DIVERSTECH® CO.

Barry Sugarman, B.S. ENGR.
President

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Re: Docket Number & Title: 1996N-0417 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients

Dear Sir or Ma'am,

I am submitting these comments on behalf of my consulting firm and on behalf of one of my clients, a small 350 person dietary supplement manufacturing firm.

111.3:
The definition of "Sanitize" is too specific and may require the use of disinfectants, which may not be necessary in all cases. In many cases, soap and hot water is enough. I suggest something like, "adequate to prevent microbial adulteration of the product." Separately, there should be a definition of a "Scientifically Valid Method" versus a "Validated Method".

111.35(d):
This section creates a problem for excipients that have been regularly used in pharmaceuticals for many years. For instance croscarmellose sodium, a disintegrant, may not be GRAS for foods, an approved food additive, or a dietary ingredient, but it has been used safely and successfully for many years in dietary supplements. Dietary supplements should be permitted to use any ingredient that has been shown to be in use prior to the date of implementation of the regulation, any recognized excipient ingredient or excipient ingredient monographed in a recognized compendium, and any ingredient permitted in any food or pharmaceutical product.

111.35(f):
This section about monitoring the in-process control points to detect any unanticipated condition is a HACCP clause, which is unnecessary for dietary supplements whose processes of production do not generally involve bacterial contamination such as with meats and juices.

111.35(g)(1):
This section requires analytical testing of all finished batches which is not necessary if the ingredients used in the batch have been tested by the ingredient supplier or the ingredient manufacturer. I believe that it should be

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clarified to state that an assay calculated "by input" which includes a review of the batch record and the yield, and a review of the certificate of analysis of the ingredients will be adequate finished product testing.

111.35(g)(2):

Testing should be optional if desired whether or not there is a scientifically valid method to test the finished goods. Testing under this section should clarify that a review of a manufacturer's certificate of analysis is enough. Retesting is an unnecessary expense.

111.35(h):

If a supplier or manufacturer of ingredients or finished goods uses a scientifically valid method, a review of their method and results is adequate protection of the public.

111.35(i)(4)(iii) & 111.50(f):

Materials that are contaminated with microbial flora can be autoclaved or gassed with Ethylene Oxide or other gases. Materials that are high in heavy metals can be diluted with non-heavy metal containing materials or reprocessed other ways. There is no reason to ban these widely accepted practices.

111.35(k):

A certificate of analysis from a supplier should be acceptable for any dietary ingredient or component versus unnecessary retesting.

111.60(d):

Methods from any published compendium should not require validation. Scientifically valid methods rather than fully validated should be required. The concept of methods validation is a drug industry GMP, and is unnecessarily rigorous for dietary supplements. The cost to formally validate is unnecessary and burdensome.

111.65(c)(5):

Many times, just sanitary practices are all that is needed to prevent microbial contamination or decomposition. These special processes are not always necessary and that should be clarified as optional.

111.65(c)(8)(iii):

Time controls should be optional. They are not always necessary.

111.125:

21 CFR 11 should apply only to records that do not have paper counterparts per the new FDA view on this matter.

Thank you very much for your consideration of these comments.

Sincerely,

Barry Sugarman, B.S.ENGR.
President, Former CEO Liquipharm Inc. Pharmaceutical Manufacturer, 25 Years Experience in the Pharmaceutical and Dietary, Supplement Industry