BIOIBERICA

Palafolls, July 31st, 2003

Dockets Management Branch (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 Fishers Lane, room 1061
Rockville, MD-20852
USA

Bioibérica, s.a. R.M. Barcelona, Hoja B-99773 - C.I.F. A-08-384190

Sirs:

Please find attached the comments prepared inside our company to the Docket No 96N-0417, concerning the "Good Manufacturing Practice in Manufacturing, Packing or Holding Dietary Ingredients and Dietary Supplements".
Should any additional information be required, please contact me.

Best regards,

Jordi Ruiz-Combalia
Quality Control Director
Phone +34 937 642 710
Fax +34 937 650 102
e-mail: jruiz@bioiberica.com

96N-0417

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Publication

Federal Register, March 13, 2003, concerning 21 CFR Parts 111 and 112 [Docket No.96N-0417].

Comments to proposed rules

111.5 (pages 12179-12181)

You ask comments on whether there are animal-derived materials from BSE countries that do not present a safety concern and, if so, whether FDA should consider exempting such materials from a possible requirement that would prevent the use of animal-derived materials from BSE countries in dietary supplements and why.

When referring to BSE or TSE, we will feel more comfortable if the terms "ruminant" or "ruminant-derived" are used instead of "animals". This word can impose undue constrains and extra costs, having into account that BSE is not common in all animals.

111.35 (d) states that any substance used as dietary ingredient must be a dietary ingredient, a dietary supplement or a GRAS material. This excludes many substances that, as such, are not dietary ingredients, but gave dietary ingredients after process. Ginkgo biloba leaves or Saw palmetto are neither dietary ingredients nor GRAS materials, but after processing, the Ginkgo biloba or the Saw palmetto extracts are common dietary ingredients found in many dietary supplements. The same holds true for cartilage, used as raw materials for the preparation of Chondroitin sulfate sodium, considered a Nutritional ingredient by USP that has included a monograph in USP26-NF21. Cartilage isn't considered a food, a dietary ingredient or dietary supplement, and is not included in the GRAS list.

We propose to consider natural products (from animal, mineral or vegetable origin) to be included in the rules as potential raw materials for nutritional ingredients or nutritional supplements.

111.35 (i) 4 (page 12199) includes the prohibition of reprocessing components, dietary supplements or dietary ingredients if contaminated by microorganisms or other contaminants, such as heavy metals. In many cases, reprocessing (repeating one or more process steps) will render the product acceptable. If the product

Oficina Comercial: Plaza Francesc Macià, 7, 8º-B. 08029 Barcelona - España. Tel. (34) 93 490 49 08. Fax (34) 93 490 97 11
Complejo Industrial Bioibérica: Ctra. Nacional II, Km. 680,6. 08389 Palafolls. Barcelona - España. Tel. (34) 93 765 03 90. Fax (34) 93 765 01 02
http://www.bioiberica.com

is obtained by extraction and concentration, repeating the heating process for a short period will render microbiologically contaminated product acceptable, without impairing the product quality, as demonstrated by the final microbiological and chemical testing, giving a product meeting all of its specifications. If heavy metals contamination by ferromagnetic particles is detected in a nutritional ingredient or nutritional supplement, passing the powdered product throughout a magnetic trapping device, even if usually not employed (rework), will render the product acceptable. The deviation review and the corrective action implemented should prove that additional measures could be taken to prevent from such contamination happen in the future. After any rework or reprocess, the product must be fully tested and found inside the required values included in the product's specifications.

111.50 (f) again prohibits reprocesses for contaminated products. We are against that extreme, by the reasons displayed in the previous paragraph, and because this will make the judgment of the quality unit limited. Reprocess or rework must be accepted if based on scientific arguments, and if data justify that the reprocess don't impairs the quality attributes of the final product when released. Such release must be provided in writing by the quality unit, based on full compliance of the product's specifications.

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