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