PMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 11/4/04 @ 8:45 a.m.
Publication Date 11/9/04
Certifier

Food and Drug Administration

[Docket No. 2004N–0458]

Dietary Supplements; Strategy for the Further Implementation and Enforcement of the Dietary Supplement Health and Education Act of 1994; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its strategy for the further implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA). The strategy sets forth a series of specific, integrated research and regulatory measures, including guidance, regulations, and science-based compliance and enforcement mechanisms. Through implementation of these measures, FDA hopes to improve the transparency, predictability, and consistency both of the agency's scientific evaluations of dietary supplement product and ingredient safety, and of its regulatory actions to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. FDA expects that this improved transparency will help engage stakeholders in the development of further measures to implement DSHEA.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the strategy for the further implementation of DSHEA to Vickey Lutwak, Center for Food Safety

NAD 1

and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1775, FAX: 301–436–2636, e-mail: *Vickey.Lutwak@fda.gov.*

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Vickey Lutwak, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1775, FAX: 301–436–2636, e-mail: *Vickey.Lutwak@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In January 2000, FDA's Center for Food Safety and Applied Nutrition (CFSAN) issued its "Dietary Supplement Strategy: Ten Year Plan" (the 10-year plan) (accessible at *http://www.cfsan.fda.gov/~dms/ds-strat.html*). The 10-year plan sets as a goal a science-based regulatory program that fully implements DSHEA and affords consumers a high level of confidence in the safety, composition, and labeling of dietary supplement products. The 10-year plan sets forth a series of critical initiatives: (1) Improving the safety of products through, for example, regulations on current good manufacturing practice requirements for dietary supplements, guidance on premarket safety notifications for new dietary ingredients, and better adverse event report monitoring; (2) improving the labeling of products by, for example, clarifying what data and information are needed to substantiate structure/function and related claims in the labeling of a product; (3) clarifying the boundaries

between dietary supplements, conventional foods, and drugs; (4) taking enforcement action against unsafe products and products whose labels are inaccurate or misleading; (5) developing a sound science base for dietary supplement regulation through enhanced research and analytical capabilities and collaboration with governmental and external partners; and (6) expanding outreach to stakeholders.

The strategy now being announced describes a series of specific, integrated steps that will bring CFSAN closer to achieving each of its longer-term goals for DSHEA implementation and enforcement under the 10-year plan. This strategy also is consistent with the "Dietary Supplement Enforcement Report" announced in December 2002 (*http://www.fda.gov/oc/mcclellan/chbn.html*), and it incorporates and is in furtherance of CFSAN's 2004 Program Priorities, announced in May 2004 (*http://www.cfsan.fda.gov/~dms/cfsan404.html*). We are making this strategy available to maximize the sharing of information among the agency, consumers, and stakeholders about implementation of DSHEA.

II. Comments

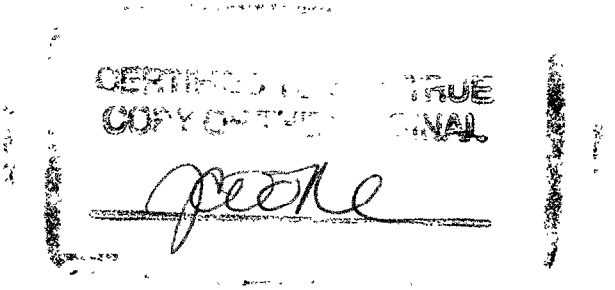
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this strategy. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The strategy and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Person with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/~dms/ds-stra3.html.*

Dated: 10/22/04
October 22, 2004

Jeffrey Shuren
Assistant Commissioner for Policy



[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S