From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, September 06, 2006 7:54 AM
To: **[Redacted]**
Subject: RE: investigational drug labeling re: expiration date

Dear Mr. **[Redacted]**:

Your inquiry about the need for expiration dating on the investigational drug product labeling was forwarded to me for a response.

FDA issued a guidance several years ago entitled "Guidance for Industry: Guideline on the Preparation of Investigational New Drug Products (Human and Animal)" (it's electronically available at 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).

Generally, 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 made available separately, for example, to the clinical investigator should the blind or randomization code need to be broken. Stability information should be available when the product is shipped from the sponsor to the clinical study site. The pharmacist should/needs to have access to expiration dating information but, as noted above, the expiration dating need not always be present on the product labeling (see page 6 of the guidance for more details).

I hope this information is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 14B17
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

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: Wednesday, August 30, 2006 3:45 PM
To: OC GCP Questions
Subject: investigational drug labeling re: expiration date

Hello,
Is it required that the label on an investigational drug vial have a drug expiration date printed on it?
Thank you,
[Redacted]