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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1268]

Guidance for Industry on Variations in Drug Products That May Be Included in a Single Abbreviated New Drug Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Variations in Drug Products That May Be Included in a Single ANDA." This guidance was developed by the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research to provide information to applicants on certain specific variations of a drug product that should be included in a single abbreviated new drug application (ANDA) and describe the general factors to be considered when determining whether single or multiple ANDA's should be submitted. It is intended to reduce the burden on industry for submitting and maintaining separate applications for certain variations of the same drug product.

DATES: Written comments may be submitted on the guidance by *(insert date 90 days after date of publication in the Federal Register)*. General comments on agency guidances are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm". Submit written requests for single copies of "Variations in Drug Products That May Be Included in a Single ANDA" to the Drug Information Branch (HFD-210), 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 Dockets Management
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Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. West, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5846.

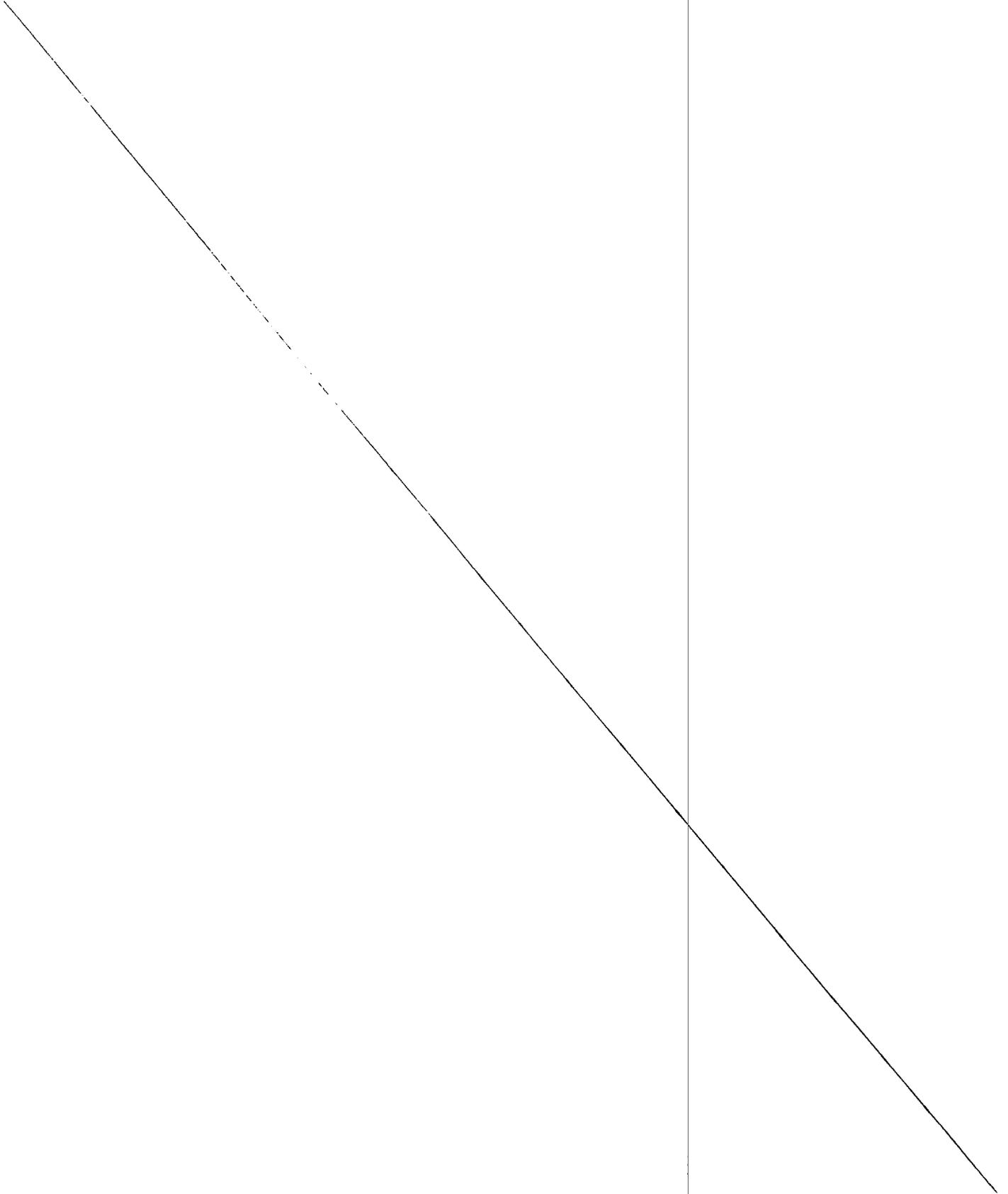
SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Variation in Drug Products That May Be Included in a Single ANDA." Prior to October 1, 1990, applicants were to submit separate ANDA's for each dosage form of a drug product and also for each variation (e.g., strength, color, shape) within a dosage form. Separate applications were requested for ease of review since having information on a number of variations within one application could make review more difficult. On October 1, 1990, the OGD Interim Policy and Procedure Guide (PPG) 20-90 was issued. This guide permitted certain variations of solid oral dosage forms and injectables to be submitted within a single abbreviated application. On June 7, 1995, PPG 20-90 was amended to allow certain variations to be filed as supplements.

This guidance incorporates the policies and procedures in PPG 20-90 and clarifies the practice of permitting variations of products in a single application.

This guidance is being issued as a level I guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because it is intended to reduce the burden on industry. However, the agency wishes to solicit comments from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance represents the agency's current thinking on variations in drug products that may be included in a single abbreviated application. 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 statute, regulations, or both.

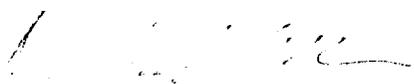
Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number



found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____

January 20, 1999



William K. Hubbard
Associate Commissioner for Policy Coordination

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

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