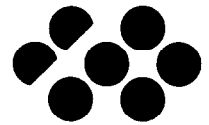


BioKyowa, Inc.

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BIOKYOWA

August 1, 2003

US Food and Drug Administration
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Md. 20852

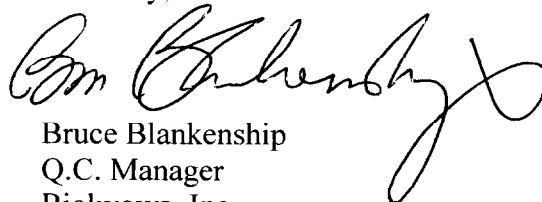
Re: 21 CFR Parts 111 and 112
Docket No. 96N-0417
Current Good Manufacturing Practice in Manufacturing Packing, or Holding
Dietary Ingredients and Dietary Supplements; Proposed Rule
(68 FR 12158, March 13, 2003)

Dear Sir or Madam:

Enclosed please find Biokyowa, Inc.'s comments on the above proposed rule. Our comments are submitted in response to 68 CFR 12158.

Should you have any questions or comments in regards to our submittal please contact our office at 573-335-4849, ext. 121.

Sincerely,



Bruce Blankenship
Q.C. Manager
Biokyowa, Inc.

96N-0417

C175

COMMENTS TO PROPOSED cGMPs FOR DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

As submitted by Biokyowa, Inc.

August 1, 2003

Subpart A

- 111.1 We generally agree with BOTH *ingredients* as well as *supplements* being subject to these regulations.
- 111.2 We also agree that the establishment of cGMPs is a positive step in helping the integrity of this industry.
- 111.3 Definitions
Generally agree with most of the definitions.
- 111.5 Agree with this section
- 111.6 Agree with this section

Subpart B

- 111.10 Agree with the precautions in this section.
- 111.12 (b) Feel that "Training and experience" should be changed to "Training and/or experience".
- Rationale: Ideally a person should have been trained and have experience. However, realistically speaking we cannot always find employees who have both.
- 111.13 (b) same comments as 111.12 (b)

Subpart C

- 111.15 (d) (2) This states that the water that contacts components must comply with National Primary Drinking Water Regulations. This section should be deleted.
- Rationale: This section is not needed because water quality has been addressed in 111.15 (d) (1).
- 111.15 (d) (3) This section states that you must have documentation to meet the requirements of paragraph (d) (2) of this section. Delete this section.
- Rationale: Since 111.15 (d) (2) Needs to be deleted, this section not needed.
- 111.15 (j) As with previous sections that require "Training and Experience", we feel that that this should be changed to "Training and/or experience".
- Rationale: Same as previous sections concerning Training/Experience.
- 111.20 (d) (5) Change this section to read "Must be able to control temperature and humidity where necessary to maintain the integrity of the product."
- Rationale: Not all products require temperature OR humidity control. Some products may vary on their requirements for temperature and humidity control during the different stages of their production also.

- Subpart D 111.25 (b) (2) Need to change the wording from “You must calibrate before first use” to “ You must calibrate, or be able to verify that the calibration has been completed, before first use”

Rationale: Many of our calibrations are performed at the manufacturer before delivery is made to the plantsite. Performance test results could be made available for this verification.

- 111.30 (b) (5) Should delete this requirement.

Rationale: This is not always possible. In the case of evaporators it is common for only the manufacturer to be able to have access to the programming of their equipment.

- Subpart E 111.35 (d) Delete this section.

Rationale: Not part of cGMP

- 111.35 (i) (4) (iii) This section should be changed to read “.....unless the reprocessing is capable of and proven to remove the contaminants.

Rationale: Many products, such as amino acids, are able to remove the listed contaminants in their process. To put such a restriction on those manufacturers would cause unnecessary waste.

- 111.37 (a) Need to change last sentence in this paragraph to read “ ...supplements meet specifications as established.”

Rationale: All of the five terms identity, purity, quality, strength, and composition are not needed for all products. In fact, to require all products to have these five would be redundant for many products.

- 111.65 (c) (3) Need to reword this section to agree with section 111.15 (d) (1)

Rationale: Water quality addressed in the section as listed.

Agree with the remaining sections

- 111.40
- 111.45
- 111.50
- 111.60
- 111.74
- 111.80
- 111.82
- 111.83
- 111.85
- 111.90
- 111.95
- 111.125