From: OC GCP Questions

To: Subject: Date:

Your help in Researching Clinical Trials Tuesday, August 04, 2015 1:04:11 PM

Good afternoon -

Clinical trials that have been submitted to FDA but not currently approved are considered confidential and therefore cannot be shared with the public. Please see the FDA websites below that lists the drugs and medical devices approved by FDA. You would need to contact the sponsors directly for updates on the drug approval processing.

<u>Drug Approvals and Databases > Drug Trials Snapshots</u>

Device Approvals, Denials and Clearances

How Drugs are Developed and Approved

You can also search ongoing clinical trials that are listed in the clinicaltrails.gov database. See the link below.

Home - ClinicalTrials.gov

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN Senior Health Policy Analyst Office of Good Clinical Practice Office of the Commissioner, FDA

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: Monday, August 03, 2015 12:47 PM

To: OC GCP Questions

Subject: Re: Your help in Researching Clinical Trials

Good morning,

I am working on a research program that involves locating Companies that have applied for FDA Clinical Trials.

Would you be so kind as to direct me where on your web site I can find;

- 1) A list of all companies that have applied for Clinical Trials.
- 2) For those companies that have been approved, how do I access how they are progressing,

such as advancing from one successful trial to the next.

Your help would be greatly appreciated. Thank you,