From: OC GCP Questions
To: [redacted]
Subject: WHODrug Coding change
Date: Thursday, August 30, 2018 11:46:00 AM
Attachments: [redacted]

Hi [redacted] –

OGCP is not familiar with this Federal Register notice (requirement). There are contacts listed at the end of the notice that would be better suited to answer your questions/concerns. I have copied the contacts from the FR notice below. I am unclear what studies you have but please note that the study contacts are product specific (drugs or biologics) Ronald.Fitzmartin@fda.hhs.gov (for drugs) or cderdatastandards@fda.hhs.gov and Stephen.Ripley@fda.hhs.gov (for biologics).

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993–0002, 301–796–5333, email: cderdatastandards@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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.

From: [redacted]
Sent: Thursday, August 30, 2018 11:12 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: WHODrug Coding change

Hi,

In preparing for the upcoming change required for submissions to use WHODG B3 format for coding of concomitant medications we have a question about studies that started in 2017 yet would not be submitted until after Mar 15 2019. According to the notice in the Federal Register (attached), the change in format to B3 only impacts studies that started after Mar 15, 2019. Yet the next sentence says B2 format will no longer be supported by the FDA after Mar 15 2019. This poses a conflict for studies that were started prior to the Mar 2019 deadline and yet will be submitted after the Mar 2019 deadline.

We have several studies underway currently that will not submit before Mar 15, 2019 or shortly thereafter. Some were started prior to the development of B3. We need some clarification. Can we submit study data in B2 format after Mar 2019 or do we need to change the coding to B3 for submission for these older studies?

Thanks for your assistance!

Take care,

[redacted]

[redacted]

[redacted]

[redacted]