 32.21 entitled, ''Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for ''in vivo'' diagnostic use for humans to persons exempt from licensing; Requirements for a license.'' The rule became effective on January 2, 1998.

On March 12, 1999, the Nuclear Regulatory Commission received a petition for rulemaking submitted by the petitioner, Metabolic Solutions, Inc., a biomedical firm located in Nashua, New Hampshire. The petitioner requests that the NRC extend the regulatory distribution exemption for one microcurie of C14 urea to include an ''Erythromycin Breath Test'' being developed by the petitioner that contains a three-microcurie dose of C14-erythromycin. To do this, NRC would have to amend its regulations pertaining to the manufacture, distribution, and use of radioactive drugs in 10 CFR Parts 30 and 32.

The breath test is a tool used by researchers and physicians in the clinical study phases of drug research studies. The petitioner states that the erythromycin breath test measures the *in vivo* activity of a liver microsomal cytochrome P450 enzyme, CYP3A4, that metabolizes about 40 to 50% of all drugs in the body. This test is currently used in clinical research studies to help determine the safety of new drugs. Specifically, the test measures the effect that drugs have on the CYP3A4 enzyme system, potential interactions with other co-administered drugs on the enzyme system, and the range of safe drug tolerance within a population. The petitioner believes that dosimetry information for the exempted C14-urea will be very similar to the results for the C14-erythromycin.

According to the petitioner, exempting the C14-erythromycin from ''regulatory control'' would make the breath test more widely available and lower the costs of clinical trials. Also, the petitioner has concluded that the exemption would not present a radiation risk to the general public any higher than the risk associated with the distribution exemption for drug capsules that contain one microcurie of C14-urea. (Note: The Commission has not exempted the C14-urea radioactive drug from ''regulatory control.'' NRC requires the manufacturer and distributor to have an NRC license that authorizes the manufacture or distribution of the product to ''persons exempt'' from licensing under 10 CFR 30.21 or an equivalent regulation of an Agreement State.) The NRC has determined that the petition meets the threshold sufficiency requirements for a petition for rulemaking under 10 CFR 2.802. The petition has been docketed as PRM–32–5. The NRC is soliciting public comment on the petition for rulemaking.

Discussion of the Petition

The petitioner believes that the NRC regulations codified at 10 CFR parts 30 and 32 extend a regulatory exemption for drug capsules that contain one microcurie of C–14 urea. According to the petitioner, this exemption should be extended to its erythromycin breath test (ERMBT). In support of this request, the petitioner contends that the dosimetry information for the exempted C14-urea capsules will be very similar to that for the ERMBT. The petitioner has provided supporting documentation for its position (Exhibit A) entitled, ''Dosimetry of C14-Erythromycin.'' Additional supporting documentation (Exhibit B), includes: information related to the trademark, chemical ingredients, pharmacology, clinical safety, contraindications, adverse reactions, dosimetry, drug storage and stability, manufacturing procedures, analysis methodology and quality assurance procedures associated with the ERMBT.

The petitioner explains that ERMBT dosimetry data has not been collected in humans because it predates FDA regulations that govern disposition and metabolism data. In the study cited by the petitioner, dosimetry calculations were based on data collected from intravenous administration of C14-erythromycin in 10 male rats. The study found that in male rats the C14-erythromycin rapidly metabolized in the liver and that the resulting metabolite was excreted in bile. The petitioner indicates that the study also found that most radioactivity resulting from administration of the C14-erythromycin in male rats was either exhaled or excreted. The study also indicated a general distribution of radioactivity in various tissues of male rats after C14-erythromycin administration. The highest concentrations were present in the liver, spleen, pancreas, kidney, adrenal and submaxillary glands, lungs, and intestinal tract. Lower amounts of radioactivity were found in the skin, fat, and brain.

The rat intracellular distribution studies concluded, petitioner states, that erythromycin and its metabolites were capable of entering various cellular components of the liver. The studies also indicated that the C14-erythromycin dose emits beta radiation to exposed individuals. The Oak Ridge Institute for Science and Education, Radiation Dose Information Center Radiation calculated dose estimates for humans administered C14-erythromycin. These estimates are based on data gathered in rats and are described in Appendix 1 of Exhibit A attached to the petition for rulemaking. The petitioner indicates that data was extrapolated to humans using a weight-based extrapolation method where possible.

The petitioner believes that the information presented in Appendix 2 of Exhibit A indicates that the effective dose equivalent from the ERMBT dose (i.e. 2.1 millirem) is comparable to about one-fourth of a chest X-ray and is significantly lower than other nuclear medicine tests. Estimated human organ radiation exposures are presented in Appendix 3 of Exhibit A. The highest calculated organ doses to humans from a three microcurie dosage of C14-erythromycin are 2.8 millirem to the ovaries, 2.3 millirem to the gallbladder, 1.47 millirem to the small intestine, and 0.6 millirem to the urinary bladder wall.

In Exhibit B, the petitioner notes that the ERMBT dose has been administered to patients since 1988 at the University of Michigan Medical Center. Although a few individuals reported a metallic taste in their mouths immediately after ingestion, no adverse reactions have been experienced or reported.

Because the product is used as a research tool, users of the test must receive approval from Investigational Review Boards to administer the ERMBT dose in clinical research studies. The petitioner states that these studies have found that allergic reactions to erythromycin are very rare. The studies also found that gastrointestinal side effects due to the erythromycin, such as abdominal pain, cramping, and mild nausea are the most common adverse reactions and are erythromycin dose related. According to the studies, adverse effects are relatively infrequent in erythromycin doses that contain less than one gram of erythromycin. The petitioner notes that the ERMBT dose contains less than 0.05 milligrams and that no adverse effects have occurred with this dose amount.

According to the petitioner, the ERMBT is currently used only by researchers and physicians who can access a site that has obtained an NRC license to handle radio pharmaceuticals. The petitioner states that it is often inconvenient to use a C14 product. As stated by the petitioner, many clinical

drug studies occur in physicians' offices where there is either a total ban on radioactivity or the facilities do not possess a license to use radioactive substances. The petitioner contends that the market size for the ERMBT is much smaller than that of the exempted urea test. Estimates by the petitioner are that less than 10,000 patients would receive the ERMBT between two to five times in clinical studies each year (less than 100,000 tests). The petitioner states that the C14-urea test encompassed 600,000 people who could be tested two or three times including diagnosis and follow-up testing. Without a regulatory exemption, the petitioner believes that the market size would be too small to be economically feasible to pursue FDA approval for the use of the ERMBT.

The Petitioner's Conclusions

The petitioner concludes that dosimetry information of the C14-erythromycin will be very similar to that of the exempted C14-urea. Also, the petitioner concludes that exempting the C14-erythromycin from regulatory control will make the ERMBT more widely available and reduce clinical trial expenses. Lastly, the petitioner concludes that the exemption would not present a radiation risk to the general public any higher than the risk associated with the distribution exemption for drug capsules that contain one microcurie of C14-urea.

The petitioner requests that the NRC grant a regulatory distribution exemption for the ERMBT similar to the current exemption for C14-urea capsules. This would require amending the regulations pertaining to use of radioactive drugs in 10 CFR Parts 30 and 32.

Dated at Rockville, Maryland, this 28th day of April, 1999.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99–11110 Filed 5–3–99; 8:45 am]

BILLING CODE 7590–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Small Business Size Standards; Health Services Industries

AGENCY: Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The Small Business Administration (SBA) is proposing to increase the size standards for eleven of the nineteen industries under Standard Industrial Classification (SIC) Major Group 80, Health Services. The current size standard is $5 million in average annual receipts for all health services industries. Depending on the industry, the proposed size standards are $7.5 million, $10 million, or $25 million. The proposed revisions are being made to better define the size of business in those industries that the SBA believes should be eligible for Federal small business assistance programs.

DATES: Submit comments on or before July 6, 1999.

ADDRESSES: Send comments to Gary M. Jackson, Assistant Administrator for Size Standards, 409 3rd Street, SW., Mail Code 6880, Washington DC 20416.

FOR FURTHER INFORMATION CONTACT: Robert N. Ray, Office of Size Standards, (202) 205–6618.

SUPPLEMENTARY INFORMATION: The SBA has historically applied a common size standard for all industries under SIC Major Group 80, Health Services. The current size standard of $5 million for all nineteen SIC codes in this major group was established on April 22, 1994 (58 FR 16513), at which time it was increased from $3.5 million. In response to requests from Federal agencies and small businesses, the SBA analyzed the size standards for the health services industries and, on the basis of that review, believes that size standards higher than $5 million should be established for eleven of the nineteen SIC codes in the health services industries. The table below lists the health services industries for which the SBA is proposing revised size standards:

SIC Code	Industry	Proposed size standard (millions of dollars)
8011	Offices and Clinics of Doctors of Medicine	$7.5
8051	Skilled Nursing Care Facilities	10.0
8052	Intermediate Care Facilities	7.5
8062	General Medical and Surgical Hospitals	25.0
8063	Psychiatric Hospitals	25.0
8069	Specialty Hospitals, Except Psychiatric	25.0
8071	Medical Laboratories	10.0
8082	Home Health Care Services	10.0
8092	Kidney Dialysis Centers	25.0
8093	Specialty Outpatient Facilities, N.E.C	7.5
8099	Health and Allied Services, N.E.C.	7.5

For the following eight health services industries, the SBA believes the current $5 million is appropriate:

SIC Code	Industry	Size standard (millions of dollars)
8021	Offices and Clinics of Dentists	$5.0
8031	Offices and Clinics of Doctors of Osteopathy	5.0
8041	Offices and Clinics of Chiropractors	5.0
8042	Offices and Clinics of Optometrists	5.0
8043	Offices and Clinics of Podiatrists	5.0
8049	Offices and Clinics of Health Practitioners, N.E.C.	5.0
8059	Nursing and Personal Care Facilities, N.E.C.	5.0
8072	Dental Laboratories	5.0