From: OC GCP Questions
To: [redacted]
Subject: GUDUFA Self-identification of generic drug facilities and organization questions
Date: Wednesday, January 10, 2018 9:16:00 AM
Attachments: [redacted]

Good morning –

The guidance was not attached. I located the guidance and you will need to contact the Office of Generic Drugs at the website below. Please see the bottom of the page "Contact FDA";

About the Center for Drug Evaluation and Research > Office of Generic Drugs

Kind regards,

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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: [redacted]
Sent: Monday, January 08, 2018 3:14 PM
To: gcp.questions@fda.gov; OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: GUDUFA Self-identification generic drug facilities and organization questions

Our clinical research sites were contacted by potential sponsors with the attachment mentioned above in the subject. I have read this document and request your opinion on this matter.

Except for the section on "removing drug from a primary container closure and subdividing the contents" I cannot think of any relevance of this Guidance document may have to a protocol not yet received or reviewed that would implicate our clinical research site involved in protocol guided sponsor specific research on volunteer subjects, as a candidate for self-identification as discussed in this on this.