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Executive Deputy Commissioner

July 8, 2004

Division of Dockets Management
5630 Fishers Ln, Rm. 1061
Rockville, MD 20852

RE: Docket No. 2003N-0324
RIN 0910-AC35

Dear Sir or Madam:

Our comments are limited to amendments of Title 21 Code of Federal Regulations, Part 201 that will require the use of a statement on all over-the-counter drug product labels, directing consumers to contact FDA to report side effects. We are in support of the requirement for the use of this statement. Additionally, since the purpose of the law is to enhance the safety and efficacy of drug products marketed for pediatric patients, we are suggesting that FDA extend this regulation to include dietary supplements; which represent a regulatory niche encompassing aspects of both drugs and foods. This addition will enhance the protection of special populations, which include children.

The Dietary Supplement Health and Education Act (DSHEA) did not include a requirement for dietary supplement manufacturers to report adverse health effects to the Food and Drug Administration (FDA). The recently proposed dietary supplement regulations concerning Current Good Manufacturing Practices (CGMPs) (68 FR 12158 Mar. 13, 2003) do not have a mechanism for consumers to report product-related adverse events directly to the FDA. Since many dietary supplements have a pharmacologic component, the requirement to use the toll-free MedWatch number, 1-800-FDA-1088, may improve the FDA's post marketing surveillance to assess the safety and efficacy of dietary supplements. Special populations are even more vulnerable to potential hazards and should have a readily available means to report problems; one in which the information is sent directly to FDA without having to wait for the manufacturer to investigate when they deem appropriate. Recent history demonstrates that manufacturers may not be forthcoming about possible product hazards.

The FDA has stated that dietary supplements are unique, being both food and pharmacologically active substances. As stated in the comments preceding the March 3, 2003 CGMP proposed rules, the FDA believes that it not only has the legal authority, but it was also Congress' intent for them to make provisions relevant to dietary supplements that are not necessarily the same for foods; including provisions that might relate to the hazards of consuming a dietary supplement. The requirement to add the toll-free MedWatch number to product labeling can only enhance the collection of data related to those hazards.

July 8, 2004

Page 2

However, FDA established a roadblock to allowing consumers to report adverse events by defining a “consumer complaint” thusly: “. . . a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient. . .”. By excluding adverse event reporting as a method of identifying potential harmful and/or adulterated products, we believe that insufficient consideration is given to the dual nature of these products; specifically, the pharmacologic aspect of the dietary supplements is intentionally being set aside. Instead of the products being regulated as BOTH food and drugs with regard to adverse events, they are regulated as NEITHER a food nor a drug. Semantics should not stand in the way of adequate protection of consumers. The FDA has gone on record on numerous occasions in support of the MedWatch program as a valuable tool in identifying trends in product-related adverse events. In fact, FDA did not object when the Texas Department of Health proposed and implemented the MedWatch number as part of the labeling on ephedrine-containing dietary supplements sold in Texas in February 2000.

Since requiring the MedWatch number on dietary supplements is excluded from the March 3, 2003 proposed rules for dietary supplement CGMPs, we are requesting that this current set of proposed regulations relating to drug labeling be extended to include dietary supplements, since it relates to the pharmacologic aspect of those products.

Thank you for the opportunity to comment on these proposed regulations. If you have any questions or need further information, please contact Dan Sowards, Director, Manufactured Foods Division at (512) 719-0243 or Karen Tannert, R.Ph., Chief Pharmacist, Drugs and Medical Devices Division at (512) 719-0237.

Sincerely,

Richard B. Bays
Associate Commissioner
Consumer Health Protection