From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, November 23, 2005 8:47 AM
To: [Redacted]
Subject: RE: Off-label use question

Dear Ms. [Redacted]:

Yes, a change in the route of administration would require an IRB approved research protocol. All studies, even if they are "exempt" studies involving lawfully marketed products, must comply with the requirements for institutional review set forth in 21 CFR 56 and with the requirements for informed consent set forth in 21 CFR 50. [See 21 CFR 312.2(b)(1)(iv).]

However, based on the minimal information that you provided in your e-mail (i.e., that the study involves a change in the route of administration of the product), it does NOT appear that the clinical investigation you described would be exempt from FDA's Investigational New Drug (IND) regulations found at 21 CFR 312. 21 CFR 312.2(b)(1) lists the criteria that would allow a study involving a lawfully marketed product to be exempt from the IND requirements. The pertinent section reads:

"(1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if ALL the following apply:...

"(iii) The investigation does NOT involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;..." [Emphasis added.]

The IRB might want to follow up with the investigator to determine if he/she has obtained an IND for this study. He/she may contact FDA's Division of Drug Information, Center for Drug Evaluation and Research, at (301)827-4573, for an IND package and to discuss this issue further.

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 9C24
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.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, November 22, 2005 12:09 PM
To: gcpquestions@oc.fda.gov
Cc: [Redacted]
Subject: Off-label use question

Hello - I have a question about a drug that is FDA-approved for intravenous administration that a physician would like to administer intra-arterially. Does this change in the route of administration require an IRB approved research protocol?

Thank you,
[Redacted]

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