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# Guidance for Industry

## Drug Product

**Chemistry, Manufacturing, and Controls Information**

### ***DRAFT GUIDANCE***

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

**January 2003  
CMC**

# Guidance for Industry

## Drug Product

### Chemistry, Manufacturing, and Controls Information

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