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]

BILLING CODE 4163–18–P

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.

[FR Doc. 04–24880 Filed 11–8–04; 8:45 am]

BILLING CODE 4160–01–S

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 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*.

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: October 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24870 Filed 11–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0465]

Draft Guidance for Food and Drug Administration Review Staff and Sponsors: Content and Review of Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for FDA Review Staff and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)'' dated November 2004. The draft guidance document, when finalized, is intended to provide guidance to FDA review staff and sponsors of human gene therapy products on IND submissions, and on the information FDA CMC reviewers record and assess as part of the review of an original IND.

DATES: Submit written or electronic comments on the draft guidance by February 7, 2005, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance 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: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for FDA Review Staff and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)'' dated November, 2004. The document provides guidance to help sponsors and reviewers to assess, given the phase of the investigation, whether an IND provides sufficient information to allow the reviewer to evaluate the proper identification (identity testing), quality, purity, and strength (potency) of the investigational product (21 CFR 312.23(a)(7)(i)). The draft guidance document is intended to help ensure that all applicable regulatory requirements are reviewed for the appropriate stage of product development.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http:/*