From: Toth-Allen, Jean
Sent: Monday, January 30, 2006 10:38 AM
To: **[Redacted]**
Subject: RE: 1572
[Redacted],

We have been answering industry inquiries as follows:

The date on the form refers to the Office of Management and Budget's (OMB's) approval period during which FDA may collect information contained in the form. Sites may continue to use the form, even though the OMB date has passed; it has no impact on the utility of the form itself. Furthermore, FDA does not expect sponsors to ask clinical investigators to routinely "update" forms previously submitted simply because the OMB expiration date has changed.

If and when a site needs to complete a new 1572, they should visit FDA's Forms Distribution Page (http://www.fda.gov/opacom/morechoices/fdaforms/cder.html) and download the most recent version posted there. It is doubtful that there will be any significant changes to the new version, merely an updated OMB expiration date.

We have no information as to when a form with an updated expiration date will be posted. Hope this us helpful.

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.

From: **[Redacted]**
Sent: Friday, January 27, 2006 6:55 PM
To: OC GCP Questions
Subject: 1572

The date on the online version of the 1572 form says it expires January 31, 2006. A requester from a clinical trial site is asking " is there any new information from the FDA regarding the FDA Form 1572 which currently expires January 31, 2006. This is the latest FDA Form 1572 posted on the FDA website and there is no information on the website that a new form will be posted in the near future. Will you please provide information on how we are to move forward with this?

Can you inform me? **[Redacted]**