From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, July 19, 2006 8:49 AM
To: [Redacted]
Subject: RE: Question about Clinical Trials and approval

Dear [Redacted]:

Your inquiry was forwarded to me for a response. You expressed interest in viewing the results of laboratory or human clinical testing performed by product sponsors and submitted to FDA in support of a product's safety or efficacy.

If a prescription medication has been approved by FDA, particularly if the approval is fairly recent, some of the publicly available information related to the approval, including reviews by FDA staff related to the drug, are posted on FDA's website. FDA's "electronic reading room", maintained by our Freedom of Information (FOI) staff also contains links to transcripts of the public portions of meetings of FDA Advisory Committees, and those documents frequently contain additional information that was presented to the agency about specific drug products.

Here is a link to FDA's electronic reading room: (http://www.fda.gov/foi/electrr.htm) and a link to a page that lets you search for information about approved drugs by typing in a drug's name: (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/)

If you don't find what you are looking for on the website, you can always file a request under FOI for additional documents. Here is a link that explains how to file an FOI request: (http://www.fda.gov/opacom/backgrounders/foiahand.html)

I hope this gets you started.

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

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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: Thursday, June 29, 2006 4:58 PM
To: DSI@fda.hhs.gov
Subject: Question about Clinical Trials and approval

Hello,

I first want to thank you for taking the time to help my son and I. I understand you must be busy and truly do appreciate your efforts.

It states on the FDA website: 'FDA reviews the results of laboratory, animal and human clinical testing done by companies to determine if the product they want to put on the market is safe and effective.'

I would like to be able to view the same results sent to the FDA for a certain prescription medicine, please let me know how I can do this. If this information is not public, then please let me know how or who to contact in the Freedom of Information Act (FOIA) for the FDA.

Thanks for your time and truly appreciate your help.

[Redacted]