From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, May 24, 2006 7:42 AM
To: [purged]
Subject: RE: Question

Dear [purged]:

FDA does not have any plans to do so at this time.

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 14-B17
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: [purged]
Sent: Monday, May 22, 2006 9:12 AM
To: OC GCP Questions
Subject: Question

Does tha agency plan on adding addtional regulations
for Good Clinical Practices regarding the Quality
Assurance unit for a company?