From: OC GCP Questions
To: [redacted]
Subject: Commercial Drug That is Subject of Sponsor"s IND Study Belongs to Another Company
Date: Thursday, June 05, 2014 11:41:34 AM

Good morning –

Sorry for the delay in responding. We had to consult with the Center for Drugs (CDER). Although we feel that we don't have enough information to specifically answer your question, it appears that "[redacted] Device Company" would be the applicant if they submit the IND and therefore safety reporting is required under 312.32(c) and it appears the reports might also need to be submitted to the manufacturer of the product. Whether the study is under IND or IDE it would be best to discuss the reporting requirements with the regulatory project manager that will be or is overseeing the study.

Additionally since you have mentioned both a device and investigational product, it might be helpful to discuss this issue with FDA's Office of Combination Products. Please see their web page below specifically the phone number and email address at the bottom of the page.

Office of Special Medical Programs > Office of Combination Products

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [Redacted]
Sent: Thursday, May 29, 2014 7:24 PM
To: OC GCP Questions
Subject: Commercial Drug That is Subject of Sponsor's IND Study Belongs to Another Company

Dear FDA Representative,

After reviewing Part 312 and the guidance "Safety Reporting Requirements for INDs and BA/BE Studies," I still have a question:

Scenario: The sponsor, [redacted] Device Company, will perform a study using their cleared device with a commercially available drug.

- The device is not cleared for use with this particular drug, and the drug is not approved for use with this device.

- The plan is to perform a study so the device can be labeled for use with such drug.
- This study will be under IND.
- The commercial drug product for use in the study will be several dosages/formulations and will come from 2 or 3 drug manufacturers.

For the study, [redacted] Device Company will comply with:

- 21 CFR 312.32(b) for review of all info from the study
- 21 CFR 312.32(c)(1)-(3) for reporting (i.e., IND safety reports)

My question is specific to the requirements of 21 CFR 312.32(c)(4), which requires the sponsor submit safety information from the clinical study as prescribed by the relevant postmarketing safety reporting requirements (i.e., 314.80). Part 314.80 discusses requirements of the "applicant," who is defined as having an approved application under Sec. 314.50 or, in the case of a 505(b)(2) application, an effective approved application. [redacted] Device Company does not meet the definition of applicant. Ultimately, is [redacted] supposed to review/submit under 314 or should they submit the info to the drug manufacturer(s) for follow up (i.e. review and submission)?

In a similar scenario but under IDE rather than IND, the advice was as follows:

> **From:** OC GCP Questions **Sent:** Monday, September 10, 2012 7:14 AM **To:** [redacted]
> **Subject:** RE: Adverse Event Reporting Procedure for Marketed Drugs being used in IDE and non-IDE Device Trials
> Dear [redacted]:
> We have inquired with staff from the Center for Devices and Radiological Health (CDRH) regarding your questions relating to adverse event reporting associated with approved drug products that are used in a device trial. Their advisement is as follows:
> If the sponsor of an device trial (IDE or non-IDE) becomes aware of an AE associated with the use of a marketed drug product in that trial, FDA recommends that the sponsor forward the AE report to the applicant of the marketed drug product so that the applicant can evaluate the report and determine whether it is reportable under the drug postmarketing AE reporting regulations (21 CFR 314.80 for products marketed under an NDA or ANDA and 310.305 for prescription drugs marketed without an approved application). The sponsor conducting the trial is not required to submit the report directly to FDA.

Your prompt response is greatly appreciated.

Kind Regards,

[redacted]