From: Kezer, Doreen M
To: [redacted]
Subject: Question retention samples for reference listed drug (RLD)
Date: Monday, August 25, 2014 3:08:59 PM
Attachments: Reserve Sample Guidance 5522fnl.pdf
Reserve Sample Final Rule.pdf

Good afternoon –

We sent your question to the Center for Drugs (CDER). Please see their answer below. Also please see the documents attached above.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

Sent: Tuesday, August 19, 2014 3:34 PM
To: Kezer, Doreen M
Cc: Clayton, Tanya; Haidar, Sam H
Subject: RE: Question retention samples for reference listed drug (RLD)

Hi Doreen,

I am following up on your request below. Since we were not provided the drug product or ANDA/NDA number it is difficult to be very specific with the answer.

Unless the sponsor conducts the clinical portions of the *in vivo* BE study, or the analytical portions of an *in vitro* BE study, in their own premises, the sponsor does not select or retain reserve samples under 320.63. Reserve sample retention is a requirement for the entity conducting clinical portions of an *in vivo* BE study or analytical portions of an *in vitro* BE study. Please refer to the final rule and sample guidance.

Regarding the first question: The RLD is an FDA approved product therefore it's specifications would be known and outlined in the approved label.

Thanks,
Nicola

Nicola Fenty-Stewart, Ph.D.
Project Manager
Office of Scientific Investigations

From: [redacted]
Sent: Friday, August 15, 2014 9:07 AM
To: OC GCP Questions
Subject: Question retention samples for reference listed drug (RLD)
Importance: High

Good morning,

I have a quick question and shall appreciate if you can please clarify it for me.

If a sponsor is intending to use a RLD in study and the sponsor has not tested RLD for use in their BE study then:

1) Does the sponsor have to test RLD as per the test article specifications?
2) If yes or no, does the sponsor have to retain 5 times quantity of RLD to meet the requirements as stated in 21 CFR 320.63

Please advice??

Regards,
[readacted]