From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, September 24, 2004 11:44 AM
To: '[purged]
Subject: RE: Intrinsa patch

Dear Ms. [purged]:

FDA is limited in the information that it can release to the public related to the products under its jurisdiction. In general, FDA is prohibited from disclosing the existence of an investigational product application unless such information has previously been disclosed by the product's sponsor.

My only suggestion would be that you or your physician would need to contact the sponsor/manufacturer of the product directly to find out if any clinical trials for the product are currently ongoing and whether you would qualify (meet the inclusion/exclusion criteria) for participation in that trial.

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 9C24
Rockville, MD 20857
Phone: 301/827-3340
Fax: 301/827-1169
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: [purged]
Sent: Thursday, September 23, 2004 9:34 AM
To: gcpquestions@oc.fda.gov
Subject: Intrinsa patch

Could you please tell me how I can be a participate in the clinical trails for this new patch? I am 40 years old, and have had a complete hysterectomy for four years now. I am on HRT, but still have a very low sex drive. This is a problem that not only effects me, but my 23 year relationship with my husband. If you could please let me know how to get involved with Procter & Gambles pharmaceutical study, I believe it would enrich my life and marriage.

Thank you,

[purged]

Do you Yahoo!?
New and Improved Yahoo! Mail - Send 10MB messages!