

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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Draft Guidance for Industry on Separate Marketing Applications and Definition of Clinical Data for Purposes of Assessing User Fees; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.” This draft guidance revises a procedural guidance entitled “Attachment E—Interim Guidance: Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees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 This draft guidance deletes two appendices in the July 1993 interim guidance and directs readers to the agency publication entitled “Approved Drug Products with Therapeutic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DATES: Submit written comments on this draft guidance by *[insert date 30 days after date of publication in the Federal Register]*. 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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at 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 Submit written requests for single copies of the draft guidance entitled “Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees” to the Drug Information Branch (HFD-210), Center for Drug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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.

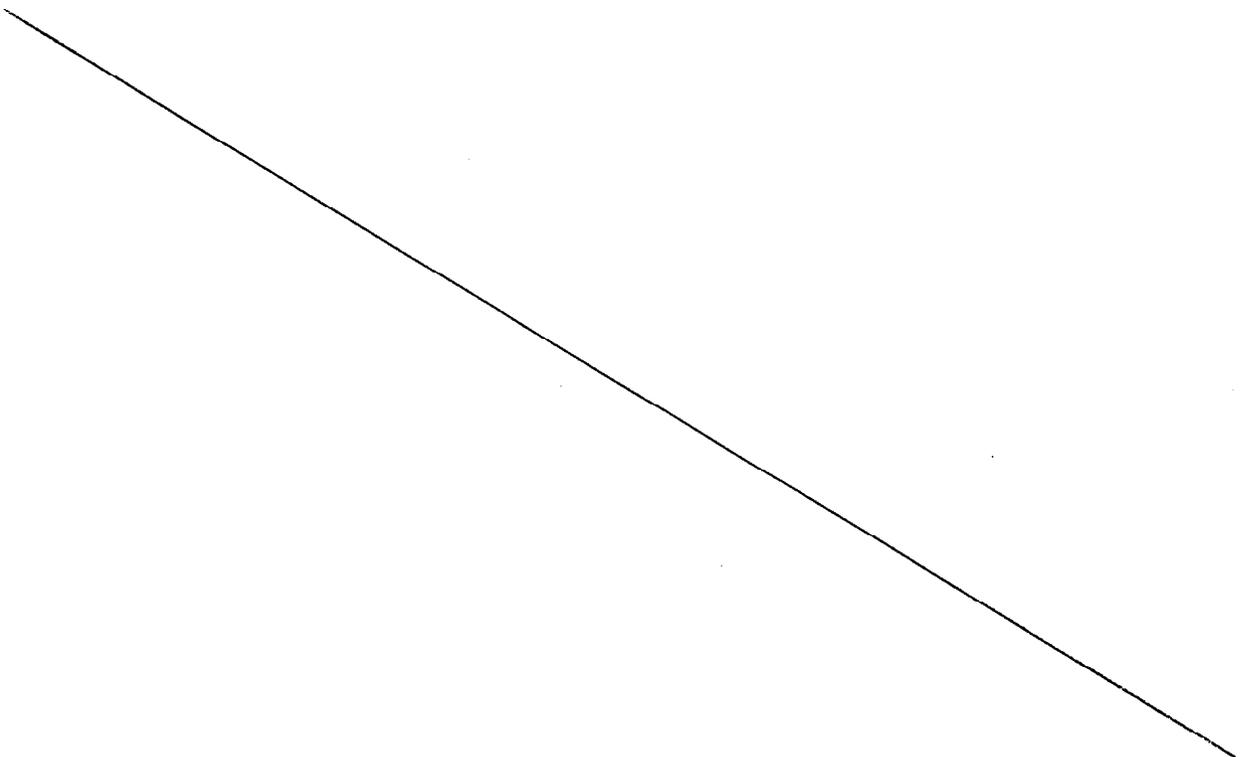
Instead, the draft guidance refers readers to the Orange Book appendix C, “Uniform Terms.” Although the Orange Book appendix C is not binding on the agency or industry, it does serve

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
February 13, 2001

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

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Acting Associate Commissioner for Policy

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