From: OC GCP Questions
To: [redacted]
Subject: ensuring compliance with 21 FCR part 211.1
Date: Tuesday, June 02, 2015 2:19:07 PM

Good afternoon –

It is best to send your email with your compounding questions directly to the Center for Drugs (CDER) at druginfo@fda.hhs.gov.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, June 02, 2015 1:14 PM
To: OC GCP Questions
Subject: ensuring compliance with 21 FCR part 211.1

Hello, I have a few questions about the compounding of [redacted] capsules and matching placebo while remaining compliant with 21 FCR part 211.1.

The protocol that has been presented to pharmacy has received NIDA funding, and calls for the over-encapsulation of lorcaserin tablets in size 00 opaque gelatin capsule shells. I would be compounding them for each patient for use within 7 days.

1. Is this manufacturing (if done per patient, and not a large batch), and do I need to validate dissolution and disintegration, etc.? If so, would you share best practices for that process?
2. Does the need to do validity testing decrease if I do not back fill the lorcaserin caps (provided that method can still maintain the blind)?
3. The gelatin caps we have are very easy to pull apart and tampering would not necessarily be detected. What is your suggestion for compounding tamper evident capsules to comply with FDA regulation?

Best regards,

[redacted]