



**ABBOTT**

**Corporate Regulatory and Quality Science**

---

Zena Kaufman  
Director  
Quality Center of Excellence  
D-03QA, AP6C-1  
Telephone: (847) 938-1750

100 Abbott Park Road  
Abbott Park, IL 60064-6091  
Facsimile: (847) 938-4422  
e-mail: zena.kaufman@abbott.com

March 17, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Ref: **Docket No 2005N-0285 Current Good Manufacturing Practice Regulation and Investigational New Drugs**

To Whom it May Concern:

Abbott is very pleased to have the opportunity to provide comments on the Proposed and Final Rule Current Good Manufacturing Practice Regulation and Investigational New Drugs published on January 17, 2006 in the Federal Register. The comments submitted to the Rule are consistent with our comments submitted on the Draft Guidance Docket No. 2005D-0286.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,

Zena Kaufman  
Encl: Comments

2005N-0285

C2



ABBOTT COMMENTS TO FDA ON

Docket No. 2005N-0285

COMMENTS

1. Comments to the Direct Final Rule preamble, section V., " Analysis of Impacts", pages 10-11. Refer to the statement *For drug manufacturers that produce Phase 1 drug products in-house and also produce approved dug products, this direct final rule is expected to reduce the amount of documentation they produce and maintain when they manufacture a Phase 1 drug. In some cases, it should also reduce the amount of component and product testing.*

**Comment:** Manufacturers will not know at the time of phase 1 clinical manufacture whether a drug will eventually move to phase 2. For this reason, manufacturers will likely elect to take a conservative approach and manufacture a drug to phase 2 requirements (Part 211) to allow the phase 1 drug to be used in future phase 2 studies. Because availability of drug in the clinical phase could be a concern, manufacturers would most likely not elect to discard phase 1 material that could be used in phase 2. For the reason, the statement regarding savings is questionable.

2. Comments to the wording of Part 210, page 16, "210.2 Applicability of current good manufacturing practice regulations".

**Comment:** The Agency recognizes that although Part 211 applies to phase 2 and phase 3 clinical material, that the extent of the controls varies based on the phase of clinical study. This is confirmed in the statement of the proposed guidance document, lines 63-65. The Agency also agrees that not all parts of 211 may apply to phase 2 or phase 3 material as stated in the proposed guidance document, line 93. For this reason it is suggested the wording of the regulation be changed:

Change from: *If the investigational drug has been made available in a phase 2 or phase 3 study or the drug has been lawfully marketed, the drug for use in the Phase 1 study must comply with part 211.*

Change to: *If the investigational drug has been made available in a phase 2 or phase 3 study or the drug has been lawfully marketed, the drug for use in the Phase 1 study must comply with **the appropriate sections of part 211***