Standard Process

Whole Food Supplements

1524 '03 AUG 11 P4:16

August 11, 2003

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

RE: Docket No. 96N-0417; Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements; Proposed Rules

To whom it may concern:

Please find enclosed the comments of Standard Process, Inc., Palmyra, Wisconsin. Standard Process has manufactured dietary supplements for over seventy years and the company supports these important proposed rules. Please consider these comments.

Sincerely yours,

Ann M. Holden

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Vice President – Quality Control

96N-0417 C180

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August 6, 2003

COMMENTS TO FDA ON GMPs FOR DIETARY SUPPLEMENTS

GENERAL COMMENTS

1) The statute requires that GMPs for dietary supplements be modeled on food GMPs, but it seems that the FDA has modeled them on the drug GMPs. Ingredients that are GRAS should not be treated in any stricter manner than the food regulations require.

2) Standard Process Inc. purchases domestic raw tissues that have been inspected by the USDA. It is unfair to impose additional regulations simply because these tissues are included in dietary supplements. They pose no more of a health risk than meat purchased through stores or restaurants. The same controls for meat related products in the food industry are all that should be required for the dietary supplement industry. With regards to meat derived powders, the USDA/FDA controls the borders and shuts down imports from any country that has outbreaks of BSE. Given that there are no BSE tests available to small companies at this time, it is unfair require tests that cannot be done. Documentation, auditing, and relying on the USDA/FDA are the only possible methods that are feasible to control the spread of BSE.

3) Standard Process would like to address the microbial limits statement made in this document. Our testing is not performed using aerobic plate counts. We, instead, perform the MPN method. This method provides better sensitivity for determining total coliform and E. coli levels in dietary ingredients/supplements. Limits should be decided for both aerobic plate counting and the MPN method.

GMP COMMENTS

111.10) Clarification is needed regarding distributors. It doesn't seem feasible that someone that holds and sells packaged products would be included in the GMPs under this section.

111.3 (4) The term "sanitize" as defined in the document requires clarification. The requirement of 5 logs of reduction in contamination assumes that such contamination exists on "nearly clean" equipment. Using USDA/FDA acceptable cleaning and sanitizing chemicals should be acceptable.

111.20 (3) Further clarification is needed as to the degree of separation that is intended in this section. Is the intent **not** to manufacture multiple products in a single room or area? If this is the case, this would be a drug GMP and seems to be too extreme. Standard Process feels that if the proper controls are in place, manufacturing and packaging of multiple products is possible in a single room or area without compromising product identity, quality, strength, purity, and composition.

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111.25 (7)(b)(1) The wording in this section should be changed to "calibration should be done, where standards are available or where it is necessary to meet product specifications."

111.35 (g) and (h) The requirement for performing analytically valid test methods on all dietary ingredients or dietary supplements will not be possible to comply with; that is to say that not all dietary ingredients or dietary supplements have valid test methods available. In addition, this requirement makes meaningful supplier Certificates of Analysis obsolete. If meaningful Certificates of Analysis are no longer recognized and dietary supplement manufactures' are required to perform testing related to the 5 requirements on all dietary ingredients/supplements *and* those test results are contrary to the manufacturer's test results, which is to be believed?

111.35 (4) (ii, iii) Reprocessing of dietary ingredients/supplements to remove microbial contamination should be allowed as long as extraordinary means are not taken beyond your normal manufacturing processes. If you have the capability to perform product sterilization within your normal manufacturing practice, testing for microbial pathogens occurs after the sterilization step and there is no final product quality, purity, safety, identity or composition risk, reprocessing to remove microbial pathogens should be allowed.

111 35 (n) Investigation and material review for out of specification product scenarios should only be required at critical control points in the manufacturing process for microbial contamination, providing sterilization normally occurs within the manufacturing process. If the variance involves a foreign object, a sub-potent or super-potent ingredient, or the like, then an investigation and material review should be necessary.

111.37 (6-8) An appropriately trained manufacturing supervisor or lead person should be allowed to conduct the review of records pertaining to equipment calibration and packaging and labeling. This does not need to be a Quality Control representative. A Quality Control representative should be involved only if a discrepancy is found.

111 50 (1, ii) (3-12) Clarification is needed as to whether all of the listed batch record requirements must exist together as a record or can they be accessible through various records within the production facility?

111.50 (f) See comments to sections 111.35 (g) (h) and sections 111.35 (4) (ii,iii)

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