

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99D-2635]

DMS

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Certifier N. Hawkins

**ANDAs: Blend Uniformity Analysis; Withdrawal of Draft Guidance**

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

**ACTION:** Notice; withdrawal.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on August 27, 1999.

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

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of August 27, 1999 (64 FR 46917), FDA announced the availability of a draft guidance for industry entitled "ANDAs: Blend Uniformity Analysis." The draft guidance was intended to provide recommendations to sponsors of abbreviated new drug applications (ANDAs) on what information should be provided in an ANDA to support the demonstration and bioequivalence batches and to establish in-process acceptance criteria related to blend uniformity analysis (BUA) for the manufacture of some drug products. Written comments on the draft guidance were to be submitted by October 26, 1999.

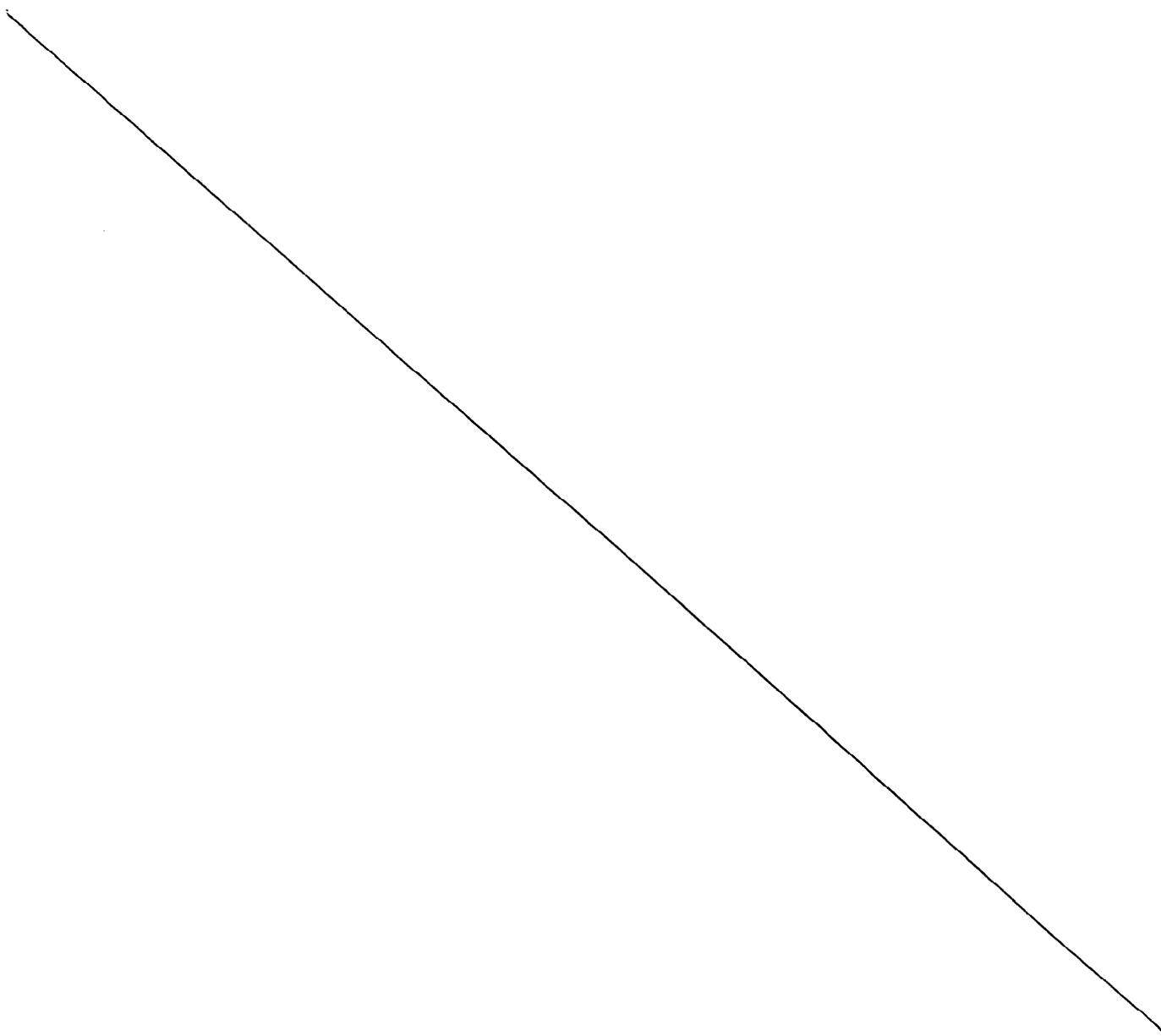
After careful consideration of the comments received, FDA has decided to withdraw the draft guidance. The information and comments from the public raised scientific issues relating to the scope of the guidance and methodology for blend uniformity analysis in general, including the: (1) Adequacy of current blend sampling techniques and (2) appropriateness of various test methods for assessing blend uniformity. The agency has decided that further research on BUA is needed. FDA is participating in research on BUA through the Product Quality Research Institute (PQRI).

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Based on the results of the research and recommendations submitted by PQRI, FDA will determine whether a new guidance on BUA will be issued.

An applicant or manufacturer must still comply with any applicable regulations regardless of the status of this guidance. For example, an application must include specifications and analytical methods to ensure the identity, strength, quality, purity, and bioavailability of the drug product (21 CFR 314.50(d)(1)(ii)(a)), and a manufacturer must monitor and validate the performance of processes that could be responsible for variability, including adequacy of mixing to ensure



uniformity and homogeneity (21 CFR 211.110(a)(3)). An evaluation of uniformity of a blend may be necessary to fulfill such requirements.

Dated: 5/6/02  
May 6, 2002.



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Margaret M. Dotzel,  
Associate Commissioner for Policy.

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Dawn P. Hawkins