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Certifier	Jen Wolcott

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2635]

Draft Guidance for Industry on ANDA's: Blend Uniformity Analysis; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDA's: Blend Uniformity Analysis." This draft guidance is intended to provide recommendations to holders of abbreviated new drug applications (ANDA's) on establishing in-process acceptance criteria related to blend uniformity analysis (BUA) for the manufacture of some drug products.

DATES: Written comments may be submitted on the draft guidance by (*insert date 60 days after date of publication in the Federal Register*).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ADDRESSES: Copies of this draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>". Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers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 the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

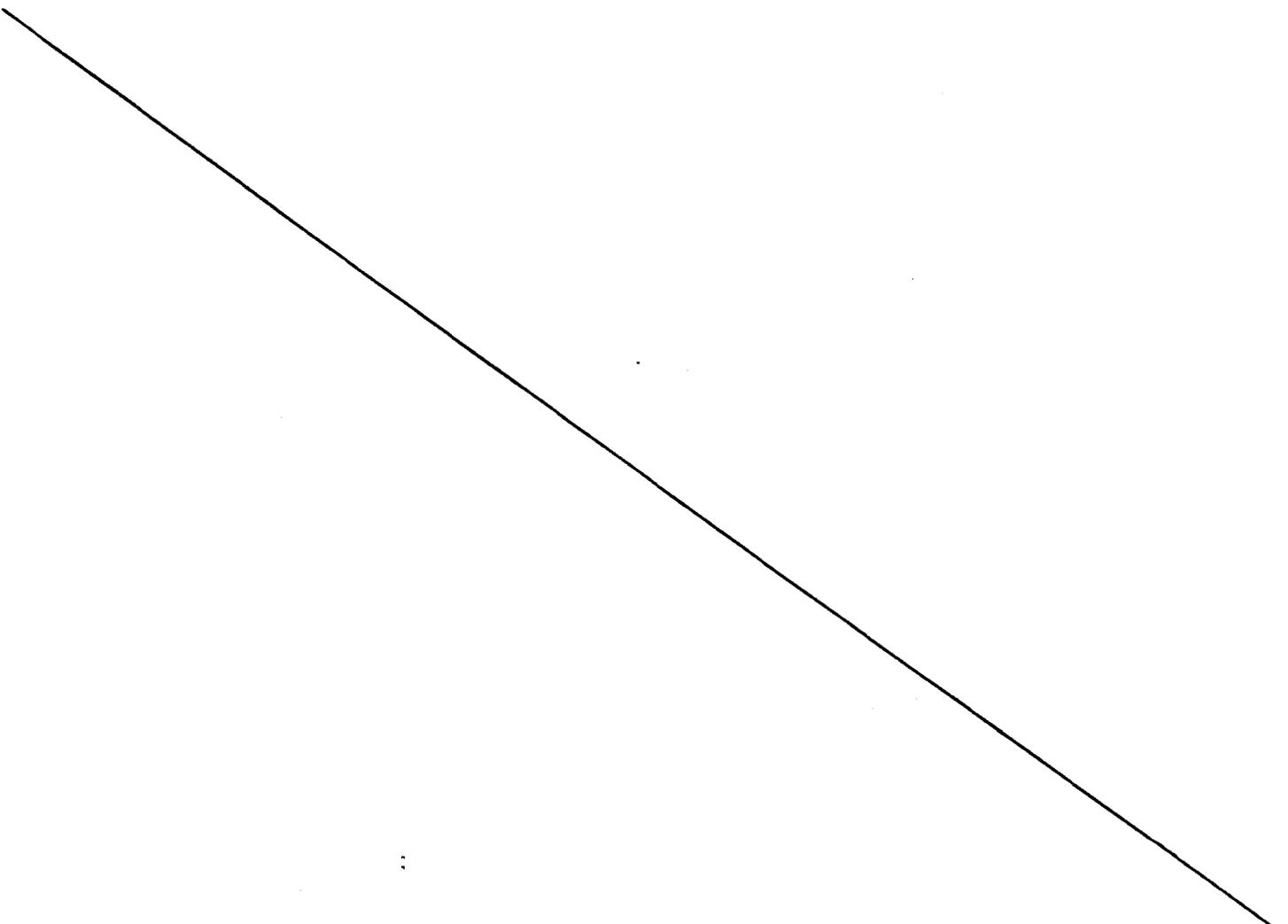
FOR FURTHER INFORMATION CONTACT: Devinder S. Gill, Office of Generic Drugs (HFD-623), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5848.

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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled “ANDA’s: Blend Uniformity Analysis.” This draft guidance is intended to provide recommendations on when BUA should be performed. The recommendations, when applicable, apply to original ANDA’s and supplemental ANDA’s for formulation and process changes.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). It represents the agency’s current thinking on BUA for ANDA’s. 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, regulations, or both.

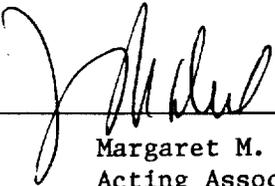
Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except



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 draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/20/99
August 20, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Margaret M. Dotzel
Acting Associate Commissioner for Policy



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

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