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June 4, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr.
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Dockets Management Branch (HFA-305):

Enclosed are comments on specific questions concerning proposed Current Good Manufacturing Practices for Dietary Supplements on pages 5707 and 5708 of Docket No. 96N-0417 of the Federal Register / Vol. 62, No. 25 / Thursday, February 6, 1997 / proposed Rules.

The comments are respectfully submitted by Triarco Industries, a supplier of bulk ingredients and semi-finished products to the dietary supplement industry. Triarco can be reached for comment at the above address or phone number.

Triarco appreciates this opportunity to contribute to the development of these regulations, and subsequently, the development of our industry.

Regards,

Mark L. Anderson, Ph.D.
Director of Research & Development

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96N-0417

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COMMENTS ON DIETARY SUPPLEMENT CGMP FROM TRIARCO INDUSTRIES: 06/04/97

The following are comments regarding specific questions proposed on pages 5707 and 5708 in Docket No. 96N-0417 of the Federal Register / Vol. 62, No. 25 / Thursday, February 6, 1997 / proposed Rules. The comments are from Triarco Industries, a supplier of bulk ingredients and semi-finished products to the dietary supplement industry.

1. Section III. Economic Issues. Request for comments on whether there should be new CGMP regulations, whether the regulations should be mandatory or voluntary.

   Triarco believes that there should be mandatory regulations for every manufacturer or supplier to the dietary supplement industry. Instead of specific CGMPs however, the economic concerns of the industry may be more effectively addressed by regulations based on the principles of Hazard Analysis and Critical Control Points (HACCP). This would enable manufacturers to develop and implement processes and controls tailored to their specific products and manufacturing operations. These regulations would be similar to those which the FDA has issued to ensure the safety of other foods (i.e., seafood).

2. Section IV. Summary and Request for Comments. Issue 1. Is there a need to develop specific defect action levels (DAL's) for dietary ingredients?

   Triarco agrees with the FDA, in that it would be inappropriate to apply the current DAL's to dietary supplements. A microscopic or macroscopic examination of a representative sample for foreign matter may be considered as a guideline for developing DAL's for dietary supplements.

3. Section IV. Summary and Request for Comments. Issue 2. Comments on appropriate testing requirements to provide positive identification of dietary ingredients.

   Since these ingredients encompass a wide variety of materials, general testing such as organoleptic and microscopic examination may be appropriate for some while more technical and specific testing using analytical and chemical techniques may be appropriate for others. For domestically produced materials such as herbs, certification by the grower and chain of evidence to the user may be adequate for identification. In every case however, the supplier or user of the ingredient should be charged with providing the appropriate documentation or performing the appropriate identity testing in accordance with documented procedures.

4. Section IV. Summary and Request for Comments. Issue 3. Comments on standards that should be met in certifying that a dietary ingredient or dietary supplement is not contaminated with filth; that it is free of harmful contaminants, pesticide residues or other impurities; that it is micropbiologically safe; and meets specified quality and identity standards.

   Certification by a supplier should provide adequate assurance that a dietary ingredient is what it purports to be and is not adulterated. Certification should require however, a minimum amount of testing. These tests may include, but may not be limited to the following; A microbiology screen for at least Salmonella and E. coli, Total ash, Foreign matter, A heavy metals screen, Acceptable levels of pesticide residue, Acceptable identity testing.

5. Section IV. Summary and Request for Comments. Issue 4. Comments on whether there is a need for CGMP to include requirements for manufacturers to establish procedures to document that the procedures prescribed for the manufacture of a dietary supplement are followed on a continuing or day-to-day basis.

   Documentation of procedures for any manufacturing process is critical for batch reproducibility, quality assurance and proof of regulatory compliance. If some manufacturers do not already have documentation procedures, it should be strongly suggested that they do so as soon as possible.

6. Section IV. Summary and Request for Comments. Issue 5. Comments on whether dietary supplement CGMP should require that reports of injuries or illnesses to a firm be evaluated by competent medical authorities to determine whether follow-up action is necessary to protect the public health.

   Reports of all injuries, illnesses or even complaints concerning quality or performance of a product should be retained by a firm in a "customer complaint file" for historical reference. Serious injuries or illnesses requiring a physicians care should be investigated by competent medical authorities to determine whether follow-up action is necessary to protect the public health.

7. Section IV. Summary and Request for Comments. Issue 6. Comments on whether CGMP for dietary supplements should require that manufacturers establish procedures to identify, evaluate and respond to potential safety concerns with dietary ingredients.

   Potential safety concerns should be identified, evaluated and responded to by an unbiased third party rather than the manufacturers of a product in question. This may be a group of medical or safety professionals trained to evaluate public safety concerns and issue proper notification if warranted.

8. Section IV. Summary and Request for Comments. Issue 7. Comments on whether specific controls are necessary for computer controlled or assisted operations.

   It would be strongly suggested that any computer controlled or assisted operation be validated by a trained computer professional.

9. Section IV. Summary and Request for Comments. Issue 8. This issue was addressed in response number 1 under Section III. Economic Issues.

10. Section IV. Summary and Request for Comments. Issue 9. Comments on whether broad CGMP regulations will be adequate, or whether it will be necessary to address the operations of particular segments of the dietary supplement industry.

    Broad CGMP regulations should be adequate to regulate safety and cleanliness for most of the dietary supplement industry. More stringent regulations however, should be considered for any segment of the industry which produces pure compounds with a therapeutic claim (i.e. Melatonin and DHEA). These products resemble pharmaceuticals and should possibly require safety testing in animals and humans as well as pharmaceutical CGMP regulations for manufacturing.