

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2004D-0524]

**Draft Guidance for Industry on ANDAs: Pharmaceutical Solid Polymorphism;
Chemistry, Manufacturing, and Controls Information; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information." The draft guidance is intended to assist applicants with the submission of abbreviated new drug applications (ANDAs) when a drug substance exists in polymorphic forms.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to

<http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Andre Raw, Center for Drug Evaluation and Research (HFD-620), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5758.

SUPPLEMENTARY INFORMATION:

I. Background

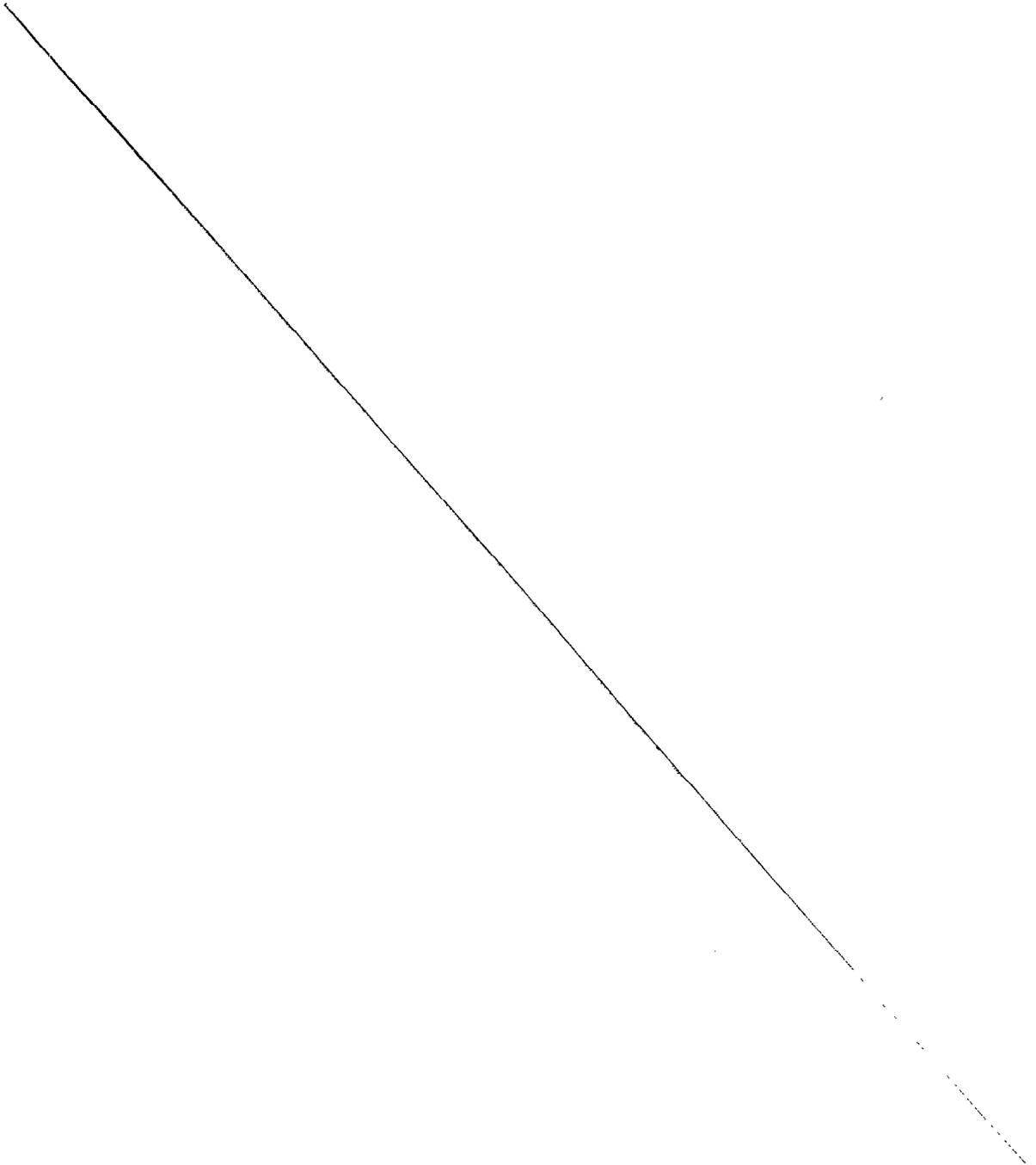
FDA is announcing the availability of a draft guidance for industry entitled “ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information.” This draft guidance provides: (1) A framework for making regulatory decisions on drug substance sameness in terms of polymorphic form, and (2) decision trees which provide a recommended course to monitor and control polymorphs in the drug substance and/or drug product when the drug substance exists in relevant polymorphic forms.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on pharmaceutical solid polymorphism. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. 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

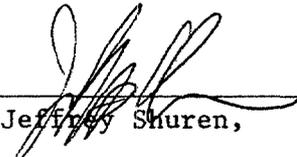
in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 12/11/04
December 11, 2004



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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