

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Address for ORO?
Date: Friday, May 09, 2014 7:44:46 AM

Hi ~~ŽŮ^ää&^ää~~

Sorry for the delay in responding. I had to reach out to a colleague in ORA. Please see his answer below.

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: Colon, Hector J.
Sent: Thursday, May 08, 2014 4:15 PM
To: OC GCP Questions
Cc: Kezer, Doreen M
Subject: RE: Address for ORO?

Hi Doreen,

The address listed under 21 CFR 11.100(c)(1) is still valid and the correspondence sent there is received by ORA/Office of Operations (after the October 2012 reorganization, the name "Office of Regional Operations" was abolished). The other valid address is that one listed in the Investigations Operations Manual (IOM) 2014 of 12420 Parklawn Drive (ELEM), Rockville, Maryland 20852. Both of these addresses can be used.

Regards,

Héctor J. Colón Torres, MPH
LCDR, US Public Health Service
CSO, BIMO Program Expert
FDA/ORO/Office of Operations
Office of Medical Products and Tobacco Operations

12420 Parklawn Drive,
Element Bldg., Rm. 2135,
Rockville, MD 20857
Tel: +1 (301) 796-3899
Fax: +1 (301) 827-4090
hector.colon@fda.hhs.gov

From: OC GCP Questions
Sent: Wednesday, April 30, 2014 11:45 AM
To: Colon, Hector J.
Subject: Address for ORO?

Hi Hector –

Can you assist with this request? I don't know the correct address either.

Thank you!
Doreen

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: Monday, April 28, 2014 7:03 PM
To: OC GCP Questions
Subject: Address for ORO?

In order to comply with 21 CFR § 11.100(c)(1), I would like to send notification of using electronic signatures to the Office of Regional Operations. I have found two address (Both in Rockville, MD) and I am not certain if either is current.

Can you please send me the correct address?

Kind regards,

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