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 Two such labeling examples are attached to the draft guidance.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agency proposes to develop will be made available for review in this docket and at the Internet site referenced in this draft guidance before the close of the comment period.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on updating labeling in ANDA's consistent with the new OTC drug products standardized labeling content and format.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

Instead, the draft guidance refers readers to the Orange Book appendix C, ''Uniform Terms.'' Although the Orange Book appendix C is not binding on the agency or industry, it does serve as informal guidance on what the ''same'' or ''identical'' dosage form or route of administration would be.

The draft guidance also updates the July 1993 interim guidance for consistency with the agency's good guidance practices (GGP's) regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The agency anticipates making additional revisions to this procedural guidance in the future.

This Level 1 draft guidance is being issued consistent with FDA's GGP's. The draft guidance represents 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 requirements of the applicable statutes and regulations. The draft guidance will be updated as appropriate.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance at any time. 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 13, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–4311 Filed 2–21–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4655–N–03]

Notice of Proposed Information Collection: Comment Request; Management Reviews of Multifamily Projects

AGENCY: Office of the Assistance Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 23, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Building, Room 8202, Washington, DC 20410, telephone (202) 708–5221 (this is not a toll-free number) for copies of the proposed forms and other available information.

FOR FURTHER INFORMATION CONTACT: Beverly J. Miller, Director, Policy and Participation Standards Division, U.S. Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone number (202) 708–3000, (this is not a toll-free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1955 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Management Reviews of Multifamily Projects.

OMB Control Number, if applicable: 2502–0178.

Description of the need for the information and proposed use: The form is completed by HUD staff and Contractor Administrators gathering and recording information during an on-site review of the project operations.

Agency form numbers, if applicable: Form HUD–9834.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated number of respondents for HUD staff and Contract Administrators is 1,120; the frequency of response is 1, estimated time to prepare form is approximately 4 hours; and the estimated total annual burden hours are 4,480.

Status of the proposed information collection: Reinstatement with change of previously approved collection for which approval has expired.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: February 13, 2001.

Wayne Eddins,

Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–4384 Filed 2–21–01; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4655–N–04]

Notice of Proposed Information Collection: Comment Request; Minimum Property Standards for Housing

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 23, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Cocke, Acting Director, Office of Consumer and Regulatory Affairs, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–6409 (this is not a toll free number) for copies of the proposed forms and other available information.