From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, May 31, 2005 11:11 AM
To: REDACTED
Subject: RE: Dangerous Goods Certification

Dear REDACTED,

FDA does not have a certification program for clinical study sites. The form that you reference may be one that is required by OHSA; it is not required by FDA regulations. You might want to clarify this point with the sponsor.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857

Telephone: 301-827-3340
.

-----Original Message-----
From: REDACTED
Sent: Thursday, April 21, 2005 4:18 PM
To: gcpquestions@oc.fda.gov
Subject: Dangerous Goods Certification
Importance: High

To Whom It May Concern:

Are there any FDA regulations regarding the certification of clinical study sites that send laboratory samples to the sponsor? REDACTED a study that requires "dangerous goods certification," and did not know if that was simply the sponsor's guideline or if it was one directly from the U.S. Food and Drug Administration.

Thank you.

REDACTED