

*Contains Nonbinding Recommendations*  
*Draft — Not for Implementation*

# Guidance for Industry

## **Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment**

### **Revised Attachments**

These attachments are intended to replace the attachments contained in the draft guidance.

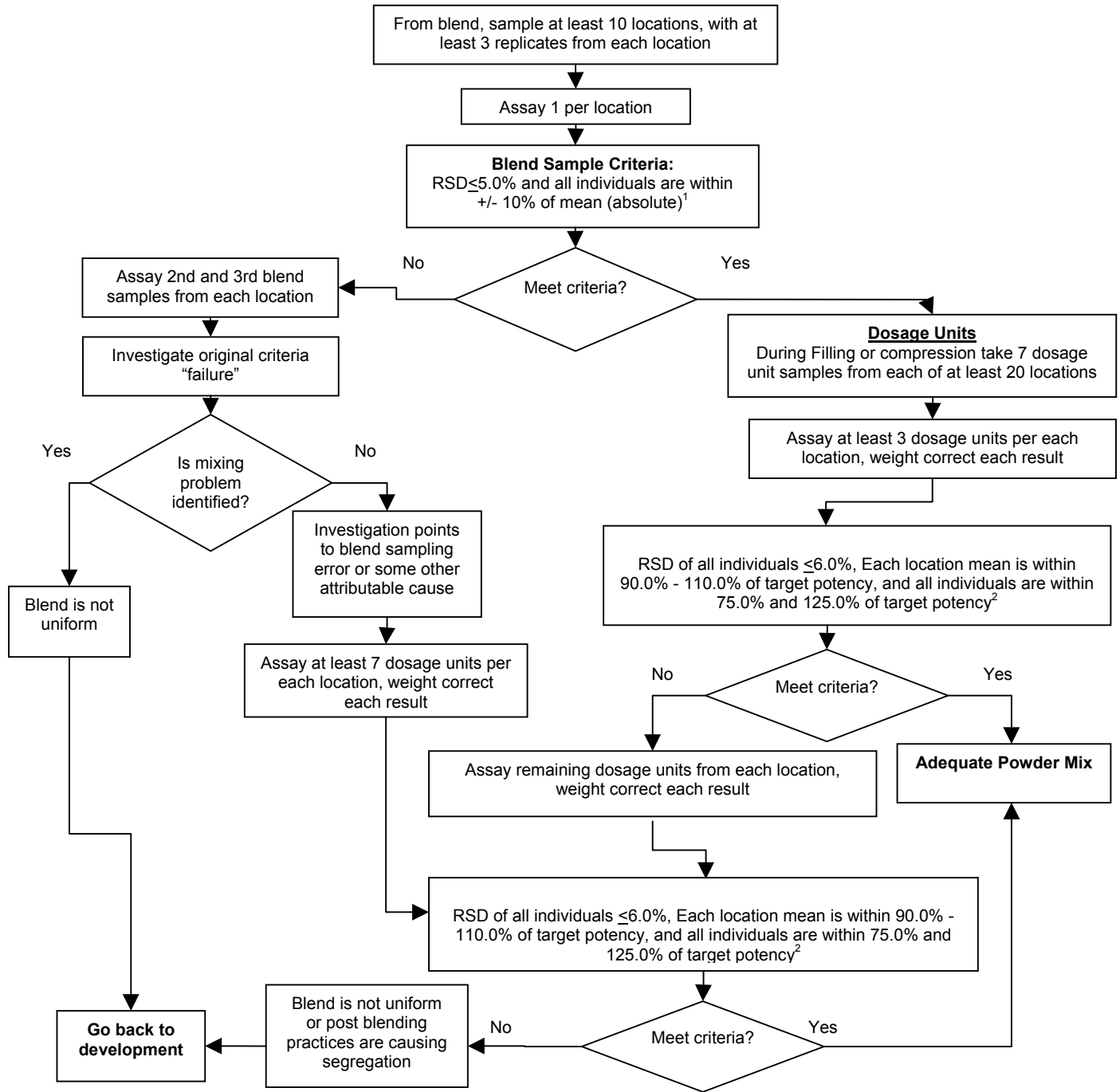
**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**November 2003**

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**REVISED ATTACHMENT 1: VERIFICATION OF MANUFACTURING CRITERIA**



<sup>1</sup> Examples of “mean +/- 10% (absolute)” are: If the mean strength = 95%, then the interval is 95% +/- 10%; thus, all individuals must fall within 85.0% to 105.0%. If the mean strength = 103.0%, then the interval is 103.0% +/- 10.0%; thus all individuals must fall within 93.0% to 113.0%.

<sup>2</sup> When comparing individual dosage units to 75.0% - 125.0% of target strength, use the *as is* results (not corrected for weight).

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**REVISED ATTACHMENT 2: ROUTINE MANUFACTURING BATCH TESTING**

**Standard Criteria**

**Continuing Routine Testing Using Standard Criteria Method (SCM):**  
 Last batch met STM acceptance criteria  
 or  
 Last 5 batches were tested using Marginal Criteria Method (MTM) and met acceptance criteria with  $RSD \leq 5.0\%$

**Beginning Routine Testing to Standard Criteria Method (SCM):**  
 No routine testing was done since completion of method development and result of method development was *readily pass*

**Marginal Criteria**

**Continuing Routine Testing Using Marginal Criteria Method (MCM):**  
 Last batch met STM acceptance criteria  
 or  
 Last batch met MTM acceptance criteria

**Beginning Routine Testing to Marginal Criteria Method (MCM):**  
 No routine testing was done since completion of method development and result of method development was *marginally pass*

