From: OC GCP Questions
To: [redacted]
Subject: Post marketing Adverse Event Reporting
Date: Tuesday, April 07, 2015 12:41:19 PM

Good afternoon –

I think that you would have to discuss the situation directly with the subject to validate and document that the adverse event actually occurred. I don't think you can solely rely on the social media posting.

Please see the web links and guidances below that discuss FDA's view on social media.

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401087.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf

FDA Issues Draft Guidances for Industry on Social Media and Internet Communications About Medical Products: Designed with Patients in Mind | FDA Voice

About the Center for Drug Evaluation and Research > Social Media Guidance Webinar – July 10, 2014

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: Tuesday, April 07, 2015 11:10 AM
To: OC GCP Questions
Subject: Post marketing Adverse Event Reporting

Office of GCP,
Please provide insights on the following scenario. If an employee or contractor of a pharmaceutical company becomes aware of an adverse event through social media (that is not affiliated with the pharmaceutical company) what is the FDA's expectations regarding reporting the AE. For example if an employee sees the following post on Facebook "Last night my friend took [redated] and then started vomiting immediately afterwards, it was disgusting!" how would the FDA expect the employee to proceed.

Thank you in advance for any information you can provide.

[redacted]