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Dockets Management Branch (HFA-305)
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

RE: Docket No. 96N-0417

The Texas Department of Health (TDH), Bureau of Food and Drug Safety, wishes to make the following comments regarding the recent Advance Notice of Proposed Rulemaking on the development of Good Manufacturing Practice Regulations (GMPs) for dietary supplements.

In responding to the U.S. Food and Drug Administration (FDA) request to answer the nine questions following the industry-proposed GMPs, TDH will answer the questions in a different sequence than was printed in the *Federal Register* in order to emphasize our position with respect to the importance of Hazard Analysis Critical Control Point (HACCP). We will, however, follow the same numbering of the questions as posed in the *Register*.

Question 8: Good Manufactured Practices (GMPs) or HACCP. TDH strongly recommends the regulation of the supplement industry through the use of HACCP, rather than through the development of a separate set of GMPs for the industry. GMPs have a role in the regulation of foods in general, including supplements, but are usually limited in scope to good sanitation principles, employee hygiene, potable water source, and similar issues. The development of another "command and control" regulation would seem to fly in the face of the development of new technology and the importance of regulating foods through a performance based system.

Additionally, GMPs developed for dietary supplements would require a combination of Food GMPs and GMPs based upon certain active ingredients. Such GMPs would be difficult to develop and confusing to industry.

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Question 9: TDH believes that reliance on HACCP, rather than on new GMPs, will adequately address the issue of safety for each of the segments of the supplement industry. Where product adulteration is concerned, rather than safety only, FDA's current regulatory scheme should suffice, including application of appropriate sections of the current food GMPs to supplements.

Question 1: Establishment of Defect Action Levels. TDH agrees there is a need for establishment of specific Defect Action Levels (DALs) for certain categories of supplements, and urges FDA to work with the industry in development of DALs where appropriate. This is particularly important in the area of herbs. Our own experience in regulating herbs as foods indicates a myriad of problems with both domestic and imported herbs (unprocessed) sold directly to the public. This includes poisonous and deleterious substances (unsafe ingredients) as well as adulteration with all manner of filth, including rodent and other animal hair, feces, insects and insect fragments, twigs, and other filth. We have also documented the presence of harmful bacteria, heavy metals, and pesticide residues. Although the last three issues should be addressed in HACCP plans, it may be important to establish DALs for bacterial contamination as well.

Question 2: Identification of Ingredients. TDH suggests that the identification of ingredients should be a function of both government and industry. Supplement ingredients for which there is no reliable testing protocol should not be permitted to be sold if there is a question of safety at any level of concentration. On the other hand, the documentation of the purity of an ingredient, where there is no safety issue, should be the responsibility of industry. It should be incumbent upon industry to develop valid test methodologies to ensure products are truthfully labeled (strength, purity, and accurate nomenclature/identification). This, however, should be secondary to any safety issues.

Question 3: Certification of Ingredients by the Supplier. Again, there are two issues involved in any certification process: safety and proper identification. Despite language in the Dietary Supplement Health and Education Act of 1994 (DSHEA) regarding industry's role in determining the safety of a supplement, TDH continues to believe that any company which "accepts the responsibility for the purity and proper labeling of a (food)...." must also take responsibility to ensure that the product is safe. It should not be incumbent upon government to establish the safety, or lack thereof, for supplements.

Industry should provide FDA with all available relevant information regarding the potential for microbiological contamination of any particular ingredient marketed as a supplement. In this way FDA can establish a database for use in making risk-based decisions with respect to which ingredients pose the greatest threats, or potential risk, to public health, and regulate accordingly. With limited resources, FDA must be permitted these management decisions which, in the end, will benefit both industry and the consumer (taxpayer).

Imported ingredients should be regulated similar to how FDA currently regulates imported raw fruits and vegetables for illegal pesticide residues and filth, concentrating resources on those ingredients imported from producers (and importers) whose track record indicates that a problem may exist.

As least initially, industry must take responsibility for verifying that the certification from a particular source is accurate in terms of safety and purity (adulteration). We should point out that the first step in any HACCP plan includes verification of the safety of the ingredients received.

We would also point out that ingredients priced too low should be a red flag to industry that the product they are purchasing is either not pure or is not properly identified. Reliance on a "certification" from any source - domestic or imported - should not leave industry with a defense against responsibility for an adulterated or misbranded supplement. The industry should be required to verify the authenticity of enough certifications to have reason to believe current and future shipments are accurately described.

Question 4: Mandating Record-Keeping Requirements for GMPs. As previously stated, TDH supports the regulation of the dietary supplement industry through the use of HACCP. By layering HACCP on top of certain food GMPs which are applicable to supplements, as FDA has done with the mandatory Seafood HACCP Regulations (or permitting the incorporation of SSOPs into the HACCP plan), FDA will have ensured that adequate records are available to ensure adherence to the regulations. Any other "new" GMPs which may be necessary to ensure purity of ingredients, for example, can be added as needed or specifically incorporated into any required HACCP plan.

Question 5: Regulation of Pharmacologically Active Ingredients. TDH strongly believes that producers and marketers of supplements which have pharmacologically active ingredients should be required to keep records and report injuries and adverse reactions to FDA, as well as to the states. Our experience in dealing with the issue of safety of products containing ephedrine is a prime example of the need for recordkeeping and reporting. In the most notable case, TDH had to obtain industry records through discovery, which in effect almost doubled the number of adverse events of which we had previously been aware.

Further, there are so many "new" supplements (ingredients) being marketed with no documented history of safe use in the U.S., that we believe the manufacturers and distributors of all dietary supplements should be required to report injuries and adverse events. This would naturally include allergic reactions as well.

TDH would prefer that this be an integral part of a HACCP plan for the processing and marketing of any ingredient where adverse events are likely to be reported. In this way the reporting of adverse events can be separated from the reporting of routine complaints, a concept regarding which the food industry is adamantly opposed.

Question 6: Determination of Safety. TDH believes that the determination of whether or not a particular ingredient is safe, in and of itself or at a given concentration, should be a collaborative effort between industry and government. If FDA or the states have questions or concerns regarding the safety or an ingredient, these concerns should be answered **before** the marketing of the ingredient or use in a supplement. Otherwise, if the concerns for safety are related to the potency (strength or concentration) of the ingredient, these concerns should be dealt with by either the HACCP plan or by separate regulation.

Question 7: Regulation of Computer Control and Assisted Operations. TDH believes that FDA should regulate computer controlled and assisted operations in much the same way as equipment is, or is soon to be, regulated for the pharmaceutical industry, but only where the safety of the product is directly related to the concentration or purity of the product. Otherwise, it should be incumbent upon the manufacturer to ensure the product is properly labeled with respect to these same issues from the standpoint of misbranding.

In conclusion, TDH believes that additional regulations to protect the public from unsafe dietary supplements are needed, and to that end we fully support the use of HACCP. Only in instances where safety is in question, or where current food GMPs cannot address non-safety-related issues, should additional regulations be proposed (in addition to HACCP). We wish to again thank FDA for the opportunity to comment.

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