From: OC GCP Questions

To:

Subject: FDA Clinical Inspections List

Date: Wednesday, January 28, 2015 11:56:48 AM

Importance: High

Good afternoon --

If this is the inspection list you are referring to, you will need to contact CDER's Office of Scientific Investigations for (drugs). Please see their contact information in the second link. Please note there are other contacts for devices and biologics.

Drug Approvals and Databases > Clinical Investigator Inspection List (CLIIL)

About the Center for Drug Evaluation and Research > FDA Good Clinical Practice Contacts

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:

Sent: Wednesday, January 28, 2015 11:01 AM

To: OC GCP Questions

Subject: FDA Clinical Inspections List

Importance: High

Good Morning,

I am working on a background investigation for a possible records from the US FDA Drug Approvals and Databases — Clinical Investigator Inspection List. Could you provide information as to what this list entails? Or provide a contact method to someone who can?

If possible, please contact me at the number below or reply to this email as soon as possible, due to the time sensitive nature of this investigation.