From: Hommel, Carolyn - OC
Sent: Wednesday, November 26, 2003 10:10 AM
To: [redacted]
Cc: Dockets, FDA
Subject: RE: Listing of FDA sanctioned resources

Dear [redacted],

Your e-mail to Dockets Management Branch was forwarded to me for a response.

In answer to your question, the Food and Drug Administration (FDA) neither endorses nor prescribes any specific education programs, nor does FDA maintain a list of "other sources of appropriate instruction."

The August 8, 2003, Federal Register notice that you mentioned in your e-mail is actually an announcement regarding the availability of grants from FDA to develop orphan products. The notice states that institutions who are awarded grants are responsible for providing their key personnel with appropriate training in human subject protection responsibilities and requirements. It notes that many institutions require such training, and identifies, as possible "appropriate sources" of instruction, the on-line tutorials available from the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP). The notice also mentions that the University of Rochester has made its training program available to individual investigators, and states that the University of Rochester's training manual may be obtained through Centerwatch, Inc. I have attached the notice for your information.

I hope this relieves any confusion you may have had.

If you have any additional questions, please do not hesitate to contact this office.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program (HF-34)
Office for Science and Health Coordination
Office of the Commissioner
US Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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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 25, 2003 11:39 AM
To: fdadockets@oc.fda.gov
Subject: Listing of FDA sanctioned resources

To whom it may concern:

My name is [redacted], a clinical research organization and I work in their training department. On your Federal Register: August 8, 2003 (Volume 68, Number 153) page 47342 there was mention of "Other sources of appropriate instruction" including a manual titled *Protecting Study Volunteers in Research* by an outside company called Centerwatch. They sent us a solicitation for this manual and obviously highlighted your endorsement.

We were wondering if there was a list the FDA had compiled that contained other "sources of appropriate instruction" or endorsed reference material not published by the FDA? We would be very interested in instructional material the FDA deems appropriate and worth reviewing.

Thank you,

[redacted]