From: OC GCP Questions
To: [redacted]
Subject: [redacted] reserve samples in comparative bioavailability clinical trial
Date: Wednesday, June 20, 2018 1:47:00 PM
Attachments: [redacted]

Good afternoon –

Thank you for your patience. Please see the response to your question from FDA's Center for Drugs, BEQ Office.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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.

Dear [redacted]

Regarding your question from June 1,

Could you please confirm us that our product is out of the scope of the requirements of 21 CFR 320.38 and that reserve samples are therefore not needed to conduct this comparative bioavailability clinical trial against the reference listed oral drug product?

Based on the information provided about your bridging relative BA study comparing two different formulations and administration routes, it appears that reserve samples would not be needed. Please refer to Guidance for Industry: Handling and Retention of BA and BE Testing Samples (https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm072869.pdf) and 21 CFR 320.38 if you need additional information.

Regards,

Nicola Fenty-Stewart, Ph.D.
Project Management Team
Office of Study Integrity and Surveillance
Office of Translational Sciences
Center for Drug Evaluation and Research
Email: CDER-OSIS-BEQ@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, June 01, 2018 4:17 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: [redacted] reserve samples in comparative bioavailability clinical trial

Dear Sir/Madam,
We intend to submit a [redacted] (b) (2) application for a long acting injection ([redacted]) drug product and we are going to perform a comparative bioavailability clinical trial in order to establish a "bridge" between our LAI product and the reference listed oral product.
We would like to confirm if reserve samples as stated in the document, Retention of Bioavailability and Bioequivalence Testing Samples. 21 CFR Parts 312, 314, and 320 [Docket No. 89N-0367] are not required for the above mentioned study considering that:
1.- Administration route is different: intramuscular versus oral
2.- The reference product is an immediate release tablet administered daily and the testing product is a long acting injection IM in prefilled syringes, administered monthly.

We consider that our product is out of the scope of the requirements of 21 CFR 320.38 Retention of bioavailability samples (text in blue colour), as explained below in green colour:
(
b) Reserve samples shall be retained for the following test articles and reference standards and for the studies described:
(1) If the formulation of the test article is the same as the formulation(s) used in the clinical studies demonstrating substantial evidence of safety and effectiveness for the test article's claimed indications, a reserve sample of the test article used to conduct an in vivo bioavailability study comparing the test article to a reference oral solution, suspension, or injection.
[redacted]

(2) If the formulation of the test article differs from the formulation(s) used in the clinical studies demonstrating substantial evidence of safety and effectiveness for the test article's claimed indications, a reserve sample of the test article and of the reference standard used to conduct an in vivo bioequivalence study comparing the test article to the formulation(s) (reference standard) used in the clinical studies.
[redacted]

(3) For a new formulation, new dosage form, or a new salt or ester of an active drug ingredient or therapeutic moiety that has been approved for marketing, a reserve sample of the test article and of the reference standard used to conduct an in vivo bioequivalence study comparing the test article to a marketed product (reference standard) that contains the same active drug ingredient or therapeutic moiety.

[redacted]

Could you please confirm us that our product is out of the scope of the requirements of 21 CFR 320.38 and that reserve samples are therefore not needed to conduct this comparative bioavailability clinical trial against the reference listed oral drug product?

Thank you in advance for your assistance and best regards.

[redacted]

[redacted]