

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004D-0524]

Display Date 4-6-07  
Publication Date 4-9-07  
Certifier L. CLAWSON  
DDM

**Guidance for Industry on ANDAs: Pharmaceutical Solid Polymorphism;  
Chemistry, Manufacturing, and Controls Information; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information.” The 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 agency guidance documents at any time.

**ADDRESSES:** Submit written requests for single copies of this 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 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Andre Raw, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9310.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

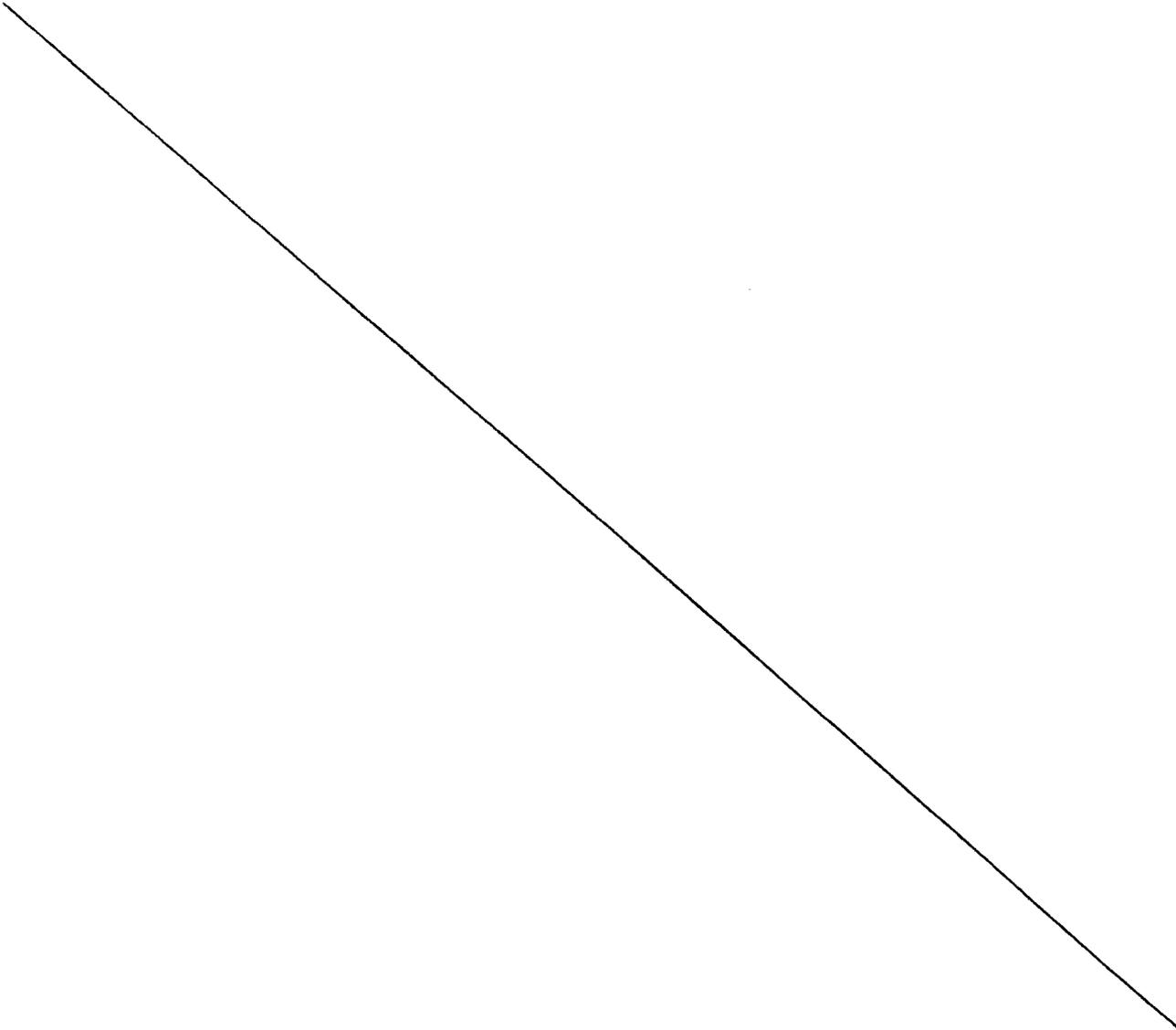
FDA is announcing the availability of a guidance for industry entitled “ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information.” This guidance provides: (1) A framework for making regulatory decisions on drug substance sameness in terms of polymorphic form and (2) 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.

On December 20, 2004 (69 FR 75987), the FDA announced the availability of the draft version of this guidance. The public comment period closed on March 21, 2005. A number of comments were received, which the agency considered carefully as it finalized the guidance and made appropriate changes. Most of the changes to the guidance were made to clarify statements in the draft guidance.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents 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

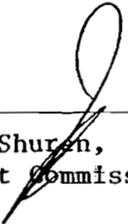
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

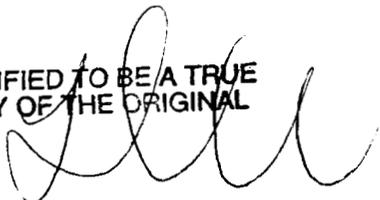
Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: 6/26/07  
June 26, 2007.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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