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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Docket No. 99N-1174

Dietary Supplements; Center for Food Safety and Applied Nutrition Strategy

The Texas Department of Health (TDH) welcomes the opportunity to provide input to assist the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) in developing a strategy for effective regulation of dietary supplements pursuant to the Dietary Supplement Health and Education Act (DSHEA). TDH and FDA share a long history of partnering in many areas related to food and drug safety.

TDH recognizes the challenges FDA faces in implementing the broad regulatory provisions contained in DSHEA. The 1999 CFSAN Program Priorities document is a studied attempt by FDA to establish structure and priority for the agency in developing a workable regulatory framework. FDA is expending considerable resources on strategic planning and TDH supports those efforts since major shifts in policy must be implemented carefully to minimize unintended consequences. FDA's demonstrated openness and inclusiveness in soliciting input from stakeholders, as well as careful establishment of priorities, are congratulated and encouraged.

TDH is well aware of the constraints placed on FDA in the current political and regulatory environment to interpret, enforce and finalize regulations related to DSHEA. However, it is imperative that FDA maintains a credible and effective program for regulatory enforcement, compliance, and consumer education during this evolving process to address unsafe or fraudulent products.

The following comments are grouped in response to the focus questions published in the June 18, 1999, Federal Register notice.

99N-1174

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Objectives for an Overall Dietary Supplement Strategy

Since enactment of DSHEA, the boundaries between drugs and dietary supplements have become less distinct. Dietary supplement products and labeling may now contain ingredients and/or claims that would have been considered drug ingredients and claims just a few years ago. Obvious examples include gamma butyrolactone (GBL), 1,4 butanediol (BD), and ephedra-containing street drug alternatives, but numerous dietary supplement products make claims that categorize them as drugs. Removal of drug claims may result in the product being considered a dietary supplement. FDA should place a high priority on developing an efficient procedure to regulate products that cross boundaries between regulatory schemes and for tracking and investigation of adverse events associated with these products. Adverse event monitoring systems should be integrated in a database that may be shared by both CFSAN and Center for Drug Evaluation and Research (CDER.)

Texas law often requires that TDH rely on FDA's determination whether a product is a dietary supplement, drug, cosmetic or food in order to take regulatory action. TDH turned to FDA for that determination as part of its regulatory action against GBL products marketed as dietary supplements. Initially, TDH worked closely with CFSAN in documenting injuries, collecting medical records to fulfill the burden of proof required by DSHEA, finding and documenting websites sales, investigating product sources and other investigations. CFSAN staff became quick experts on the products and the unique manner in which they were marketed. When the FDA declared GBL an unapproved new drug, the entire project was transferred to CDER staff, who then had to learn about the products. Concerning "boundary" products, FDA should place high priority on categorizing a product early so that efforts are not duplicated and/or lost.

As evidenced by TDH and FDA's regulatory actions concerning ephedra products and the recently released General Accounting Office (GAO) report, the imminent hazard or adulteration provisions of DSHEA necessitates timely and extensive investigation of adverse events. Follow up may include patient interviews, documentation of use, label directions, collection of samples and Medical records. TDH suggests that both CFSAN and CDER conduct similar and thorough investigations, particularly for new or poorly defined substances about which little is known, so that adverse events associated with "boundary" products are thoroughly documented.

FDA should begin the process of carefully delineating what constitutes significant scientific agreement, taking into consideration the recommendations of the Presidential Commission on Dietary Supplement Labeling and the FTC guidelines. Examples of unacceptable or inadequate criteria would also be helpful for industry, consumers, and regulators. The Food Advisory Committee or a special working group would be an appropriate resource to assist FDA in outlining acceptable criteria. In light of recent court rulings, FDA should finalize the definition of "significant scientific agreement" as a regulation.

TDH supports FDA's continued reliance on input from the Food Advisory Committee, which is well qualified to reach science-based conclusions and provide FDA with solid recommendations to posed questions or to evaluate the safety of dietary supplement products. Working groups consisting of experts from fields related to the special product and/or disease condition under consideration, are the most effective method to gain external opinions regarding unusual situations or products. Because it would divert and dilute resources needed to address other priorities, TDH does not recommend that a formal dietary supplement committee be convened at this time.

As recommended by the Presidential Commission, CDER should investigate a better method to deal with traditional medicine and botanical products that are used for purposes other than to supplement the diet, but that cannot meet OTC drug requirements. The study should include what types of disclaimers are necessary and how or if the system can fit within the U.S. regulatory framework. The study should include the scope of products, the means of assuring safety and preventing deception, appropriate OTC uses of products, and types and appropriateness of disclaimer statements.

CDER should consider convening a dedicated panel on botanicals to review appropriate OTC claims. The Commission believed this would not require new legislation or regulation and would be appropriate for products that are generally recognized as safe and effective based on adequate current scientific evidence comparable to the evidence used to approve other OTC drugs. TDH agrees with the Commission on this point. In fact, if unison is not possible between the two centers, consideration should be given to a new center within the FDA. The dietary supplement industry is large enough to support a new Center of Dietary Supplements. Because it is a new regulatory entity, and one already legislated to be regulated differently than drugs or foods, it would have to be a funded mandate, providing FDA with the funding to procure the resources to support the new center.

Priorities

TDH agrees that consumer safety and truthful, non-misleading labeling should be FDA's top priorities for dietary supplements. Considering the current number of manufacturers making unsubstantiated disease claims and the lack of manufacturing standards, achieving these priorities would go a long way toward ensuring consumer access to safe dietary supplements that are truthfully labeled. Truthful labeling can only be achieved when good manufacturing practices are followed and FDA should place a high priority on finalizing GMP regulations that ensure that products meet the identity, quantity and quality they are purporting to contain on the label.

TDH believes that well-positioned and high profile regulatory actions, possibly in cooperation with FTC, are taken against products that make obvious disease claims for serious diseases such as cancer, AIDS, and arthritis.

How to Implement Tasks

TDH does not recommend that FDA rely on guidance documents to establish standards for safety, GMPs, product quality, structure/function claims, significant scientific agreement, or labeling of dietary supplement products. Guidance documents are unenforceable, and the uneven playing field resulting from uncooperative players promotes a further noncompliance. Finalizing effective regulations that promote the intended result is a challenging and resource intensive process, but it is necessary.

There are issues that may be more appropriately addressed using guidance documents. Examples include guidance on what FDA expects to find in quality clinical or epidemiological studies and analyses or explanations of the boundaries between dietary supplements, foods and drugs. Guidelines may also be appropriate to “flesh out” FDA’s interpretation of future regulations such as GMPs and structure/function claims.

Issues that FDA should address quickly

The ephedra regulations should be finalized, taking into consideration the GAO report published on August 4, 1999. The serious public health risks associated with these products have not changed since the FDA regulations were proposed in June 1997 and top priority should be placed on finalizing regulations to address the risks.

Herbal street drug alternatives have proliferated in retail stores and on Internet websites. Products containing herbs such as *Salvia divinorum* claim to contain powerful hallucinogens. Quick and decisive regulatory action is required to show that the marketing of unapproved drugs will not be tolerated. GBL and BD products with untruthful labeling and claims continue to proliferate on the Internet and in certain retail settings and serious injuries and deaths continue to be reported. By simply ordering these products, FDA can easily document interstate distribution of unapproved new drugs and take regulatory action. The longer the delay, the less imminent the health hazard appears, but the more imminent the health hazard becomes.

Products that claim to treat or cure disease continue to proliferate and many companies ignore the requirement to send notification letters to FDA. FDA should identify products with disease claims for serious conditions and take regulatory action. Cooperative enforcement actions could also be conducted with FTC.

Research

The lack of sound scientific evidence for safety and for substantiation of claims is widespread with currently marketed products and TDH acknowledges the difficulty FDA faces in encouraging research

when manufacturers are not required to submit studies to gain marketing approval or for making claims. FDA should educate consumers to demand evidence for safety and for substantiation of claims to promote research by marketplace demand.

FDA should conduct or review ongoing studies about consumer attitudes toward dietary supplements to gain an understanding of consumer expectations of use, conditions for use, sources of information about dietary supplements and perceptions about the meaning of labeling and claims. This information can be used to target consumer education and outreach.

Leveraging Resources

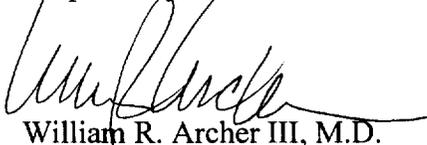
FDA should continue to work closely with state regulatory agencies, many of which have extensive food safety and drug regulatory programs in place. Continue outreach to states through teleconferences such as the July 27, 1999, 50 state conference call, and training such as the July 29, 1999, supplement labeling satellite conference. Many state officials are eager for information and guidance concerning this rapidly evolving field. In addition, FDA should continually remind state health officials about the role of MedWatch in identifying potentially unsafe products.

For more efficient evaluation of adverse events, FDA should amend MedWatch forms to include the specific information needed to properly evaluate the event such as product label, ingredients, directions for use and where product was obtained. FDA should encourage states to forward copies of their own investigations of adverse events.

FDA should work more closely with FTC to identify unsafe or misbranded products with unapproved drug claims. FDA should share information about unsafe products or unapproved claims with consumer groups like the American Association of Retired Persons (AARP), AIDS groups, American Heart Association, American Dietetic Associations, American Medical Association and dietary supplement trade associations at a minimum.

TDH appreciates this opportunity to comment on FDA's overall strategy for achieving effective regulation of dietary supplements. Please feel free to contact Cynthia Culmo at (512)719-0237 for further information.

Respectfully Submitted,



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