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.

[FR Doc. 01–4374 Filed 2–21–01; 8:45 am]

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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

addition, CVM will identify those documents in guidances or regulations. This docket is accessible on the Internet at http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm. The GPEA of 1998 (Public Law 105–277) requires Federal agencies, by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.

CVM accepts certain types of submissions by e-mail with no requirement for a paper copy. These types of documents are listed in public docket 97S–0251 as required by § 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the electronic records; electronic signatures regulation. This guidance outlines general standards that should be used for the successful electronic submission of any information by e-mail.

II. Significance of Guidance

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking about using e-mail to submit information electronically. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

In the notice announcing the availability of the draft version of this guidance, FDA published notice of the proposed collection of information related to the guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance documents. No comments were received on the estimated annual reporting burden. The annual reporting burden estimate of 140 hours therefore remains unchanged. In the **Federal Register** of September 21, 2000 (65 FR 57192), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance document have been approved under OMB control number 0910–0453. This approval expires November 30, 2003. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cvm.

V. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 14, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–4313 Filed 2–21–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1314]

Guidance for Industry on How to Use E–Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes; 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 (#87) entitled ''How to Use E–Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes.'' The purpose of this document is to provide guidance to new animal drug sponsors (sponsors) on how to submit an electronic notice of intent to slaughter for human food purposes (slaughter notices) to the Center for Veterinary Medicine (CVM) and the U.S. Department of Agriculture (USDA). This electronic submission is 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 this 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. 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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 40106), FDA published the notice of availability of the draft guidance entitled ''How to Use E–Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes.'' Interested persons were given until August 28, 2000, to submit comments. FDA received no comments.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records; electronic signatures regulation. This regulation (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 92N–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, as an e-mail attachment by Internet, as those documents are identified in final guidance or regulations. This docket is accessible on the Internet at http://