**From:** OC GCP Questions
**To:** [redacted]
**Subject:** trying to locate 483 issued in late 1980"s
**Date:** Thursday, June 14, 2018 12:24:00 PM
**Attachments:** [redacted]

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Good afternoon –

You will need to make an FOI request asking for the 483 in question for the specific firm. You'll need to identify the firm name and inspection date. Before you make such a request, please visit our FOI web page http://www.fda.gov/foi/foia2.htm, Whom to Contact About FOIA for more information on how to get information through FOI Regarding 483s for clinical investigators (CI) studying drugs and biologics.

Please be aware, it can take some time to actually receive the copy, even though acknowledgement of your request may be returned quite rapidly. The FDA unit that would supply the copy needs to appropriately redact the 483 and then issue the copy to you. They likely have a substantial backlog of requests.

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

U.S. FOOD & DRUG ADMINISTRATION

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.

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**From:** [redacted]
**Sent:** Thursday, June 14, 2018 11:49 AM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** trying to locate 483 issued in late 1980's

Good Morning:

How can we locate an historic 483? I have tried but to no avail. If this is not the correct venue for this could you please direct me to the proper department?

Thank you.

[redacted]