

AMERICAN SOCIETY FOR
CLINICAL PHARMACOLOGY AND THERAPEUTICS



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December 2, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

TO: FDA Division of Dockets Management

SUBJ: Docket No. 2004N-0454; Dietary Supplements; Premarket Notification for New Dietary Ingredient Notifications

The American Society for Clinical Pharmacology and Therapeutics (ASCPT) commends the Food and Drug Administration (FDA) for holding a public meeting and soliciting comments regarding its premarket notification program for new dietary ingredients (NDIs). The current proposal by the FDA to require that NDI (new dietary supplements marketed after 1994) regulations be more vigorously enforced with respect to safety, and that the manufacturer and distributor supply the FDA with adequate information to reasonably evaluate safety is welcome. Should such information not be provided, the FDA would have the authority to deem the product unsafe.

ASCPT strongly agrees with this regulatory strategy and believes that it can only serve to enhance the safety of new dietary supplements for the consumer. In addition to the information listed in Sections B and C of the Notice (Chemical Identification of the NDI and Information About the Dietary Supplement), all of which are relevant, ASCPT is particularly concerned that safety of NDIs, as well as existing products, be established. Therefore, ASCPT supports the establishment of reasonable preclinical safety requirements that may include some or all of the studies included in Section D (Establishing a Reasonable Expectation of Safety).

Dietary supplements are regularly used by a large number of Americans with the belief that they improve human health and well-being. Most consumers also believe that dietary supplements are subject to significant government regulation and have undergone extensive review by your agency to ensure their safety and efficacy. Quite to the contrary, the Dietary Supplement Health and Education Act (DSHEA) assumes that supplements (unlike drugs and food additives) are safe and therefore exempt from laws related to proving compound safety. Consequently, it has the potential to severely limit the control that the FDA can exert over the dietary supplement industry to ensure product safety.

ASCPT supports FDA plans to substantiate that dietary supplements marketed prior to DSHEA do not pose significant health risks to consumers. Improving safety enforcement via collaborations with other government agencies is the first step in a process to provide much

needed oversight of adverse reactions associated with these agents. Plans to improve detection of adverse events through more careful monitoring of databases within and outside the government will contribute, as will efforts to enhance public awareness of the need to report adversities.

Although DSHEA does not require adverse event reporting by dietary supplement manufacturers or distributors, ASCPT supports FDA attempts to have them voluntarily do so. Further, ASCPT favors additional, more stringent monitoring of adverse events including the initiation of a mandatory adverse reporting system for supplement manufacturers and distributors.

We urge FDA to finalize its work on current good manufacturing practices (cGMP) for dietary supplements to ensure supplement quality and safety. These regulations are long overdue. Publication of a final rule on dietary supplement cGMP is urgently needed, and should be followed by prompt implementation and strict enforcement.

We applaud FDA proposals to more carefully regulate information on dietary supplement labels. Manufacturers and distributors frequently make label claims related to the use of substances to treat disease and provide label statements regarding structure and function relationships, many of which are unsubstantiated. Attempts to more carefully regulate these inaccurate labeling claims are supported by ASCPT, and we encourage the FDA to take action against improperly labeled agents.

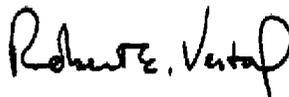
Finally, ASCPT commends the FDA for developing the new guidance for the dietary supplement industry titled "Substantiation for Dietary Supplement Claims Made Under Section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act," which was released in draft form on Nov. 9, 2004. This guidance document should help to ensure that the best available evidence in support of proposed claims is submitted to the FDA. Such action will facilitate appropriate decisions regarding their approval or disapproval.

In summary, despite the limitations of DSHEA to regulate the safety of dietary supplements, ASCPT believes that the recent FDA proposals are a step in the right direction and will further provide consumers with safer and more efficacious agents.

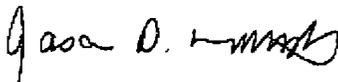
Sincerely,



Andre Terzic, M.D., Ph.D.
President



Robert Vestal, M.D.
Chair, Government Affairs Committee



Jason D. Morrow, M.D.
Chair, Task Force on Dietary Supplements