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]

BILLING CODE 4160–01–S

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

Labeling in ANDA's.'' This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the recently issued final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products. This rule is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation for this new standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. This new format will require revision of all existing labeling.

Following issuance of the final rule, the agency received several inquiries from manufacturers of generic OTC drug products seeking guidance on whether they may convert products to the new labeling format before the applicable innovator (or RLD) product revises its labeling. This guidance addresses those inquiries.

Generally, the agency believes manufacturers of generic OTC drug products (i.e., products marketed under ANDA's) need not wait to implement the new labeling format until after the RLD holder has submitted its labeling. This guidance is intended to facilitate the updating of labeling in ANDA's to meet the new OTC drug products format requirement. Accordingly, the agency has developed labeling examples as guidance for manufacturers to follow. Two such labeling examples are attached to the draft guidance. The additional labeling examples that the agency proposes to develop will be made available for review in this docket and at the Internet site referenced in this draft guidance before the close of the comment period.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on updating labeling in ANDA's consistent with the new OTC drug products standardized labeling content and format. 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 an approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may, on or before April 23, 2001, submit written comments on the draft 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 draft 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 8, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–4312 Filed 2–21–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0059]

Draft Guidance for Industry on Separate Marketing Applications and Definition of Clinical Data for Purposes of Assessing User Fees; 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 ''Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.'' This draft guidance revises a procedural guidance entitled ''Attachment E—Interim Guidance: Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees Under the User Fee Act of 1992'' issued in July 1993 (the July 1993 interim guidance), which provided guidance on the agency's policy on ''bundling'' applications and a definition of ''clinical data'' for user fee purposes. This draft guidance deletes two appendices in the July 1993 interim guidance and directs readers to the agency publication entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book) for a listing of routes of administration and dosage forms.

DATES: Submit written comments on this draft guidance by March 26, 2001. General comments are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http:/www.fda.gov/cder/guidance and http:/www.fda.gov/cder/pdufa/default.htm. Submit written requests for single copies of the draft guidance entitled ''Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The document may also be obtained by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Send one self-addressed adhesive label to assist the 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:

Michael D. Jones, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, FAX 301–827–5562, or

Carla A. Vincent, Center for Biologics Evaluation and Research (HFM–110), 1401 Rockville Pike, Rockville, MD 20852, 301–827–3503, FAX 301–827–2875.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.'' This draft guidance revises the July 1993 interim guidance.

The agency is deleting from the 1993 interim guidance the list of routes of administration in appendix A and dosage forms in appendix B.

FDA is deleting appendices A and B so that the guidance reflects current agency policy, as developed over the past few years (see Docket Nos. 93P–0421, 95P–0262, 96P–0317, and 96P–0459). Among other things, in the review of abbreviated new drug applications, the Center for Drug Evaluation and Research generally has not considered different mechanisms of release, particularly for suppository, delayed, and controlled release products, as different dosage forms.