From: OC GC 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 5522fnl.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.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
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,

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