(3) Multiplying the product by your price election.

If no market price has been established for the grade of the damaged tobacco, its value will be determined by reducing the lowest market price available by 20 percent for each grade that the production falls below the grade for which the lowest price is available.

(e) To enable us to determine the fair market value of tobacco not sold through auction warehouses, we must be given the opportunity to inspect such tobacco before it is sold, contracted to be sold, or otherwise disposed of; failure to provide us the opportunity to inspect such tobacco may result in rejection of any claim for indemnity.

(f) If the best offer you receive for any such tobacco is considered by us to be inadequate, we may obtain additional offers on your behalf.

(g) Once we agree that any carryover or current year's tobacco has no market value due to insured causes, you must destroy it. If you refuse to destroy the tobacco with no value, we will determine the value and include it as production to count.

13. Written Agreements

Terms of this policy that are specifically designated for the use of written agreements may be altered by written agreement in accordance with the following:

(a) You must apply in writing for each written agreement no later than the sales closing date, except as provided in section 12(e);

(b) The application for a written agreement must contain all variable terms of the contract between you and us that will be in effect if the written agreement is not approved;

(c) If approved, the written agreement will include all variable terms of the contract, including, but not limited to, crop type or variety, the guarantee, premium rate, and price election;

(d) Each written agreement will only be valid for one year (if the written agreement is not specifically renewed the following year, insurance coverage for subsequent crop years will be in accordance with the printed policy); and

(e) An application for a written agreement submitted after the sales closing date may be approved if, after a physical inspection of the acreage, it is determined that no loss has occurred and the crop is insurable in accordance with the policy and written agreement provisions.

Signed in Washington, D.C., on June 10, 1997.

Kenneth D. Ackerman,

Manager, Federal Crop Insurance Corporation

[FR Doc. 97–15715 Filed 6–13–97; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 927

[Docket Nos. AO–99–A7; FV96–927–1]

Winter Pears Grown in Oregon, Washington, and California; Recommended Decision and Opportunity To File Written Exceptions To Proposed Further Amendment of Marketing Agreement and Order No. 927

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and opportunity to file exceptions.

SUMMARY: This recommended decision invites written exceptions on proposed amendments to the marketing agreement and order for winter pears grown in Oregon, Washington, and California. The proposed amendments would remove the State of California from the order and make related changes to provisions concerning the production area, districts, and establishment and membership of the Winter Pear Control Committee (Committee). Another amendment would allow the use of telecopiers or other electronic means in Committee voting procedures. The proposed amendments are intended to improve the administration, operation and functioning of the order.

DATES: Written exceptions must be filed by June 26, 1997.

ADDRESSES: Written exceptions should be filed with the Hearing Clerk, U.S. Department of Agriculture, room 1079–S, Washington, DC 20250–9200, Facsimile number (202) 720–9776. Four copies of all written exceptions should be submitted and they should reference the docket numbers and the date and page number of this issue of the **Federal Register**. Exceptions will be made available for public inspection in the Office of the Hearing Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Kathleen M. Finn, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, room 2523–S, Washington, DC 20250–0200; telephone: (202) 720–2491, or FAX (202) 720–5698; or Teresa Hutchinson, Marketing Specialist, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, 1220 S.W. Third Avenue, room 369, Portland, OR 97204–2807; telephone (509) 326–2724 or FAX (509) 326–7440. Small businesses may request information on compliance with this regulation by contacting: Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456; telephone (202) 720–2491; Fax (202) 720–5698.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Hearing issued on June 24, 1996, and published in the June 26, 1996, issue of the **Federal Register** (61 FR 33047).

This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12866.

Preliminary Statement

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to the proposed further amendment of Marketing Agreement and Order No. 927, regulating the handling of winter pears grown in Oregon, Washington, and California, and the opportunity to file written exceptions thereto. Copies of this decision can be obtained from Kathleen M. Finn or Teresa Hutchinson whose addresses are listed above.

This action is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), hereinafter referred to as the ''Act,'' and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR Part 900).

The proposed amendment of Marketing Agreement and Order No. 927 is based on the record of a public hearing held in Sacramento, California, on July 9, 1996, and in Portland, Oregon, on July 10, 1996. Notice of this hearing was published in the **Federal Register** on June 26, 1996. The notice of hearing contained proposals submitted by the Winter Pear Control Committee (Committee), which locally administers the order.

The Committee's proposed amendments would: (1) Revise the definition of ''production area'' to mean only the States of Oregon and Washington; (2) revise ''district'' by removing California, leaving only those districts designated in the States of Oregon and Washington; (3) revise ''establishment and membership'' of the Committee to be consistent with the reduction in size of the regulated production area; (4) revise ''procedure of Control Committee'', ''(a) Quorum and voting'', so that the number of members needed for a quorum is consistent with the revised Committee representation, and amend ''(b) mail

voting'', to allow for the use of telecopiers and other electronic means; and (5) revise the definition of ''pears'' to exclude pears produced in California.

The Notice of Hearing also included a proposal by the Fruit and Vegetable Division, Agricultural Marketing Service (AMS), U.S. Department of Agriculture, to make such changes as are necessary to the order, if any or all of the above amendments are adopted, so that all of its provisions conform with the proposed amendment.

At the conclusion of the hearing, the Administrative Law Judge fixed August 16, 1996, as the final date for interested persons to file proposed findings and conclusions or written arguments and briefs based on the evidence received at the hearing. No briefs were received.

Small Business Considerations

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Small agricultural producers have been defined by the Small Business Administration (SBA) (13 CFR 121.601) as those having annual receipts of less than $500,000. Small agricultural service firms, which include handlers regulated under the order, are defined as those with annual receipts of less than $5,000,000.

Interested persons were invited to present evidence at the hearing on the probable regulatory and informational impact of the proposed amendments on small businesses. The record indicates that handlers would not be unduly burdened by any additional regulatory requirements, including those pertaining to reporting and recordkeeping, that might result from this proceeding.

During the 1995–96 crop year, approximately 100 handlers were regulated under Marketing Order No. 927. In addition, there were about 1,800 producers of winter pears in the production area. Production for the 1995–96 season showed that 15,316,776 standard boxes were produced in Oregon and Washington, while California produced 434,380 standard boxes.

The Act requires the application of uniform rules on regulated handlers. Marketing orders and amendments thereto are unique in that they are normally brought about through group action of essentially small entities for their own benefit. Thus, both the RFA and the Act are compatible with respect to small entities.

The proposed amendment to remove the State of California would allow the Northwest winter pear industry to operate more efficiently. There are approximately 60 growers and 19 handlers of winter pears in California who have asked to be removed from the marketing order since the harvesting and marketing seasons for California pears are different than those for pears grown in Oregon and Washington. Production for the 1995–96 season showed that 15,316,776 standard boxes were produced in Oregon and Washington, while California produced 434,380 standard boxes. Revenue generated from assessments collected in 1995–96 would be $175,923 from California compared to $6,203,295 from Oregon and Washington.

Record evidence indicated that during the 1994–95 crop year winter pears were assessed at $.43 per standard box. According to preliminary figures in the record, returns to handlers per standard box for that year were $8.31. The assessment rate is about 5 percent of the preliminary returns.

California growers believe they are funding promotion programs that are in direct competition with their own product. Record evidence showed that there would not be any additional burden imposed on handlers if such an amendment was implemented. In fact, handlers in the State of California would be relieved of any regulatory burden. Those in Oregon and Washington could continue to benefit from operation of the program. There are currently 1700 winter pear growers and 93 winter pear handlers in Oregon and Washington producing over 15 million standard boxes of pears annually. In California, there are approximately 60 winter pear growers and 19 handlers of winter pears producing over 400,000 standard boxes of pears annually.

Record evidence also showed that the collection of information under the marketing order would not be effected if California was removed from the marketing order. A witness testified that there are alternatives that would replace the current information that is being collected from the State of California, if it is needed. Accordingly, this action would not impose any additional reporting or recordkeeping requirements on either small or large pear handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule.

The proposal to allow Committee members to vote by telecopiers or other electronic means would provide members with the option to use these methods if available when voting on an action is to be done quickly. This would allow Committee members to vote without assembling at a meeting place and, therefore, reduce administrative costs and act quickly on a recommendation that needs the Committee's attention. ''Other electronic means'' includes the use of modems, video and teleconferencing. The term is flexible to allow for the use of new technologies by the Committee for voting.

The additional proposals are changes that would need to be made to the marketing order to reflect the removal of the State of California.

All of these changes are designed to enhance the administration and functioning of the marketing agreement and order to the benefit of the industry.

The amendments proposed herein have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have retroactive effect. If adopted, the proposed amendments would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with the amendments.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after date of the entry of the ruling.

Material Issues

The material issues of record addressed in this decision are as follows:

(1) Whether to revise the definition of ''production area'' to mean only the States of Oregon and Washington;

(2) Whether to revise ''district'' by removing California, leaving only those districts designated in the States of Oregon and Washington;

(3) Whether to revise ''establishment and membership'' of the Committee to be consistent with the reduction in size of the regulated production area;

(4) Whether to revise ''procedure of Control Committee,'' ''(a) quorum and voting'', so that the number of members needed for a quorum is consistent with Committee representation, and amend ''(b) mail voting'', to allow for the use of telecopiers and other electronic means; and

(5) Whether to revise the definition of ''pears'' to exclude pears produced in California.

Findings and Conclusions

The findings and conclusions on the material issues, all of which are based on evidence presented at the hearing and the record thereof, are:

Material Issue Number 1

The definition of production area under § 927.10 should be amended by removing the State of California from the production area. The new production area would include only the States of Oregon and Washington.

Currently, § 927.10 defines the production area to include the States of Oregon, Washington and California. The winter pear marketing order has been in effect since the early 1930's. Record evidence showed that the primary operations of the marketing order have changed since the inception of the order from establishing minimum quality requirements within the industry to primarily providing an extensive promotion and research program.

Record evidence indicated that there is also a Pear Bureau (Bureau) that works in conjunction with the marketing order. The Bureau has been in existence for 60 years. Its purpose is to represent the winter pear industry in Oregon, Washington and California, and the Bartlett industry in Oregon and Washington, in market development and promotion and advertising throughout the international marketplace. The Bureau, through contractual agreement, is responsible for conducting market development and paid advertising activities authorized by the Committee.

Currently, § 927.4 of the order defines the varietal types of pears that are covered under the order to be the Beurre, D'Anjou, Beurre Bosc, Winter Nelis, and Doyenne du Comice varieties of pears grown in Oregon, Washington, and California. Also, the Forelle and Seckel varieties that are grown in Washington and Oregon are covered by the order. The major variety grown in California that is covered under the marketing order is the Beurre Bosc pear. The marketing order does not cover Bartlett pears, however there are programs conducted for Northwest Bartlett pears by the Bureau.

Record evidence showed that California Bartlett pears are included under a California pear promotion program and therefore, are not part of the Bureau's programs. In the past, the California Bartlett industry has been encouraged to be represented by the Bureau but they have not wished to be part of the Bureau. Record evidence indicated that Oregon, Washington and California winter pear handlers work in conjunction with each other to market most varieties of winter pears, but are segregated where Bartlett pears are concerned. A witness testified that California winter pear and Bartlett pear growers question why they should pay assessments promoting winter pears as well as Northwest Bartlett pears.

Record evidence also indicated that the harvest and marketing seasons are different for California pears and Northwest pears (i.e., those grown in Oregon and Washington). Winter pears grown in California are typically harvested and marketed from late July through October although the season sometimes extends into November. Northwest pears are harvested and marketed beginning late in September and continuing through the following June.

Record evidence showed that the timing of the promotional activities for winter pears are not as effective for California handlers of winter pears. For example, the majority of Bosc promotional activities conducted under the order are scheduled to commence in September or October each season. Bosc pears produced in the Greater Sacramento District of California are typically harvested and shipped by August. Therefore, California handlers are not able to take advantage of such promotional activities.

Record evidence also indicated that the pesticide research programs conducted under the marketing order may not benefit the California grower or handler. The Committee has assessed additional money to retain the registration of post-harvest fungicides, Ethoxyquin and Sodium O-Phenyl phenate (SOPP). These two materials may not be used by California shippers because of State regulatory differences. However, the California handler is still required to pay such assessment.

Record evidence showed that there are currently 1,700 winter pear growers in Oregon and Washington and 60 growers of winter pears in California. There are also 93 handlers of winter pears in Oregon and Washington and 19 handlers of winter pears in California. Production for the 1995–96 season showed that 15,316,776 standard boxes were produced in Oregon and Washington, while California produced 434,380 standard boxes. Revenue generated from assessments collected in 1995–96 would be $175,923 from California and $6,203,295 from Oregon and Washington, for a total of $6,379,218. Record evidence showed that the loss of revenue would be approximately 2.76 percent of the total current assessment income if California was excluded from the production area. A proponent testified that this loss of revenue to the total program would be relatively insignificant. Such a loss would not effect the current level of promotional and research activities and would not adversely effect the Northwest pear industry.

Record evidence showed that the production area of Oregon and Washington is the smallest practicable area which should be regulated under the marketing order for winter pears.

Material Issue Number 2

Section 927.11 should be amended by deleting paragraph (e) which specifies the district of the State of California. Section 927.11 states the districts to be covered under the marketing order. The districts are specified under the order for purposes of representation on the Committee. If California is removed from the production area as proposed by the proponents, such a change would have to be made to this section to reflect the amendment.

Material Issue Number 3

Section 927.20 should be amended by decreasing the number of Committee members from 14 members to 12 members. Also, the number of grower and handler members on the Committee would be decreased from seven members to six members for each category. Currently, the district of California is represented by one grower member and one handler member on the Committee. Since the proposed amendment would remove the State of California from coverage under the marketing order, record evidence also

supports decreasing the Committee membership by the two California members. A corresponding change would be made in the number of grower and handler members. The number would be decreased from seven to six members for each category. If California is removed from the production area as proposed by the proponents, such a change would have to be made to this section to reflect the amendment.

Material Issue Number 4

Section 927.33 should be amended by revising paragraph (a) to reflect the number of Committee members that need to be present for a quorum. Also, paragraph (b) should be revised by allowing for the use of telecopiers when Committee members need to vote on an action.

Currently, § 927.33(a) states that 10 members need to be present to constitute a quorum. Record evidence supports decreasing the quorum size to reflect the change in the Committee membership due to the removal of California. The amendment would decrease the quorum size to nine members. If California is removed from the production area as proposed by the proponents, such a change should be made to this section to reflect the amendment.

Section 927.33(b) states that the Committee may provide for members to vote by mail, telephone, or telegraph, upon due notice to all members. Record evidence supported adding the use of telecopiers as a method of voting by Committee members. This would allow the Committee to vote without being assembled at a meeting place and, therefore, reduce administrative costs and act quickly on a recommendation that needs the Committee's attention. ''Other electronic means'' is envisioned to include the use of modems, video and teleconferencing. The term is flexible to allow for the use of new technologies by the Committee for voting.

Material Issue Number 5

Section 927.4 should be amended by deleting the reference to the State of California. Currently, § 927.4 lists the varieties of pears that are covered under the marketing order. Record evidence showed that Forelle and Seckel pear varieties are exclusively grown in Oregon and Washington and are referenced as such under § 927.4. Other pear varieties are listed and are specified as being grown in the States of Oregon, Washington and California. If California is removed from the production area as proposed by the proponents, such a change would have to be made to this section to reflect the amendment.

The Notice of Hearing also included a proposal by the Fruit and Vegetable Division, Agricultural Marketing Service (AMS) to make such changes as are necessary to the order, if any or all of the above amendments are adopted, so that all of its provisions conform with the proposed amendment. One proposed amendment has been made deleting California from the title of the marketing order.

General Findings

(1) The findings hereinafter set forth are supplementary to the previous findings and determinations which were made in connection with the issuance of the marketing agreement and order and each previously issued amendment thereto. Except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein, all of the said prior findings and determinations are hereby ratified and affirmed;

(2) The marketing agreement and order, as amended, and as hereby proposed to be further amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

(3) The marketing agreement and order, as amended, and as hereby proposed to be further amended, regulate the handling of pears grown in the production area in the same manner as, and are applicable only to, persons in the respective classes of commercial and industrial activity specified in the marketing order and agreement and order upon which a hearing has been held;

(4) The marketing agreement and order, as amended, and as hereby proposed to be further amended, are limited in their application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivision of the production area would not effectively carry out the declared policy of the Act; and

(5) All handling of winter pears grown in Oregon and Washington as defined in the marketing agreement and order, as amended, and as hereby proposed to be further amended, is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

Ten days has been determined to be an appropriate comment period for this rule because: (1) The fiscal period of the marketing order begins on July 1, 1997, and shipments of winter pears for the 1997–98 season begin in July. It would be difficult for the committee to administer this amendment part-way into the season, especially after shipments have begun. In addition, making this amendment effective as close to the beginning of the annual pear shipments would be more equitable to all handlers; (2) these issues were presented at a public hearing before an administrative law judge and no opposing testimony was presented; and (3) any comments received will be considered and a producer referendum will be conducted prior to finalization of this rule.

List of Subjects in 7 CFR Part 927

Marketing agreements, Pears, Reporting and recordkeeping requirements.

Recommended Further Amendment of the Marketing Agreement and Order

For the reasons set forth in the preamble, 7 CFR part 927 is proposed to be amended as follows:

1. The authority citation for 7 CFR part 927 continues to read as follows:

Authority: 7 U.S.C. 601–674.

PART 927—[AMENDED]

2. The part heading is revised to read as follows:

PART 927—WINTER PEARS GROWN IN OREGON AND WASHINGTON

3. Section 927.4 is revised to read as follows:

§ 927.4 Pears.

Pears means and includes any and all of the Beurre D'Anjou, Beurre Bosc, Winter Nelis, Doyenne du Comice, Forelle, and Seckel varieties of pears, and any other winter pear varieties or subvarieties that are recognized by the Control Committee and approved by the Secretary.

4. Section 927.10 is revised to read as follows:

§ 927.10 Production area.

Production area means and includes the States of Oregon and Washington.

§ 927.11 [Amended]

5. In § 927.11, paragraph (e) is removed.

§ 927.20 [Amended]

6. Section 927.20 is amended by removing the number ''14'' in the first sentence and adding in its place the number ''12'', and removing the word ''seven'' each time it appears in the third sentence and adding in its place the word ''six''.

§ 927.33 [Amended]

7. In § 927.33, paragraph (a) is amended by removing the word ''ten'' in the first sentence and adding in its place the word ''nine''; and adding the words ''telecopier or other electronic means,'' and a comma after the word ''mail'' in paragraph (b) first sentence.

Dated: June 9, 1997.

Lon Hatamiya,

Administrator, Agricultural Marketing Service.

[FR Doc. 97–15663 Filed 6–13–97; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1753

Acceptance Test Policy

AGENCY: Rural Utilities Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service (RUS) is proposing a minor amendment to its test acceptance procedures to correct 7 CFR part 1753.39, paragraph (c), to reflect new acceptance tests guidelines covered under RUS Bulletin 1753E–201, Acceptance Tests for Digital, Stored Program Controlled Central Office Equipment.

In the final rules section of this **Federal Register**, RUS is publishing this action as a direct final rule without prior proposal because RUS views this as a noncontroversial action and anticipates no adverse comments. If no adverse comments are received in response to the direct final rule, no further action will be taken on this proposed rule and the action will become effective at the time specified in the direct final rule. If RUS receives adverse comments, a document will be published withdrawing the effective date of the direct final rule and all public comments received will be addressed in a subsequent final rule based on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed action must be received July 16, 1997.

ADDRESSES: Written comments should be sent to Orren E. Cameron III, Director, Telecommunications Standards Division, Rural Utilities Service, STOP 1598, United States Department of Agriculture, 1400 Independence Ave., SW, Washington, DC, 20250–1598. RUS requires, in hard copy, a signed original and three copies of all comments (7 CFR part 1700.30(e)). All comments received will be available for public inspection at room 2835 (address as above) during regular business hours (7 CFR part 1.27(b)).

FOR FURTHER INFORMATION CONTACT: John J. Schell, Chief, Central Office Equipment Branch, Telecommunications Standards Division, Rural Utilities Service, United States Department of Agriculture, STOP 1598, 1400 Independence Avenue, SW, Washington, DC 20250–1598, telephone number (202) 720–0671.

SUPPLEMENTARY INFORMATION: See the Supplementary Information provided in the direct final rule located in the final rules section of this **Federal Register** for the applicable supplementary information on this section.

Dated: June 9, 1997.

Jill Long Thompson,

Under Secretary, Rural Development.

[FR Doc. 97–15756 Filed 6–13–97; 8:45 am]

BILLING CODE 3410–15–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 32

RIN 3150–AF70

Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; request for comments.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing an amendment to its regulations that would permit NRC licensees to distribute a radioactive drug containing one microcurie of carbon-14 urea to any person for ''in vivo'' diagnostic use. The NRC has determined that the radioactive component of such a drug in capsule form presents a minimal radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. If adopted, this amendment would make the drug more widely available, and reduce costs to patients, insurers, and the health care industry. This action is being taken in response to a petition for rulemaking (PRM–35–12) submitted by Tri-Med Specialties, Inc.

DATES: Submit comments by July 16, 1997. Comments received after this date will be considered if it is practicable to do so, but the Commission is able to assure consideration only for comments received on or before this date.

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

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

The public may examine comments received, the environmental assessment and finding of no significant impact, and the regulatory analysis at the NRC Public Document Room, 2120 L Street NW., (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6233 or e-mail at ANT@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background
II. Discussion
III. Summary of Proposed Amendments
IV. Agreement State Compatibility
V. Electronic Access
VI. Finding of No Significant Environmental Impact: Availability
VII. Paperwork Reduction Act Statement
VIII. Regulatory Analysis
IX. Regulatory Flexibility Certification
X. Backfit Analysis
XI. List of Subjects

I. Background

The Petition for Rulemaking

On October 6, 1994, the Commission docketed a petition for rulemaking (Docket No. PRM–35–12) from Tri-Med Specialties, Inc (Tri-Med). In a letter dated August 23, 1994, Tri-Med petitioned the NRC to amend its regulations ''to allow for the general licensing and/or exemption for the commercial distribution by licensed pharmaceutical manufacturers of a capsule containing one micro-Curie (μCi) of ^{14}C-urea for in vivo diagnostic testing.'' The purpose of this diagnostic test is to detect the presence of the bacterium Helicobacter pylori (H. pylori), a cause of peptic ulcers.

''Peptic ulcer disease is a chronic inflammatory condition of the stomach and duodenum that affects as many as 10 percent of people in the United States at some time in their lives. The disease has relatively low mortality, but it results in substantial human suffering and high economic costs.'' (Source: Article included as an appendix to the petition, from JAMA, July 6, 1994, Vol-272, No. 1, ''H. pylori in Peptic Ulcer Disease—NIH Consensus Conference'').

In the petition, the petitioner stated the following:

Recent medical research has found that peptic ulcers are commonly caused by a bacterium called H. pylori. This