From: OC GCP Questions
To: [redacted]
Subject: Can you give us guidance please
Date: Friday, October 02, 2015 1:44:50 PM

Good afternoon --

I believe this email was sent earlier in the week perhaps by a colleague. I had to refer her/him to the Center for Drugs (CDER) at druginfo@fda.hhs.gov. They will respond to your directly. They might have to consult with one of the review divisions in CDER (Respiratory) to get their take on the situation and give you advice. I cannot comment from an FDA perspective on OSHA standards.

Additionally you can always call them as well and explain your situation **(301-796-3400).** If you have the IND number it would be helpful for you to give this number to them. This way they can consult with the regulatory project manager (RPM) of the IND to get an answer to your question/situation.

Kind regards,

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

From: [redacted]
Sent: Friday, October 02, 2015 12:31 PM
To: OC GCP Questions
Subject: Can you give us guidance please

GCP,
We are currently conducting a clinical trial for a COPD medication in liquid form. The medication in liquid form, comes in Pods that are torn open by a razor blade and placed in a nebulizer. Please guide our site in a situation where the Sponsor is demanding us to collect the torn open pods with Investigation product still in them from our subjects. The protocol says only to collect the torn open used study drug pods containing COPD medication. There is no guidance as to how we are to handle and store these used, contaminated containers. It is our position that collecting these containers that contain open liquid IP would expose my employees and others to physical contact with investigational product. I have suggested that I give the subjects a hazmat container to collect these pods after use, but feel uncomfortable letting anyone open the hazmat container to count them in my facility. There is a foil packet that contained the unused pod. We have been collecting all empty and unused packets along with the boxes they come in for compliance. The local chapter of OSHA has guided me not to expose my employees in any way with the collection of open containers and vials of IP that cannot be resealed.
What guidance can the FDA office give us?
Thank you,