From: OC GCP Questions
To: [redacted]
Subject: FDA Audit
Date: Thursday, November 20, 2014 2:55:43 PM

Good afternoon –

You will need to contact someone from FDA's Regional District Office in the Office of Regulatory Affairs. I believe in NC, it would be the Atlanta District. If this is not the correct regional office, they can direct you. Please see the web link below.

Investigations Operations Manual > SOUTHEAST REGION

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, November 20, 2014 10:19 AM
To: OC GCP Questions
Subject: FDA Audit

Hello,

[Redacted] is an investigative site performing drug clinical trials in [redacted]
. On January 14, 15, and 16, 2014 our site had an FDA audit which was performed by FDA Inspector, [redacted], out of Charlotte, NC. The following two studies were audited:

[redacted]

As of today's date, we have not received any written correspondence from the FDA with the results of the audit. We were told that it would take some time to get results, but we feel that at this point we should have received something. We just want to be sure that we did not miss something. Could someone please contact me to give me an idea of when our site could expect to receive our letters?

Thank you for your attention to this very important matter.

Best regards,

[redacted]