From: OC GCP Questions
To: [redacted]
Subject: UADE reporting requirements
Date: Sunday, April 20, 2014 10:38:41 AM

Good morning –

Please see CDRH's answer below to your question.

Kind regards,

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

From: [redated]
Sent: Friday, April 18, 2014 5:25 PM
To: OC GCP Questions
Cc: [redacted]
Subject: RE: UADE reporting requirements

Hi Doreen,

In regard to the first question, the regulations do not require reporting the results of the evaluation to FDA within 10 days if determined by the sponsor not to be a UADE. If the sponsor is in doubt, we recommend over-reporting rather than under-reporting.

If the sponsor determines that the event is not related to the device as described in 21 CFR 812.3(s), the regulations do not specify that such an event needs to be reported. The term "associated with" is not defined.
However, it is important to remember that FDA can request reporting of any adverse event information related to the investigation under 812.150(b)(10):

Other. A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

If you or your requestor have further questions, please let us know.

Regards,

Lynn

From: OC GCP Questions
Sent: Sunday, April 13, 2014 11:00 AM
To:
Subject: FW: UADE reporting requirements

Dear CDRH, could someone please assist this person with her question. She has been waiting a long time. Thank you! Doreen

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

From: [Redacted]
Sent: Friday, March 15, 2013 8:13 AM
To: OC GCP Questions
Subject: RE: UADE reporting requirements

I have not seen a response to this email and am resending. Thank you for your prompt response.

[redacted]

From: [Redacted]
Sent: Wednesday, February 27, 2013 12:45 PM
To: gcp.questions@fda.hhs.gov
Subject: UADE reporting requirements

Dear Dr. Toth-Allen-
I have a two questions regarding Sponsor reporting requirements for UADEs.

> Per 21 CFR 812.3(s) a UADE is defined as:
> any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

And per 21 CRF 812.150(b)(1) Sponsor reports:

> A sponsor shall prepare and submit the following complete, accurate, and timely reports:
> (1)Unanticipated adverse device effects. A sponsor who conducts an evaluation of an unanticipated adverse device effect under 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests.

First, if a sponsor conducts an evaluation of an occurrence initially classified by the Investigator as a UADE but determined by the Sponsor NOT to be a UADE, do the regulations require reporting the results of the evaluation to FDA within 10 days?

Second, if a sponsor conducts an evaluation of an occurrence and determines it is SERIOUS + UNANTICIPATED but NOT RELATED to the device (i.e. a Serious, Adverse Device ***Event*** but not a

Serious Adverse Device ***EFFECT***), do the regulations require reporting the results of the evaluation to the FDA within 10 days? Please note the regulations use the word effect not event when defining a UADE.

A definition of the term “associated with” would be helpful in understanding the intent of the regulation.
Thank you in advance
[Redacted]