From: Cheng, James M.
Sent: Tuesday, April 26, 2005 11:40 PM
To: [purged]
Cc: Phillips, Robert A (CDRH); Lepay, David; Lochner, Donna R.; Mallis, Elias; Less, Joanne
Subject: Response to email request

Importance: High
Dear Mr. [purged],

I have been asked to respond to your email request below.

Diagnostic ultrasound devices are primarily reviewed by our Division of Reproductive, Abdominal, and Radiological Devices (DRARD) group, and echocardiography clinical trials would likely also involve input from medical officers in the Division of Cardiovascular Devices (DCD).

FDA has a guidance document for diagnostic ultrasound devices available at www.fda.gov/cdrh/ode/ulstran.pdf. The primary contact for such devices is Dr. Robert Phillips of DRARD (rap@cdrh.fda.gov), who has been copied on this email. DRARD will co-ordinate the review of cardiac ultrasound device trials with DCD, if necessary.

Please let us know if you require any further assistance.

James Cheng
FDA/CDRH/ODE/DCD

-----Original Message-----
From: [purged]
To: 'gcpquestions@oc.fda.gov' <gcpquestions@oc.fda.gov>
Sent: Thu Apr 21 16:29:20 2005
Subject: Echocardiography - Clinical Trials

Good afternoon,
I am hoping you can assist me with the following request.

After a comprehensive reading on your website, I was unable to gather information about echocardiogprahy clinical trials FDA regulations. I would greatly appreciate if you let me know where I can obtain such information.

Thank you,

[purged]