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]

BILLING CODE 4160–01–S

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://

www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm.

The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submissions. The final guidance implements provisions of the GPEA. 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.

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)(j)) gives FDA the authority to issue regulations setting out conditions for marketing animals treated with investigational new animal drugs for food use. Under this authority, FDA issued § 511.1(b)(4) (21 CFR 511.1(b)(4)), which requires that sponsors obtain authorization to slaughter these animals for use as human food. Under § 511.1(b)(5), CVM issues to sponsors a slaughter authorization letter that sets the terms under which the animals treated with investigational new animal drugs may be slaughtered. USDA also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act (21 U.S.C. 601–95). To assist CVM and USDA with this monitoring, the slaughter authorization states that sponsors must submit slaughter notices each time such animals are to be slaughtered unless CVM waives the notice in the authorization letter. Currently, slaughter notices are submitted to CVM on paper. This guidance will give sponsors the option to submit a slaughter notice as an e-mail attachment to CVM and USDA by the Internet.

Before submitting slaughter notices by e-mail, sponsors should first register and follow the instructions in the guidance for industry (#108) entitled ''How to Use E–mail to Submit Information to the Center for Veterinary Medicine.''

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 a slaughter notice. This guidance 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.

III. Paperwork Reduction Act of 1995

In the notice announcing the availability of the draft version of this guidance, FDA published a 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 27 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 0910–0450. 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. A copy of the document 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. 01–4419 Filed 2–21–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0005]

Draft Guidance for Industry on Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's.'' This draft guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products marketed under abbreviated new drug applications (ANDA's) and manufacturers of reference listed drugs (RLD's) to implement the agency's regulation on standardized content and format requirements for the labeling of OTC drug products.

DATES: Submit written comments on the draft guidance for industry by April 23, 2001.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products; Updating