From: OC GCP Questions
To: [redacted]
Subject: Questions on the requirements for the withdrawal of investigational drug products
Date: Thursday, July 31, 2014 11:45:37 AM

Good morning –

We reached out to the Center for Drugs (CDER) to answer your email. Please see their instructions below.

CPG Sec. 444.100 states that investigational product recalls is better termed "stock recovery" and not "recalls" in the regulatory sense: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074384.htm.

And the Regulatory Procedures Manual (RPM) define stock recovery in the glossary (chapter 11) and explicitly states that recalls do not include "stock recovery" (chapter 7, footnote 2): http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/default.htm.

In addition, FDA CDER recommends that the IND holder speak to their regulatory project manager (RPM) for guidance in a specific situation.

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

From: [redacted]
Sent: Tuesday, July 29, 2014 9:28 AM
To: OC GCP Questions
Subject: Questions on the requirements for the withdrawal of investigational drug products

Dear Sir / Madam,

this email reaches You from [redacted], asking for information on a topci concerning investigational drug products - in the US. If with the following questions I address the wrong FDA office, I´d like to ask You for the corresponding contact information of the office concerned with this subject.

What are the US FDA / CDER requirements and demands for a recall i.e. withdrawal of investigational drug products from clinical trial sites or trial participantes / patients? I´m afraid even after some research including several FDA webpages and quite a few doucments I could not come to any clear conclusion as to what is required or expected from FDA / CDER in such a case.

- Must the trial sponsor notify the FDA in case of the withdrawal of an investigational drug product from trial participants / sites?
- What circumstances make it mandatory to notify the FDA of a recall of clinical trial supplies (investigational products)? Recall due to a product quality issue? Due to an adverse event?
- Is a suspected issue with a investigational drug product reason enough to notify the FDA?
- What are the time requirements / timelines? For example: How many days before or after start of the withdrawal does FDA have to be informed?
- Who at FDA needs to be addressed in a recall case of investigational products?
- Are there forms to be used to notify FDA? Or is an electronic communication platform to be used, such as MedWatch?
- Does FDA categorize and monitor the recall of an investigational drug product the same way it does with marketed products?
- Does the sponsor have to provide a final recall report to the FDA? What information is to be provided in that report? Is there a report template to be used?

I realize that several of these questions may be covered by the regulations for marketed drug produts, but I simply could not find any direct link between those and investigational drug products. Please accept my apology should I have missed a plain and clear cut guidance out there. Thank You for Your help.

Sincerely,

[redacted]