From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Debarment
Date: Thursday, August 30, 2018 8:34:00 AM

Good morning -

Please see the links below to CI disqualifications and debarment lists. I believe that these proceedings can take place for CIs outside the US conducting FDA regulated studies. However, I don't recall one in recent years.

Compliance Actions and Activities > Clinical Investigators - Disqualification Proceedings

FDA Debarment List (Drug Product Applications)

Kind regards,

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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.

-----Original Message-----
From: [redacted]
Sent: Tuesday, August 28, 2018 1:26 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Debarment

Can the / does the FDA debar/disqualify clinical investigators located ex-US (assuming they participate in studies being submitted to the FDA for US clearance)?

Kind regards,

[redacted]

[redacted]