activities are intended to assist the public in understanding the proposed rule and in providing comments on the proposed rule.

DATES: See Supplementary Information for dates of hearings.

ADDRESSES: See Supplementary Information for locations of hearings.

FOR FURTHER INFORMATION CONTACT: Dan Vitiello, Director, Planning and Analysis, Planning Office, Policy, Evaluation and Planning Staff, FSIS, USDA, Room 6904 Franklin Court, Washington, DC 20250, (202) 501–7138.

SUPPLEMENTARY INFORMATION: On February 3, 1995, FSIS published a proposed rule titled ''Pathogen Reduction; Hazard Analysis and Critical Control Points (HACCP) Systems'' (60 FR 6774). The proposal provides a number of requirements applicable to Federal and State-inspected meat and poultry establishments. The proposed requirements are designed to reduce the occurrence and numbers of pathogenic organisms in meat and poultry products, thereby reducing the incidence of foodborne illness associated with the consumption of these products.

Information Briefings

To assist the public in understanding the proposal, FSIS is holding six briefings as follows. Each briefing will run from 1:00 p.m. to 5:00 p.m. Any person who wishes to attend any of the information briefings should contact the FSIS Planning Office at (202) 501–7138.

Date	City/state	Location	Contact
Mar. 7	San Francisco, Oakland, CA	Henry J. Kaiser Convention Center, 10 Tenth Street, Oakland, CA 94607.	Linda Russell, (202) 501–7138.
Mar. 14	Dallas, TX	Dallas Grand Hotel, 1914 Commerce St., Dallas, TX 75201, (214) 747–7000; 1–800–421–0011.	Dan Vitiello (202) 501–7138.
Mar. 16	Chicago, IL	Holiday Inn O'Hare Airport, 5440 North River Rd., Rosemont, IL 60018, (708) 671–6350.	Ken Elane, (202) 501–7138.
Mar. 21	Atlanta, GA	Richard Russell Federal Building, 75 Spring St., SW., Atlanta, GA 30303.	Ron Niemeyer, (202) 501–7138.
Mar. 23	New York, NY	Federal Building, 26 Federal Plaza, Room 305, New York, NY 10278.	Ken Elane, (202) 501–7138.
Mar. 30	Washington, DC	Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202, (703) 418–1234.	Linda Russell (202) 501–7138.

The format for each briefing will be the same:

1. A panel of subject matter specialists will explain various aspects of the proposal.
2. Attendees will submit any questions they have, in writing.
3. Panelists will answer the questions.

Scientific/Technical Conferences

FSIS also plans to hold three conferences, each addressing a specific scientific/technical issue. Information on each specific conference will be published separately at a later date.

The three conferences are scheduled to be held as follows:

Issue: ''New Technology to Improve Food Safety''

April 12–13, Chicago, IL, Holiday Inn O'Hare Airport, 5440 North River Road, Rosemont, IL 60018, (708) 671–6350

Issue: ''The Role of Microbiological Testing in Verifying Food Safety''

May 1–2, Philadelphia, PA, Holiday Inn-Independence Mall, Fourth and Arch Streets, Philadelphia, PA 19106, (215) 923–8860

Issue: ''An Evaluation of the Role of Microbiological Criteria in Establishing Food Safety Performance Standards in Meat and Poultry Products''

May 18–19, Washington, DC, Georgetown University, Conference Center, 3800 Reservoir Road, Washington, DC 20007, (202) 687–3200

Public Hearing

Lastly, FSIS is planning to hold a two-day public hearing for those commenters who wish to submit oral comments in response to the proposed rule. (Oral comments may also be provided to FSIS by contacting the persons listed in the proposed rule). The public hearing will be held:

May 30–31, Washington, DC, Georgetown University Conference Center, 3800 Reservoir Road, NW., Washington, DC 20007, (202) 687–3200

Done at Washington, DC, on: February 17, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

[FR Doc. 95–4498 Filed 2–24–95; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 94N–0421]

RIN 0905–AE63

Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to permit manufacturers of positron emission tomography (PET) radiopharmaceuticals to apply to the agency for approval of an exception or alternative to the requirements of the current good manufacturing practice (CGMP) regulations. This action is intended to relieve PET manufacturers, nearly all of whom are small entities, from regulations that might result in unsafe handling of PET radiopharmaceuticals, that are inapplicable or inappropriate, or that otherwise do not enhance safety or quality in the manufacture of PET radiopharmaceuticals.

DATES: Written comments by March 29, 1995. FDA proposes that any final rule that may issue based on this proposal become effective on its date of publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John W. Levchuk, Center for Drug Evaluation and Research (HFD–322), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0095.

SUPPLEMENTARY INFORMATION:

I. Introduction

PET is a diagnostic imaging modality consisting of onsite production of radionuclides that are intravenously injected into patients for diagnostic purposes. The potential usefulness of a PET radiopharmaceutical is based upon

the product's interaction with a biochemical process in the body. For example, the product may be substituted for glucose in anaerobic glycolysis, theoretically localizing in ischemic tissues where glucose metabolism is the predominant energy source (epileptic foci, acute vascular insufficiency states).

The manufacture of PET radiopharmaceuticals consists of a process that takes place within a few hours. A target material is irradiated by a cyclotron; chemical synthesis takes place in a programmed, automated apparatus; and the final solution is compounded and filled. The biological distribution of a PET radiopharmaceutical in the body is monitored by a positron tomograph, or PET scanner, which detects the photons emitted as a result of the radioactive decay of the PET radiopharmaceutical.

PET manufacturing procedures differ in a number of important ways from those associated with the manufacture of conventional drug products:

- Because of the short half-lives of PET radiopharmaceuticals (some of which are only minutes long), PET facilities generally manufacture the products in response to daily demand for a relatively small number of patients.
- Manufacturing is typically done on a small scale and only a few lots are produced each day. Thus, the daily production of a PET facility is normally handled by few employees, sometimes by one production operator and a part-time support person.
- PET radiopharmaceuticals must be administered to patients in a short period of time because of the brief half-lives of the products. Any prolonged manufacturing time or testing or release delays would reduce the useful clinical life of the product.
- Unlike most pharmaceuticals, PET radiopharmaceuticals usually do not enter a general drug distribution chain. An entire lot (one vial) is usually distributed directly from the PET facility to a single medical department, to a physician for administration to patients, to a radiopharmacy for dispensing, or to another site close to the PET facility. The receiving facilities are in a geographic proximity that will allow for receipt and use within the product's half-life parameters.

The agency believes that there are fundamental principles of the CGMP regulations that need to be applied to drug manufacturing processes, including those for PET radiopharmaceuticals, to ensure the safety and efficacy of the finished products. However, as just noted, certain features are unique to the manufacture of PET products. Part 211 (21 CFR part 211), which is primarily directed to the regulation of conventional drug products, contains requirements and specific language which might result in unsafe handling of PET radiopharmaceuticals, are inapplicable or inappropriate, or which otherwise do not enhance drug product quality in the manufacture of PET radiopharmaceuticals.

FDA is therefore proposing to amend its regulations to permit manufacturers of PET radiopharmaceuticals to apply to the agency for approval of an exception or alternative to the requirements of part 211 as they apply to the manufacture of PET radiopharmaceuticals. A request for an exception or alternative must contain either an explanation why compliance with a particular requirement of the CGMP regulations is unnecessary or cannot be achieved, or a description of alternative procedures or controls that satisfy the purpose of the CGMP requirement. Both of these must include all necessary supporting data. Alternatively, the request may include other information justifying an exception or alternative. The request for an exception or alternative may be approved by the agency if it is determined that the requestor's compliance with the CGMP requirement is unnecessary to provide suitable assurance that the drug meets the requirements of the act as to safety and it has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess, or if compliance with the requirement cannot be achieved. In addition, the request for an exception or alternative may be approved if the requestor's alternative procedures or controls satisfy the purpose of the CGMP requirement, or if the requestor's submission otherwise justifies an exception or alternative. The agency may withdraw approval of an exception or alternative if it finds, on the basis of new information, that the criteria for approval are no longer met. Such withdrawal will be accomplished by providing written notice, and the reasons for the action, to the original requestor.

The agency will also periodically provide guidance to the industry on the application of the CGMP regulations to PET radiopharmaceuticals.

Elsewhere in this issue of the Federal Register, FDA is publishing: (1) A notice of availability of a draft guideline to assist persons in determining whether certain manufacturing practices, procedures, and facilities used for PET radiopharmaceuticals are in compliance with FDA's CGMP regulations; and (2) a notice of a public workshop and FDA guidance on the regulation of PET radiopharmaceuticals.

FDA is requesting written comments within 30 days after the date of publication of this proposed rule. In addition, FDA is proposing that any final rule that may publish as a result of this proposal become effective on its date of publication in the Federal Register. The proposed rule would permit manufacturers of PET radiopharmaceuticals to apply to FDA for approval of an exception or alternative to the requirements of the CGMP regulations. Accordingly, the proposed rule, if finalized, is a substantive rule which, in the discretion of the agency, grants or recognizes an exemption or relieves a restriction. (See 5 U.S.C. 553(d)(1) and 21 CFR 10.40(c)(4)(i).) In addition, the Commissioner of Food and Drugs finds good cause under 21 CFR 10.40(a)(2) for providing 30 days for comments instead of 60 days and under 5 U.S.C. 553(d)(3) and 21 CFR 10.40(c)(4)(ii) for making a final rule based on this proposal effective upon its publication in the Federal Register. The manufacturing process for PET radiopharmaceuticals is sufficiently different from that of other regulated products that application of certain CGMP requirements to PET radiopharmaceuticals is impractical. Because PET radiopharmaceuticals are already in use, a longer comment period or a later effective date may delay FDA approval or hinder appropriate application of CGMP regulations to PET radiopharmaceuticals, that are necessary to protect the integrity of the drug manufacturing process.

II. Request for Comments

Interested persons may, on or before March 29, 1995, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that the proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

For the reasons explained above, FDA proposes that any final rule based on this proposal become effective on the date of publication in the Federal Register.

V. Paperwork Reduction Act of 1980

This proposed rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Current Good Manufacturing Practice for Finished Pharmaceuticals: Positron Emission Tomography

Description: The proposal would permit manufacturers of PET products to apply to the agency for approval of an exception or alternative to the requirements of the CGMP regulations. The regulation is intended to relieve PET manufacturers, nearly all of whom are small entities, from regulations that might result in unsafe handling of PET radiopharmaceuticals, that are inapplicable or inappropriate, or that otherwise do not enhance safety or quality in the manufacture of PET radiopharmaceuticals.

Description of Respondents: Businesses; small businesses.

ESTIMATED ANNUAL REPORTING BURDEN:

Section	Number of Respondents	No. of Responses Per Respondents	Total Annual Responses	Hours Per Response	Total Hours
21 CFR 211.1(d)	60	1	60	4	240

We have submitted a copy of this proposed rule to OMB for its review of these information collections. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the agency official designated for this purpose whose name appears in this preamble, and to the Office of Information and Regulatory Affairs, OMB, Washington, D.C. 20503.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 211 be amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 506, 507, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374).

2. Section 211.1 is amended by adding new paragraph (d) to read as follows:

§ 211.1 Scope.

* * * * *

(d) The Director of the Center for Drug Evaluation and Research or the Director of the Office of Compliance, Center for Drug Evaluation and Research, may approve an exception or alternative to any application of this part to the manufacture of positron emission tomography (PET) radiopharmaceuticals. Requests for such exceptions or alternatives should ordinarily be made in writing. However, in certain circumstances, such requests may be made orally and permission may be granted orally. Oral requests and oral approvals must be followed by written requests and written approvals. Approval of a request for an exception or alternative must be obtained from either specified Director prior to the use of any affected PET radiopharmaceutical.

(1) A request for an exception or alternative is required to contain one of the following:

(i) An explanation, with supporting data as necessary, why compliance with a particular requirement of this part is unnecessary or cannot be achieved;

(ii) A description, with supporting data as necessary, of alternative procedures or controls that satisfy the purpose of the requirement; or

(iii) Other information justifying an exception or alternative.

(2) The Director may approve a request for an exception or alternative if the Director finds one of the following:

(i) The requestor's compliance with the requirement is unnecessary to provide suitable assurance that the drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess, or compliance with the requirement cannot be achieved;

(ii) The requestor's alternative procedures or controls satisfy the purpose of the requirement; or

(iii) The requestor's submission otherwise justifies an exception or alternative.

(3) The Director may withdraw approval of an exception or alternative if the Director finds, on the basis of new information, that the criteria for approval in paragraph (d)(2) of this section are no longer met. Withdrawal of approval shall be accomplished by providing written notice of such

withdrawal, and the reasons for the withdrawal, to the original requestor.

Dated: February 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–4690 Filed 2–24–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 902

Alaska Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed program amendment.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the Alaska permanent regulatory program (hereinafter, the ''Alaska program'') under the Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*) (SMCRA). The proposed amendment consists of revisions to rules pertaining to fees, adoption by reference, general permitting requirements, permit application information requirements, environmental resource information requirements, reclamation and operation plan, processing of permit applications, permitting for special categories of mining, exploration, small operator assistance program, bonding, performance standards, inspection and enforcement, and general provisions. The amendment is intended to revise the Alaska program to be consistent with the corresponding Federal regulations, clarify ambiguities, and improve operational efficiency. The amendment consists of proposed changes to the Alaska program as required by Part 902.16 of the Code of Federal Regulations and program deficiency letters dated November 1, 1989, February 7, 1990, and January 15, 1993.

DATES: Written comments must be received by 4:00 p.m., m.s.t. March 29, 1995. If requested, a public hearing on the proposed amendment will be held on March 24, 1995. Requests to present oral testimony at the hearing must be received by 4:00 p.m., m.s.t. on March 14, 1995.

ADDRESSES: Written comments should be mailed or hand delivered to Guy Padgett at the address listed below.

Copies of the Alaska program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contracting OSM's Casper Field Office.

Guy Padgett, Director, Office of Surface Mining Reclamation and Enforcement, Casper Field Office, 100 East B Street, Room 2128, Casper, WY 82601–1918, (307) 261–5776

Mr. Jules Tileston, Director, Division of Mining and Water Resources, Alaska Department of Natural Resources, 3601 C Street, Suite 800, Anchorage, Alaska 99503–5935, (907) 762–5163

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Director, Telephone: (307) 261–5776.

SUPPLEMENTARY INFORMATION

I. Background on the Alaska Program

On March 23, 1983, the Secretary of the Interior conditionally approved the Alaska program as administered by the Alaska Department of Natural Resources. General background information on the Alaska program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Alaska program can be found in the March 23, 1983, Federal Register (48 FR 12274). Subsequent actions concerning Alaska's program and program amendments can be found at 30 CFR 902.15 and 902.16.

II. Proposed Amendment

By letter dated January 26, 1995 and FAX transmittals dated February 13 and 14, 1994 (Administrative Record No. AK IV–01), Alaska submitted proposed Amendment IV to its permanent program pursuant to SMCRA (SPATS AK–004–FOR). Alaska's proposed Amendment IV consists of: changes to the Alaska program as required by 30 CFR Part 902.16; changes in response to program deficiency letters from OSM dated November 1, 1989, February 7, 1990, and January 15, 1993; and changes to Alaska's own initiative. The provisions of the Alaska Administrative Code (AAC) that Alaska proposes to revise are: 11 AAC 05.010(a)(9) and 11 AAC 90.011, fees; 11 AAC 90.001, adoption of rules by reference; 11 AAC 90.002, responsibilities; 11 AAC 90.003, interim permits; 11 AAC 90.023, identification of interests and compliance information; 11 AAC 90.025, authority to enter and ownership information; 11 AAC 90.045(a), geology description; 11 AAC 90.049, surface water information; 11 AAC 90.083(b), reclamation plan requirements, roads; 11 AAC 90.097, transportation facilities; 11 AAC 90.099, placement of coal mine waste in underground workings; 11 AAC 90.117, processing of permit applications; 11 AAC 90.125, commissioner's findings; 11 AAC 90.126, improvidently issued permits; 11 AAC 90.127, permit conditions; 11 AAC 90.129, permit revisions and renewals; 11 AAC 90.149, alluvial valley floors; 11 AAC 90.163, exploration that substantially disturbs or is conducted in areas designated unsuitable for mining; 11 AAC 90.173, eligibility for small operator assistance; 11 AAC 90.207, self-bonding provisions; 11 AAC 90.321, hydrologic balance; 11 AAC 90.323, water quality standards; 11 AAC 90.325, diversions and conveyance of flow; 11 AAC 90.327, stream channel diversions; 11 AAC 90.336, impoundment design and construction; 11 AAC 90.337, impoundment inspection; 11 AAC 90.341, underground mine discharges; 11 AAC 90.345, surface and ground water monitoring; 11 AAC 90.375, public notice of blasting; 11 AAC 90.391, disposal of excess spoil or coal mine waste; 11 AAC 90.401, coal mine waste, refuse piles; 11 AAC 90.407, coal mine waste, dams and embankments; 11 AAC 90.409, coal mine waste, return to underground workings; 11 AAC 90.423, protection of fish and wildlife; 11 AAC 90.443, backfilling and grading; 11 AAC 90.457, Revegetation success standards; 11 AAC 90.491, construction and maintenance of roads and other transportation and support facilities; 11 AAC 90.601, inspections; 11 AAC 90.613, cessation orders, 11 AAC 90.901, applicability; 11 AAC 90.902, exception for coal extraction incidental to the extraction of other minerals; 11 AAC 90.907, public participation; and 11 AAC 90.911, definitions.

Specifically, Alaska proposes to:

—Revise 11 AAC 05.010(a)(9) and 90.011 to move the regulatory requirements for permit fees to the fee provisions for the whole department, and to set a fee for incidental boundary revisions;

—Revise 11 AAC 90.002 and delete 90.003, to eliminate provisions for continued operation or exploration under interim permits;

—Repeal and readopt 11 AAC 90.023 to clarify and add requirements for identification of ownership and control interests and compliance histories;

—Revise 11 AAC 90.025 to require ownership information for owners, lessees, and purchasers of record of