From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, September 15, 2003 3:05 PM
To: [redacted]
Cc: Lepay, David
Subject: RE: Clinical Supply Maintenance

Dear [redacted]:

Your question about retention of reserve samples of any test article was referred to me for a response. Per 21 CFR 312.59, a sponsor may dispose of unused supplies of the investigational drug, but must maintain records of its disposition.

I have pasted the text of 21 CFR 312.59 into this e-mail for your convenience:

> Sec. 312.59 Disposition of unused supply of investigational drug.
>
> The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. **The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with Sec. 312.57.**

As for retention of reserve samples of any test article and reference standards, 21 CFR 312.57(d) Recordkeeping and record retention, states:

> **"(d) A sponsor shall retain reserve samples of any test article and reference standard identified in, and used in any of the bioequivalence or bioavailability studies described in, Sec. 320.38 or Sec. 320.63 of this chapter, and release the reserve samples to FDA upon request, in accordance with, and for the period specified in Sec. 320.38."**

21 CFR 320.28 (e) sets forth the time period that retention samples and standards should be maintained. The entire section has other useful information about retaining these samples:

> Sec. 320.38 Retention of bioavailability samples.
>
> **(e) Each reserve sample shall be stored under conditions consistent with product labeling and in an area segregated from the area where testing is conducted and with access limited to authorized personnel. Each reserve sample shall be retained for a period of at least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at least 5 years following the date of completion of the bioavailability study in which the sample from which the reserve sample was obtained was used.**

You may access FDA's regulations pertaining to good clinical practice from the GCP website:

www.fda.gov/oc/gcp Once there, click on "Good Clinical Practice/Clinical Trials Regulations," which is the first item listed in the center column under "Regulations."

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Friday, September 05, 2003 10:32 AM
To: gcpquestions@oc.fda.gov
Subject: Clinical Supply Maintenance

Once a clinical trial is completed, how long is the pharmaceutical company (sponsor) required to maintain the returned/unused investigational product? If the company stores "retain" samples from each lot, is it acceptable to destroy the remaining medication immediately after the conclusion of the study, or should all medication supplies be stored according to the same standards that apply to the retaining of documentation which is 7 years according to GCP.

Thank you for your assistance.
[redacted]