From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, August 17, 2004 9:47 AM
To: **[Redacted]**
Subject: RE: Question regarding advertisement

Dear Mr. **[Redacted]** ,

If you have any doubts as to whether the IRB approved the advertisement for your study, I suggest that you (or the clinical investigator) contact the IRB to confirm whether the IRB indeed reviewed and approved it. FDA's regulations are fairly general and do not specifically address this situation, however, having the IRB's response in writing is an excellent practice, and would make it clear that you received IRB approval for the advertisement should the question later arise.

For more information on this topic, you could consult FDA's "Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators." This document is posted on FDA's Good Clinical Practice website: http://www.fda.gov/oc/gcp. Once at the web page, click on "Guidances and Information Sheets" in the middle column; the Information Sheets are the first item on the list. The section that discusses advertisements and their review by the IRB is titled "Recruiting Study Subjects."

I hope this 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)
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Rockville, MD 20857

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-----Original Message-----
From: **[Redacted]**
Sent: Monday, August 16, 2004 1:52 PM
To: 'gcpquestions@oc.fda.gov'
Subject: Question regarding advertisement

Hello,

I am conducting a Phase 4 Clinical trial and I came across a question that I could not find the answer to.

In order to bolster enrollment, we planned on advertising on the web and in patient mailings. My question is this: If the IRB has already approved the protocol but did not specifically approve the advertisement (although submitted), do we still need to obtain stamped approval of the advertisement before posting it on the web or mailing it to patients?

If the advertisement was submitted and returned without comments, would that be considered "approved"? I was thinking that maybe a verbal confirmation/approval from the site would suffice, but I wanted to confirm.

Please advise.

Where can I find more information on this?

Thank you,

[Redacted]