Mead Johnson Nutritionals

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 96N-0417 (RIN 0910-AB88) Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

Mead Johnson & Company, a major manufacturer of infant formula and nutritional products, is submitting these comments with respect to the subject proposed rule published in the Federal Register on May 19, 2003 (21 CFR Parts 111 and 112). Mead Johnson supports FDA's proposed rule to establish the minimum current good manufacturing practices (CGMPs) necessary to ensure that, if we engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, we do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. The proposed rule will provide more specific guidance for the manufacture of dietary supplements. We have suggestions, however, which we believe are needed to clarify some sections or modify others that do not appear to be consistent with reasonable industry practice or the statute.

Sec. 111.3

Current Proposed Wording:
"Sanitize means to adequately treat equipment, containers, utensils, or any other dietary product contact surface by applying cumulative heat or chemicals on cleaned food contact surfaces that when evaluated for efficacy, yield a reduction of 5 logs, which is equal to 99.999 percent..."

Suggested Wording:
Sanitize means to adequately treat *dietary product contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.*

Comment:
It is incumbent on the manufacturer to provide assurance that its sanitization practices are adequate to destroy microorganisms of public health significance without adversely affecting the product or its safety for the consumer "Reduction of 5 logs" is overly prescriptive and could be offered as a guideline or as an example, but should not be included within the definition for

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"sanitize." Wording similar to the definition for "sanitize" as in 21 CFR 110.3(o) is recommended. The definition for "sanitize" in 21 CFR 110.3(o) is:

> "Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer."

Sec. 111.37

Current Proposed Wording:
" (7) Review all records for calibration of instruments, apparatus, gauges, and recording devices;
(8) Review all records for equipment calibrations, inspections, and checks;"

Suggested Wording:
(7) Review *(by either the quality control unit or by the unit responsible for calibration)* all records for calibration of instruments, apparatus, gauges, and recording devices;
(8) Review *(by either the quality control unit or by the unit responsible for calibration)* all records for equipment calibrations, inspections, and checks;

Comment:
Review of calibration records may occur outside the quality control unit, e.g., by a separate department dedicated to equipment maintenance and calibration. The quality control unit should approve calibration processes, but review of completed calibration records by the dedicated department is sufficient to assure compliance with the approved process.

Current Proposed Wording:
"(11) Collect representative samples of:
(i) Each shipment lot of components, dietary ingredients, dietary supplements, packaging, and labels received to determine whether the component, dietary ingredient, dietary supplement, packaging, or labels meet specifications;
(ii) Inprocess materials at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;
(iii) Each batch of dietary ingredient or dietary supplement manufactured to determine, before releasing for distribution, whether the dietary ingredient or dietary supplement meets its specifications for identity, purity, quality, strength, and composition; and
(iv) Each batch of packaged and labeled dietary ingredients or dietary supplements to determine that you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record.
(12) Keep the reserve samples for 3 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."

Suggested Wording:
(11) Collect representative samples of:
(i) Each shipment lot of components, dietary ingredients, dietary supplements, packaging, and labels received to determine whether the component, dietary ingredient, dietary supplement, packaging, or labels meet specifications;

(ii) Inprocess materials at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;

(iii) Each batch of dietary ingredient or dietary supplement manufactured to determine, before releasing for distribution, whether the dietary ingredient or dietary supplement meets its specifications for identity, purity, quality, strength, and composition; and

(iv) Each batch of packaged and labeled dietary ingredients or dietary supplements to determine that you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record.

(12) Keep ~~the~~ *final packaged and labeled* reserve samples for 3 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.

Comment:
It is unclear if collection of representative samples as described in (11)(i), (ii), (iii), and (iv) equates to retention of reserve samples described in (12). The collection of representative samples of components and dietary ingredients should not equate to reserve samples since it may not be possible to comply with this requirement. For example, certain raw materials in their natural states may be subject to degradation; but when processed into a finished product form, are stable. Additionally, reserve samples of each shipment lot of components, dietary ingredients, packaging and labels would require an increase in the size of reserve sample storage facilities for most manufacturers, and would impose unreasonable costs in relation to any benefits that would be realized. Finished product reserve samples will be collected in the same packaging as is provided to consumers, thereby providing reserve samples of labeling, containers, and closures.

Sec. 111.70

Current Proposed Wording:
"(g) (1) The identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use;"

Suggested Wording:
(g)(1) The identity and quantity of the packaging and labels used and *either* reconciliation of any discrepancies between issuance and use *or use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for labeling during or after completion of finishing operations*;

Comment:
This section should include the "Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling..." as described in 211.122(g)(2) and 211.125(c).

Sec. 111.85

Current Proposed Wording:
"Section (b) You must not salvage returned dietary ingredients and dietary supplements, unless:"

Suggested Wording:
Returned dietary ingredients and dietary supplements may not be salvaged unless the following requirements are met:

Comment:
Clarification of proposed wording is suggested.

We hereby submit these comments and believe they will help in the overall objective of enabling both the Dietary Supplement industry and FDA to assure consumers that these products are safe and effective.

Respectfully yours,

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