DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0058]

Guidance on Applying the Structure/Function Rule; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on the types of information that should be included in a guidance on applying the regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. This action is being taken to assist the agency in preparing a guidance that will be optimally useful for industry and other interested persons.

DATES: Submit written comments on the topics for the proposed guidance by May 23, 2001.

ADDRESSES: Submit written comments on the topics for the proposed guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of this document are available on the Internet at http://vm.cfsan.fda.gov/~dms/ds-ind.html.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5468.

SUPPLEMENTARY INFORMATION:

I. Background

The Dietary Supplement Health and Education Act (DSHEA) authorizes manufacturers of dietary supplements to claim effects on the ''structure or function'' of the body, but not to make claims to mitigate, treat, prevent, cure, or diagnose disease (21 U.S.C. 343(r)(6)). To explain how this part of DSHEA was to be implemented, FDA published the ''structure/function rule'' on January 6, 2000 (65 FR 1000) (§ 101.93(f) and (g) (21 CFR 101.93(f) and (g))). This rule distinguishes between disease claims, which create a requirement that evidence of safety and efficacy be presented to the agency before marketing, and structure/function claims, which do not create such a requirement. In the preamble to that final rule, FDA stated that it would publish guidance on applying the rule. FDA is seeking public comment on the topics that should be included in the guidance.

II. Description of the Guidance

In the preamble to the structure/function rule, FDA stated that it would provide, through guidance, examples of labeling claims that would and would not be considered disease claims under the rule, including examples of product names. FDA also stated that it would issue guidance, if necessary, on the citation of a publication or a reference implying the treatment or prevention of a disease (§ 101.93(g)(2)(iv)(C)). The agency invites comments on whether guidance on this topic is necessary. Because issues pertaining to the substantiation of structure/function claims are outside the scope of the rule (see 65 FR 1000 at 1032), the agency does not plan to address such issues in the guidance that is the subject of this notice. However, the agency does plan to issue a separate guidance on the substantiation of claims.

III. Request for Comments

FDA invites all interested parties to comment on the topics to be included in the guidance, to suggest additional topics for inclusion in the guidance, and to address any other issue appropriate for this guidance. Interested persons may submit to the Dockets Management Branch (address above) written comments by May 23, 2001. Two copies of any comments are to be submitted, except that individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1315]

Guidance for Industry on How to Use E–Mail to Submit Information to the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#108) entitled ''How to Use E–Mail to Submit Information to the Center for Veterinary Medicine'' (CVM). This guidance provides guidelines on how to submit information to CVM as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2000 (65 FR 40109), FDA published the notice of availability of the draft guidance entitled ''How to Use E–Mail to Submit information to the Center for Veterinary Medicine'' giving interested persons until August 28, 2000, to submit comments. We received no comments.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records; electronic signatures regulation. This rule in part 11 (21 CFR part 11) provides for the voluntary submission of parts, or all, of regulatory records in electronic format without an accompanying paper copy. This rule also established public docket number 97S–0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify in this public docket the types of documents which may be submitted in electronic form. In