

DMB

Display Date	7/2/99
Publication Date	7/18/99
Certifier	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1938]

**Review of Guidances for Industry on the Development of Generic Drug Products;
Development and Use of FDA Guidance Documents; Request for Comments**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) is providing notice to drug manufacturers on its plans for reviewing policy and procedure guides (PPG's) and other existing OGD documents that provide guidance on the development of generic drug products. This effort is being undertaken consistent with the agency's good guidance practices (GGP's) policy. The goal of this long-term effort is to identify documents that need to be revised, reformatted to fit the GGP policy, or withdrawn because they are no longer current. OGD hopes this process will result in guidances for industry that better reflect the current thinking of the agency on generic drug development. OGD also is seeking input from the public on topics for future guidance development.

DATES: Written comments by *(insert date 60 days after date of publication in the Federal Register)*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of agency guidance documents can be obtained on the Internet at "http://www.fda.gov/cder/guidance/index.htm". Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rita R. Hassall, Center for Drug Evaluation and Research (HFD-600) Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5845.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice explaining its policy for guidance document development, issuance, and use. The notice included an agency document entitled "Good Guidance Practices" (GGP's), which sets forth agency policies and procedures for developing, issuing, and using guidance documents.

Since the early 1990's, OGD has developed and issued more than 40 PPG's to provide information to industry on the development of generic drug products and to set forth procedures for the review of generic drug applications. In addition, other guidance has been provided in the form of letters and other communications to industry. OGD is undertaking a long-term effort to review all of its guidances and identify those that need to be revised, those that need to be reformatted for consistency with GGP's, and those that need to be withdrawn because they are no longer current. As an initial step in this process, OGD is planning to withdraw a number of drug-specific bioequivalence guidances that are outdated and no longer reflect the current thinking of the agency. Guidances that are being withdrawn include the following:

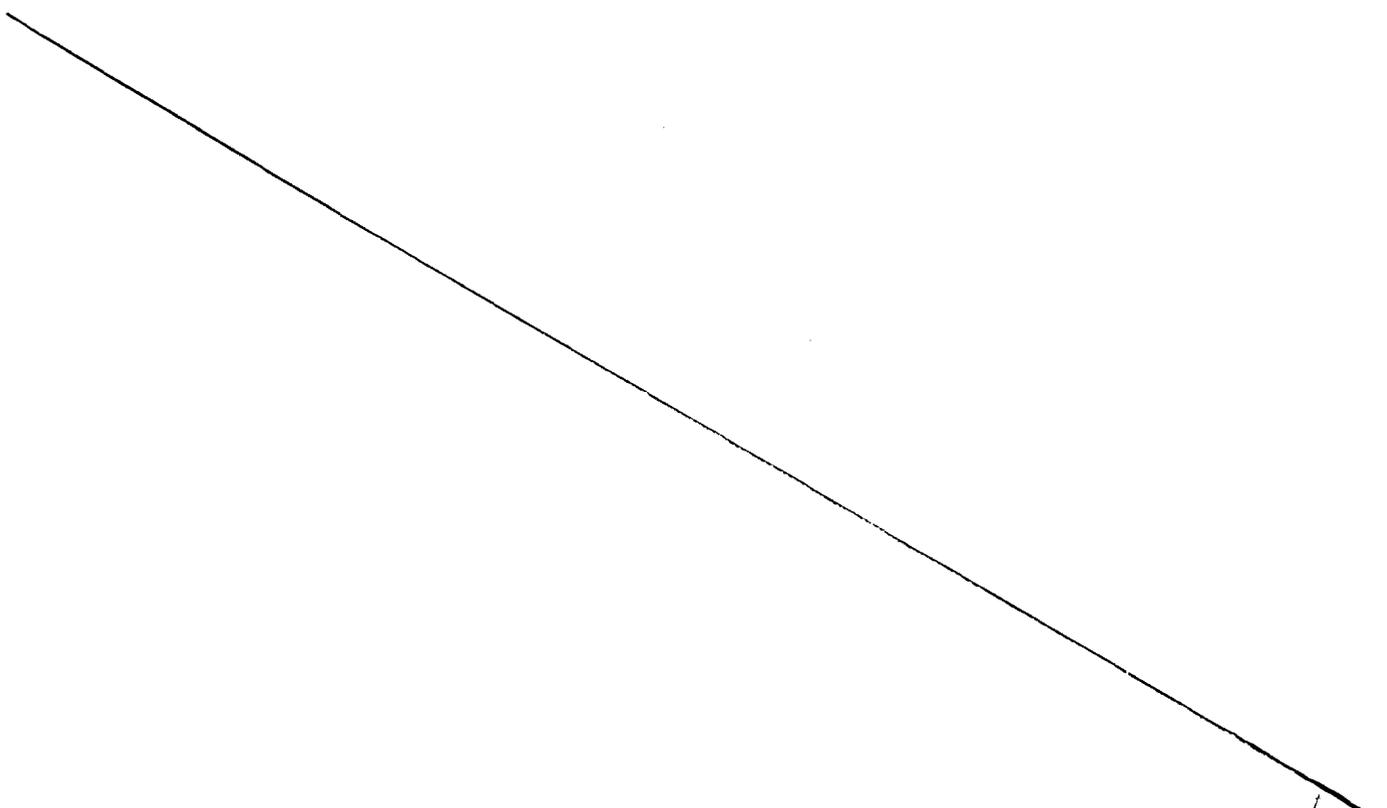
Guidance	Date of Issuance
Alprazolam (tablets)	November 27, 1992
Bumetanide (tablets)	April 23, 1993
Captopril (tablets)	May 13, 1993
Carbidopa and Levodopa (tablets)	June 19, 1992
Cefaclor (capsules and suspension)	April 23, 1993
Diflunisal (tablets)	May 16, 1992
Diltiazem Hydrochloride (tablets)	May 16, 1992
Flurbiprofen (tablets)	June 8, 1995 (2d Revision)
Gemfibrozil (tablets and capsules)	June 15, 1992 (Revision)
Guanabenz Acetate (tablets)	April 23, 1993
Hydroxychloroquine Sulfate (tablets)	December 28, 1995
Indapamide (tablets)	April 23, 1993
Ketoprofen (capsules)	April 23, 1993
Leucovorin Calcium (tablets)	August 4, 1988 (Revision)
Medroxyprogesterone Acetate (tablets)	September 17, 1987 (Revision)
Metoprolol Tartrate (tablets)	June 12, 1992
Nadolol (tablets)	May 16, 1992
Naproxen (tablets)	June 8, 1995 (Revision)
Nortriptyline Hydrochloride (capsules)	June 12, 1992
Pentoxifylline (extended-release tablets)	December 22, 1995
Pindolol (tablets)	April 23, 1993
Piroxicam (capsules)	June 15, 1992
Ranitidine Hydrochloride (tablets)	April 23, 1993
Trazodone Hydrochloride (tablets)	April 30, 1988 (Revision)

It is possible that some of the remaining drug-specific guidances on bioavailability and bioequivalence also will be withdrawn after they are reassessed. However, several CDER guidances currently under development will serve as core guidances on bioavailability and bioequivalence once they have been finalized, and they will replace the product-specific guidances. On rare occasions, the agency may wish to provide bioavailability and bioequivalence guidance for specific drug products, and these will be developed and issued consistent with the agency's GGP policy.

The agency welcomes public comment on its efforts to review existing guidances related to the development of generic drugs and revise, reformat, or withdraw them as appropriate. The agency also is requesting public comment on topics for future guidance development regarding generic drugs.

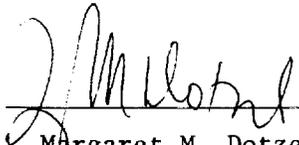
This information is being issued consistent with FDA's GGP's. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may submit written comments 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. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/30/99
June 30, 1999



Margaret M. Dotzel
Acting Associate Commissioner for
Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F