From: OC GCP Questions

Sent: Wednesday, October 21, 2015 4:09 PM

To:

**Subject:** RE: Clinical trials on hold

Dear :

Federal law in general prohibits FDA employees from providing information about investigational products that may be of a commercial, confidential nature --- which would include information about product applications and/or approval status. Clinicaltrials.gov is a searchable database would have public information regarding clinical trials; however, it would not disclose whether or not the trial had been placed on clinical hold.

I hope that this information is helpful. Please contact us at <a href="mailto:screen;">screen;</a> gcp.questions@fda.hhs.gov</a> if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address:

 $\frac{http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGo}{odClinicalPractice/default.htm}\,.$ 

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

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.

From:

Sent: Tuesday, October 20, 2015 3:54 PM

To: OC GCP Questions

Subject: Clinical trials on hold

Dear FDA,

I was hoping you could help me find or direct me to either a database or document that lists the number of clinical trials that are placed on hold. Thank you for your help!