From: Toth-Allen, Jean
Sent: Tuesday, August 22, 2006 2:00 PM
To: '**[Redacted]**'
Subject: RE: Phase 4

Dear Ms. **[Redacted]**:

Thank you for your inquiry regarding the use of the Form FDA 1572 in phase 4 studies.

Form FDA 1572, while an FDA form, is provided for the benefit of study sponsors - to provide one form to both capture essential information regarding all involved with the use of an investigational product and provide a signed contract with study investigators which promises their compliance with applicable regulations. (While sponsors often submit copies of completed 1572s as part of their IND application, it is not required.) Phase 1, 2, and 3 studies involve investigational products, i.e., products whose safety and effectiveness/efficacy has not yet been demonstrated. It is therefore essential that sponsors have pertinent information about the use of these products. Phase 4 studies are conducted on approved products, whose safety and effectiveness/efficacy for the indicated uses have been reasonably demonstrated. Therefore, while still advisable for sponsors to ensure compliance with applicable regulations it is not quite so urgent that they are knowledgeable about where their product is being used. However, sponsors are free to use a 1572 for phase 4 studies if they wish, even though it is not specifically required.

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.

From: **[Redacted]**
Sent: Wednesday, August 16, 2006 11:29 AM
To: OC GCP Questions
Subject: Phase 4

Dear FDA,
For a phase 4 study, is a 1572 form required?
If yes, what box is checked on page 2 (box 8)?

Thanks and please advise,
[Redacted]