

**Part E: Production
& Process Controls**

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FDA 21 CFR Part 111 Proposed Regulation Changes (Blue Text Indicates ALI Suggested Modifications)

SUBPART E: PRODUCTION AND PROCESS CONTROLS

111.35 WHAT PRODUCTION AND PROCESS CONTROLS MUST YOU USE?

Recommended Changes: Paragraph(c) You must use a quality control unit in your manufacturing, packaging, and label operations for producing the dietary ingredient or dietary supplement to ensure that these operations are performed in a manner that prevents adulteration and ensures that the dietary ingredient or dietary supplement meets manufacturing specifications. ~~for identity, purity, quality, strength, and composition.~~

Recommended Changes: Paragraph (e)(1) Eliminate this paragraph, (e)(2) fully describes requirements for product testing to meet the manufacturers product specifications.

Recommended Changes: Paragraph (g)(2): For any manufacturer specification for ~~identity, purity, quality, strength and composition~~ for which you document cannot be tested on the finished batch of dietary ingredient or dietary supplement, because there is no scientifically valid analytical method available for testing, then you must: (see P12257).

Recommended Changes: Paragraph (g)(2)(ii) For any specification ~~for identity, purity, quality, strength, or composition~~ for which you document cannot be tested on the finished batch of a dietary ingredient or dietary supplement, because there is no scientifically valid analytical method available for such testing, then you must:

Recommended Changes: Paragraph (k) You must test or examine components, dietary ingredients, and dietary supplements for those types of contamination that may adulterate or may lead to adulteration unless retrospective data or three repeated processes on separate batches have demonstrated a product manufacturers process has eliminated those possibilities. Further, if raw materials are shown to be free of such contamination, finished product testing only need confirm freedom of such contamination.

Recommended Changes: Paragraph (o)(6) The identity of the individual qualified by training and/or experience or any combination of the two, who investigated any deviation from specifications or unanticipated occurrence and the identity of the individual from the quality control unit who reviewed the results of that investigation.

111.37 WHAT REQUIREMENTS APPLY TO QUALITY CONTROL?

Recommended Changes: Paragraph (b)(12) Keep reserve samples for one year past the product life indicated on the label or two (2) years from the date of manufacture for use in appropriate investigations including, but not limited to, consumer complaint investigations to determine for example, whether the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications ~~for identity, purity, quality, strength, and composition.~~ the reserve samples must:

111.40 WHAT REQUIREMENTS APPLY TO COMPONENTS, DIETARY INGREDIENTS, DIETARY SUPPLEMENTS, PACKAGING, AND LABELS YOU RECEIVE?

No Recommended Changes for this section.

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11.45 WHAT REQUIREMENTS APPLY TO ESTABLISHING A MASTER MANUFACTURING RECORD?

No Recommended Changes for this section.

11.50 WHAT REQUIREMENTS APPLY TO ESTABLISHING A BATCH MANUFACTURING RECORD?

Recommended Changes: Paragraph (d)(2): The quality control unit must not approve and release for distribution any batch of dietary ingredient or dietary supplement that does not meet essential product identity, purity, quality, strength, and composition, manufacturer specifications.

Recommended Changes: Paragraph (e)(4): The identity of the person qualified by training and/or experience or any combination of the two, who performed the investigation in accordance with paragraph (d) of this section.

Recommended Changes: Paragraph (f): You must not reprocess a batch that deviated from the master manufacturing record unless approved by the quality control unit. You must not reprocess a dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms of public health significance or other contaminants, such as heavy metal, unless you have validated processes to reduce the contamination to acceptable levels and it is approved by the quality control unit.

Recommended Changes: Paragraph (h): You must collect reserve samples of each batch of dietary ingredient or dietary supplement and keep the reserve samples for one (1) year past the product life on the shelf or two (2) from the date of manufacture for use in appropriate investigations including, but not limited to, consumer complaint investigations to determine whether, for example, the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for ~~identity, purity, quality, strength, and composition; and~~

11.60 WHAT REQUIREMENTS APPLY TO LABORATORY OPERATIONS?

Recommended Changes: Paragraph (d): You must identify and use the appropriate ~~validated~~ test method established by the manufacturer for each established specification for which testing is required to determine whether the specification is met.

11.65 WHAT REQUIREMENTS APPLY TO MANUFACTURING OPERATIONS?

No Recommended Changes: Paragraph (c)(5): Sterilizing, irradiation, pasteurizing, freezing, refrigerating, controlling hydrogen-ion concentration (pH), controlling humidity, controlling water activity (a_w), or using any other effective means to remove, destroy, or prevent the growth of microorganisms and prevent decomposition;

11.70 WHAT REQUIREMENTS APPLY TO PACKAGING AND LABEL OPERATIONS?

No Recommended Changes for this section.

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111.74 WHAT REQUIREMENTS APPLY TO REJECTED COMPONENTS, DIETARY INGREDIENTS, AND DIETART SUPPLEMENTS, PACKAGING AND LABELS?

No Recommended Changes for this section.