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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Rm 1-23
Rockville, MD 20857

Docket No. 96N-0417, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements

Mead Johnson & Company, a manufacturer of dietary supplements, is submitting these comments with regard to the subject advanced notice of proposed rulemaking (ANPR) published in the Federal Register on Thursday, February 6, 1997 (62 FR 5700).

Mead Johnson has been manufacturing dietary supplements for many years. Although the industry draft CGMP in the ANPR is reasonably close to our own manufacturing practice, we are not convinced that there is a need for specific CGMP regulations for dietary supplements. We believe that current 21 CFR part 110 provides an adequate basis for the manufacture of these products.

Since, however, FDA raised some specific questions in the ANPR, we are providing responses to these nine questions on pages 5707 and 5708. Please note that we have paraphrased these questions to make our response easier to read.

1. FDA Issue: Is there a need to develop specific defect action levels (DALs) for dietary ingredients?

   MJ Response: We have no comments on this issue.

2. FDA Issue: What constitutes adequate testing to identify dietary ingredients, particularly plant materials, used in dietary supplements?

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MJ Response: If no identification test currently exists for dietary ingredients, we recommend using a combination of auditing the ingredient vendor and requiring a Certificate of Analysis with each vendor lot received.

3. FDA Issue: Would a vendor certificate provide adequate assurance that dietary ingredients are not contaminated or are specific testing requirements needed?

MJ Response: We suggest that provisions be made to allow either a vendor certificate or specific testing as required by the manufacturer.

4. FDA Issue: Is there a need for CGMP to include requirements to assure that CGMPs are being followed?

MJ Response: We believe this issue is adequately addressed in the proposed rule. No other comments are necessary.

5. FDA Issue: Should the CGMP include a requirement that all reports of injuries or illnesses be evaluated by competent medical authorities to determine whether follow up action is necessary?

MJ Response: A medical evaluation of all reported adverse events could be overly burdensome. We suggest that this be limited to serious adverse events or perhaps adopting procedures similar to infant formula records and reports in 21 CFR 106.100(k). Additionally, it might be useful to require a periodic (annual) trend analysis of all reported adverse events.

6. FDA Issue: Should the CGMP include a requirement that the manufacturer establish procedures to assess safety concerns with dietary ingredients?

MJ Response: As with the development of any food product, the manufacturer has the responsibility of selecting safe and suitable ingredients. There is no need to include a specific requirement for making this determination for dietary ingredients currently being used. If a particular dietary ingredient meets the statutory definition of a "new dietary ingredient," a safety evaluation and submission of information is required by statute 75 days before the dietary supplement is marketed.

7. FDA Issue: Are specific controls necessary for computer controlled or assisted operations?

MJ Response: We suggest that the procedures proposed in the infant formula CGMP rule be considered for adaptation to dietary supplements. This was published in the Federal Register on Tuesday, July 9, 1996 (61 FR 36154) as proposed 21 CFR 106.35.

8. FDA Issue: Would a HACCP approach for manufacturing and handling dietary ingredients and dietary supplements be preferred over the industry submission?

   MJ Response: We suggest that a HACCP approach to dietary supplement controls be permitted as an alternate to the proposed rule but not required.

9. FDA Issue: Will broad CGMP regulations for the dietary supplement industry be adequate or should more specific regulations be developed for particular segments of the industry?

   MJ Response: We do not see a need for more specific regulations at this time.

In addition to the responses above, we have one comment on the industry draft. Under "Warehousing, Distribution and Post-Distribution Procedures," paragraph (f), we suggest replacing "and" with "or" immediately before subparagraph (2). Laboratory testing is not always necessary to evaluate product acceptability if it has been involved in an accident or an equipment failure. Depending upon the circumstances, a physical inspection may be all that is needed. The above modification would allow this flexibility.

We appreciate this opportunity to provide comments and suggestions on the above ANPR for dietary supplements.

Sincerely,

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