From: Toth-Allen, Jean
Sent: Wednesday, May 17, 2006 12:58 PM
To: **[Redacted]**
Cc: **[Redacted]**
Subject: RE: Investigational Drugs

Dear Ms. **[Redacted]**:

Thank you for your inquiry with regard to investigational drugs.

The regulations require that a sponsor ensure that unused drugs are returned or otherwise disposed of in a way that does not expose humans to risk and that records be maintained as to disposition of all such drugs (21 CFR 312.59). Allowing individual study sites to dispose of unused investigational drugs would not be inappropriate. You as the core pharmacy/sponsor can specify the conditions for such drug disposal or allow the site(s) to follow their own disposal policy if it is acceptable to you. The individual sites would need to maintain proper documentation regarding the amounts of drug, identifying codes, date of disposal, and actual method of disposal and a copy of such documentation would need to be sent to you for your records. While you might not have the resources to monitor actual drug disposal at each study site, review of drug accountability records, which would include such disposal documentation, is usually part of the final study monitoring or close-out visit for each site.

The degree to which temperatures at which drugs are maintained is monitored is highly dependent upon the temperature range involved. For ambient or room temperature, it would seem issues would only arise if building operational conditions resulted in a disruption to either the heating or cooling system for a substantial enough period of time to allow temperatures to fall or rise significantly, depending upon the season. Drugs usually have a range of temperatures under which they are required to be maintained. When the required temperatures are noted as ambient or room temperature, the appropriate maintenance range commonly spans most ordinary building fluctuations.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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.

-----Original Message-----
From: **[Redacted]**

Sent: Tuesday, May 09, 2006 1:52 PM
To: Fitzpatrick, Cynthia
Subject: Investigational Drugs

Dear Ms. Fitzpatrick-
I acquired your business card while visiting with the FDA representative who
attend the ACRP meeting in Phoenix last week.

I am **[Redacted]**. I need clarification on regulations affecting clinical trials.
I looked through the regulations but did not find definitive answers for my
two issues. I hope you can help or suggest someone who can.

1-We serve as the core pharmacy/sponsor for an outpatient drug study. Is
there anything in the regulations that states that the used and empty
bottles for such a study must be returned to the core pharmacy? Is it
possible for a site to perform a count of the remaining drug, then destroy
the bottles on location assuming they have a drug destruction policy? We do
not have a monitor or CRO visiting each site to witness such destruction.

2-Is there any regulation stating the frequency that temperatures must be
monitored for study drugs? The study I was asked about is for outpatients
and the drug is kept at ambient or room temperature.

Thank you in advance for your professional opinion.
[Redacted]