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#### List of Subjects

##### 21 CFR Part 112

Dietary foods, Drugs, Foods, Packaging and containers.

##### 21 CFR Part 112

Drugs, Packaging and containers, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR chapter I, parts 111 and 112 as set forth below:

#### PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

1. The authority citation for part 111 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 348, 371, 374, 381, 393; 42 U.S.C. 264.

2. The part heading for part 111 is revised as set forth above.

3. Add new subpart A to part 111 to read as follows:

##### Subpart A—General Provisions

Sec.

111.1 Who is subject to these regulations?

111.2 What are these regulations intended to accomplish?

111.3 What definitions apply to this part?

111.5 Do other statutory provisions and regulations apply?

111.6 Exclusions.

##### Subpart A—General Provisions

###### § 111.1 Who is subject to these regulations?

You are subject to the regulations in this part if you manufacture, package, or hold a dietary ingredient or dietary supplement.

###### § 111.2 What are these regulations intended to accomplish?

The regulations in this part establish the minimum current good manufacturing practices that you must use to the extent that you manufacture, package, or hold a dietary ingredient or dietary supplement.

###### § 111.3 What definitions apply to this part?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to such terms when used in these regulations. For the purpose of these regulations, the following definitions also apply:

*Actual yield* means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular dietary ingredient or dietary supplement.

*Batch* means a specific quantity of a dietary ingredient or dietary supplement that is intended to meet specifications for identity, purity, quality, strength,