From: Toth-Allen, Jean
Sent: Tuesday, March 07, 2006 8:41 AM
To: **[Redacted]**
Subject: RE: Recruiting Placebo Patients from Previous Studies

Dear Mr. **[Redacted]**:

Thank you for you inquiry regarding subjects who receive placebos in clinical trials.

There are neither FDA regulations nor guidance that specifically address this issue. However, if the informed consent process is adequate in the clinical studies and there is no coercion to participate, there does not appear to be an ethical concern here. Potential subjects, who were randomized to a placebo treatment in a past study, would again be made aware of the nature of the on-going study and the potential to once again be given a placebo rather than the investigational product. It would then be their decision whether to participate or not. In addition, while offering active treatment to subjects who were randomized to the placebo group is not uncommon, it is not a universal practice.

The "placebo effect" and how individuals respond to placebos in general are complicated issues that are not fully understood. Given what is presently known in this regard, the potential for introducing bias from "recycling" subjects who received a placebo in a past study does not seem great.

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: Thursday, March 02, 2006 2:29 PM
To: OC GCP Questions
Subject: Recruiting Placebo Patients from Previous Studies

Dear Ms/Sir,

At a recent symposium, it had come to my attention that a few pharmaceutical companies, due to recruiting difficulties, have initiated programs of recycling placebo patients from their past trials.

As I understood the discussion, patients who had been on placebo in a recent study would be asked to participate in the new studies with the same potential of being on placebo or active product. They would return to their previous physician who is aware of their placebo status and would be re-screened. As I understood, this was taking place on Phase III studies not Phase I.

This does not seem to be an appropriate. The possibility of bias is strong for both the patient and investigator who have first hand knowledge of the patient's experiences on placebo. It also seems unethical to not offer the patients open label active treatment.

Has there been anything published in the FDA guidances etc. addressing this recruiting process. Are there regulations which would address this type of activity?

Any insight you can offer on the matter is greatly appreciated.

Thank you in advance,

[Redacted]