From: OC GCP Questions
To: [redacted]
Subject: EIR
Date: Friday, August 14, 2015 3:01:20 PM

Good afternoon [redacted] –

I reached out to our ORA field BIMO inspection expert to make sure we answer your question. Please see his response below.

Have a great weekend.

Doreen

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

From: Colon, Hector J.
Sent: Friday, August 14, 2015 2:35 PM
To: OC GCP Questions
Subject: RE: EIR

Hi Doreen,

There are two different issues here that I would like to clarify:

1- It seems [redacted] is confusing "verbal items" (which are inspectional observations that are not issued in written but discussed verbally) with the acronym VAI (which stands for "voluntary action indicated", and defined on your response below). VAI is not a "finding" as she says, VAI is a classification for the inspection. Most importantly, the Center who issues the assignment has the final determination on the inspection classification after further review of the EIR, exhibits, firm's response to the 483, etc. The field CSO and his/her District management might recommend a VAI classification, for example, but that recommendation could potentially be upgraded (to OAI) or downgraded (to NAI) by the Center. I always tell the firm that the Center will determine the final classification of the inspection and initiate any applicable regulatory actions, if warranted.
2- As far as I'm concerned, ORAHQ has **not** issued any instructions to the field to stop issuance of FMD-145 copies of the EIRs to the inspected firms. I know the FMD was being updated but in the meantime District Offices should continue to do business as usual, including the issuance of FMD-145 copies. The firm should wait for a reasonable period of time (at least 6 months in my opinion) and if the EIR is not received then either make a new request to their home District Office (for domestic inspections) or to the assignment issuing Center (for

foreign inspections); or initiate a FOIA request.

Hope this helps,
Thanks,

Héctor J. Colón Torres, MPH
LCDR, US Public Health Service
CSO, BIMO Program Expert
FDA/ORA/Office of Operations
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From: [redacted]
Sent: Friday, August 14, 2015 11:22 AM
To: OC GCP Questions
Subject: Re: EIR

To be clear, the 483 and the VAI were separate findings the 483 was going to the PI who was removed from the study and no longer employed by the site) as indicated by FDA field agent the VAI was a separate finding in another study and a finding for the site. My only question is are there ANY circumstances when an FDA audit has no follow-up EIR.