

From: OC GCP Questions
To: [REDACTED]
Subject: Question on Warning Letters & Foreign Inspections
Date: Tuesday, October 10, 2017 12:32:46 PM
Attachments: [REDACTED]

Good afternoon –

Please see FDA's Office of Regulatory Affairs answer below. I have also included a link to the RPM as referenced below.

[Regulatory Procedures Manual](#)

Kind regards,

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



This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Glasgow, David K
Sent: Tuesday, October 10, 2017 11:53 AM
To: OC GCP Questions; ORA BIMO Inspection POC
Subject: RE: Question on Warning Letters & Foreign Inspections

Hi, Doreen.

FDA does issue Warning Letters to inspected foreign establishments when appropriate. The FDA Regulatory Procedures Manual is available on the fda.gov web site. Warning Letter processes are covered in chapter 4.

David K. Glasgow

Deputy Program Director, Office of Bioresearch Monitoring Operations

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From: OC GCP Questions

Sent: Tuesday, October 10, 2017 11:43 AM

To: ORA BIMO Inspection POC <orabimoinspectionpoc@fda.hhs.gov>

Subject: Question on Warning Letters & Foreign Inspections

Dear ORA –

Can you assist with answering this query?

Thank you!

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



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From: [REDACTED]

Sent: Tuesday, October 10, 2017 10:50 AM

To: OC GCP Questions

Subject: Question on Warning Letters & Foreign Inspections

Hello,

With regard to inspection of a foreign site, can you tell me if the FDA sends warning letters to non-US sites? If not, can you tell me why? Is there another process that is used to communicate findings and is there some kind of policy for this that I can find on your web site? Thank you in advance for any information you can provide.

Kind regards,

[REDACTED]

[REDACTED]