



ABBOTT

Corporate Regulatory and Quality Science

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September 18, 2002

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

Ref: Docket No 02D-0350 - “Guidance for Industry: Handling and Retention of BA and BE Testing Samples”

To Whom It May Concern:

Abbott Laboratories is very pleased to have the opportunity to provide comments on the “Guidance for Industry: Handling and Retention of BA and BE Testing Samples” published on August 21, 2002 in the *Federal Register*.

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).

Please contact me at (847) 938-1750 with any questions or concerns that you may have.

Sincerely,

Richard M. Johnson
Director of Information & Policy, COE Drugs
Corporate Regulatory & Quality Science
Abbott Laboratories, Inc.

Attachment: Comments

02D-0350

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Comments to FDA Docket No. 02D-0350

- 1) Section IV. D (Lines 363 - 367). Recommended changes are **bold**:

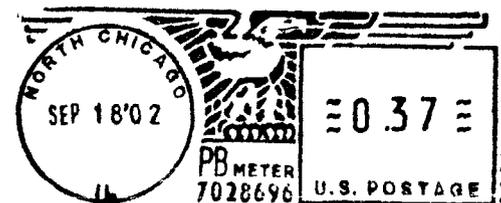
“Reserve samples should be retained in a secure ~~room~~ **area (i.e. secure room, locked storage unit)** in the clinical study unit. To protect the drug sponsor or drug manufacturer from challenge to the authenticity of the reserve samples, access to the room **or locked storage unit** where the samples are stored should be limited to the clinical investigator or research pharmacist. An entry log to the storage room **or locked storage unit** should also be maintained.”

Recommended changes:

To allow for other secure options for storing reserve samples. Securing an entire room may be impractical and unnecessary if the samples are controlled in an equally secure contained area.



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