The agency does not believe such additional measures are necessary. This CGMP provision does not stand alone but must be read in context with other CGMP regulations. Those regulations provide a variety of safeguards for different stages and aspects of the drug manufacturing process. It is the CGMP regulations, taken as a whole, that help ensure drug quality. Moreover, the consequences of widespread disclosure of problems with drug product quality resulting from a recall or other ameliorative action are sufficiently severe to provide most firms with a continuing incentive to maintain product quality. The agency has carefully reviewed this issue and believes that the final rule will not reduce drug product quality.

## IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(10) 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.

## V. Analysis of Impacts

FDA has examined the impacts of the final 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 rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The amendments to the CGMP regulations are intended to allow drug manufacturers more flexibility and discretion in manufacturing drug products while maintaining those CGMP requirements necessary to ensure drug product quality. Because this may encourage innovation and the development of more efficient manufacturing procedures that should lead to cost savings for drug manufacturers. In addition, the 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

final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

## **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, 21 CFR part 211 is 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 211.42 is amended in the introductory text of paragraph (c) by revising the second sentence to read as follows:

## $\S 211.42$ Design and construction features.

(c) \* \* \* There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

\* \* \* \* \*

3. Section 211.68 is amended by adding a new sentence after the second sentence in paragraph (b) to read as follows:

## § 211.68 Automatic, mechanical, and electronic equipment.

\* \* \* \* \*

(b) \* \* \* The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system. \* \* \*

4. Section 211.137 is amended by redesignating paragraph (g) as paragraph (h), and by adding new paragraph (g) to read as follows:

## § 211.137 Expiration dating.

\* \* \* \* \*

(g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be

reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product.

\* \* \* \* \*

5. Section 211.170 is amended by revising the fourth sentence in the introductory text of paragraph (b) to read as follows:

## § 211.170 Reserve samples.

\* \* \* \* \* \*

- (b) \* \* \* Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. \* \* \*
- 6. Section 211.180 is amended by revising paragraph (e)(1) to read as follows:

## § 211.180 General requirements.

(e) \* \* \*

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.

\* \* \* \*

Dated: January 11, 1995.

## William K. Hubbard,

Interim Deputy Commissioner for Policy. [FR Doc. 95–1361 Filed 1–19–95; 8:45 am] BILLING CODE 4160–01–F

# ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[PP 1F4013/R2101; FRL-4930-9]

RIN 2070-AB78

#### Pesticide Tolerances for Imazethapyr

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This rule establishes tolerances for the sum of the residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methy1-4-(1-methylethyl)-5-oxo-1*H*-imidazo1-2-yl]-5-ethy1-3-pyridine carboxylic acid, as its ammonium salt and its metabolite, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazo1-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid, both free and conjugated, in or on