

Dated: November 3, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-24893 Filed 11-8-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0480]

The Minor Use and Minor Species Animal Health Act; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a new Office of Minor Use and Minor Species (MUMS) Animal Drug Development and is requesting comments on the implementation of the newly enacted MUMS Animal Health Act. This notice is intended to provide the public with contact information for the new MUMS office as well as to provide a venue for public comment.

DATES: Submit written or electronic comments by January 10, 2005.

ADDRESSES: 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 www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Andrew Beaulieu, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301-827-2945, abeaulie@cvm.fda.gov. Alternatively, you may contact Margaret Oeller, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301-827-3067, moeller@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The MUMS Animal Health Act became law on August 2, 2004 (Public Law 108-282). Several elements of the law became immediately effective on that date. These include the provisions for designation of MUMS drugs under section 573 and for conditional approval of MUMS drugs under section 571. The indexing provisions under section 572

of the law will only become effective upon publication of final implementing regulations. As mandated by the MUMS law, FDA has established the new Office of MUMS Animal Drug Development in the Center for Veterinary Medicine (CVM). FDA is requesting comments on any aspect of implementation of the MUMS legislation (see section II of this document). Requests for further information should be directed to the Office of MUMS Animal Drug Development (see **FOR FURTHER INFORMATION CONTACT**).

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 Vickie 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.

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