From: OC GCP Questions
To:

Subject: info needed

**Date:** Tuesday, May 06, 2014 11:24:55 AM

## Good morning --

I am sorry but FDA does not oversee franchises. You will find useful information on our clinical trial website regarding clinical trials, good clinical practice, and other resources. See the web link below.

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

Also please see FDA's Center for Tobacco Products website below.

## **Tobacco**

Kind regards,

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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.

----Original Message-----

From: [Redacted]

Sent: Monday, May 05, 2014 10:45 AM

To: OC GCP Questions Subject: info needed

I need information on what is required when opening a franchise doing soft laser treatment for smoking cessation. What is an Internal Review Board. What paperwork has to be filed monthly and where. I need to know what the entire process is as I will be selling franchises. Please advise.

[Redacted]