

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Question on retention time period for plasma samples  
**Date:** Monday, August 25, 2014 2:51:36 PM  
**Attachments:** [Reserve Sample Guidance 5522fml.pdf](#)  
[Reserve Sample Final Rule.pdf](#)

---

Good afternoon –

Please see the attached guidance and rule on reserve samples. If the documents do not answer your question, please contact the Center for Drugs (CDER) directly at [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov).

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

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.

**From:** GYXUM/XQ  
**Sent:** Monday, August 25, 2014 7:19 AM  
**To:** OC GCP Questions  
**Subject:** Question on retention time period for plasma samples

Dear Sir or Madam,

We would appreciate your advice on what is the recommended retention time period for plasma samples collected and used for demonstrating bioequivalence studies for NDA/ANDA that were submitted and/or approved by FDA?

Thank you and best regards,