From: OC GCP Questions
To: [redacted]
Subject: Study Drug
Date: Monday, December 18, 2017 7:12:00 AM
Attachments: [redacted]

Good morning –

Even though drug is FDA approved, it is being used in a clinical study under IND (I assume), the following still needs to apply.

§312.59 Disposition of unused supply of investigational drug.
The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with §312.57.

FDA's regulations on records about disposition of the investigational drug state, "An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59."

As you can see, the regulations are very general to allow sponsors and study sites the necessary flexibility to account for the supplies of investigational product that were received, administered, returned, and the final disposition (e.g., destruction) of any unused investigational articles. Please note that the records maintained at the site need to be adequate to show "disposition of the drug, including dates, quantity, and use by subjects.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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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: Friday, December 15, 2017 3:24 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Study Drug

If a clinical trial utilizes a drug that is FDA approved, as long as the drug is accounted for, can this study drug be disposed of in a similar manner as it recommended for patient disposal (e.g. in household trash)?

Thanks.