From: OC GCP Questions
To: [redacted]
Subject: RE: Compliance and Enforcement
Date: Tuesday, November 28, 2017 2:27:00 PM
Attachments: [redacted]

Good afternoon,

The FDA has authority for certain enforcement activities under provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and through a delegation of authority from the Secretary of Health and Human Services. FDAAA amended the Federal Food, Drug, and Cosmetic (FD&C) Act to include specific "prohibited acts" for violations of the ClinicalTrials.gov requirements for registering clinical trials, submitting results information, and submitting false or misleading information to the ClinicalTrials.gov database. As it has done in the past, the FDA will undertake activities to encourage voluntary compliance with ClinicalTrials.gov requirements similar to those types of activities the agency takes to encourage compliance with other FDA statutory provisions, although such actions will be tailored to the unique requirements of ClinicalTrials.gov. For example, typically when the FDA believes there may be a violation of the law, it sends a letter to give notice of the potential violation and an opportunity for voluntary correction. If a responsible party fails to voluntarily correct the clinical trial information, FDAAA then expressly requires the agency to send a notice of non-compliance once the agency has determined that there is a violation. This provides a party with an additional opportunity to correct the violation.

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

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Office of Good Clinical Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Monday, November 27, 2017 1:00 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Compliance and Enforcement

Good morning,

I am developing some training modules and was hoping to include some additional information around the enforcement process for non-compliance issues related to clinicaltrials.gov:

- What method or process does the Secretary (or NIH) use to notify the responsible party that they have 30 days to remedy a non-compliance prior to implementing a penalty/fine? Is it a formal letter, or email?

Thank you for any guidance you can offer.

Kind regards,

[redacted]