From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, March 09, 2006 7:54 AM
To: **[Redacted]**
Subject: RE: Information to be included on labels for clinical trial drug supplies

Dear Ms. **[Redacted]**,

I will provide you wilth very basic information concerning investigational product labeling. However, I strongly suggest you contact the appropriate review division as the division may have other suggestions on what needs to included on the investigational product label.

As a rule of thumb, the label of an IND drug product should comply with the general labeling requirements under 21 CFR 201.1. FDA issued a guidance several years ago entitled "Guidance for Industry: Guideline on the Preparation of Investigational New Drug Products (Human and Animal)" (see www.fda.gov/cder/guidance/old042fn.pdf). This guidance explains that FDA expects investigational drug products that will be used in human subjects to be manufactured in compliance with good manufacturing practices (CGMPs). Normally, to be in compliance with CGMPs, drug products must bear certain information on the product labeling, such as control numbers (or lot numbers) and expiration dates. However, in the case of investigational drug products, FDA recognizes there may be instances when including this information on the product labeling might have an adverse impact on the "blinding" of the product. So FDA permits excluding control numbers and expiration dates from the product labeling for "blinding" purposes, provided this information is provided separately to, for example, the clinical investigator for the code-breaking purposes.

But again, I think contacting the appropriate review division would be your best source of labeling information.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

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: Wednesday, March 08, 2006 6:34 PM
To: OC GCP Questions
Subject: Information to be included on labels for clinical trial drug supplies

[Redacted]

Dear Sirs:
My name is **[Redacted]** and I work for **[Redacted]**.

We are currently working on a project concerning labelling for clinical trial drug supplies, and I am therefore searching for information on clinical trial labelling requirements in various countries, including the U.S.A.

Having searched the FDA's website I could find that such labelling, as per 21 CFR para. 312.6, must include the statement "Caution: New Drug – Limited by United States law to investigational use". Other than this, what other regulatory requirements are there in terms of language/terms to be used, and what information should be included as a minimum in clinical trial drug labels?

I thank you in advance for any help you can provide us, and send you my best regards,

[Redacted]