From: Toth-Allen, Jean
Sent: Tuesday, October 03, 2006 2:31 PM
To: [purged]
Subject: DEA requirements

Dear Ms. [purged]:

As promised in an earlier e-mail, the office in the Center for Drug Evaluation and Research that is responsible for controlled drugs has received information with regard to your inquiry. I have copied and pasted it below.

Below is the answer I got from DEA:

"Controlled substances must be sent to the address of the registrant. Assuming we are talking about Drs who are doing research as an ancillary activity of their practitioner registration with controlled substances in Schedule II-V; if they want the drugs to go directly to the site that may be different than their office, then they should get a schedule II-V research registration and use the site location for research." The necessary registration is Form DEA-225.

A contact in DEA for more information is Ms. Gretchen K. Feussner, Office of Diversion Control, DEA, 202-307-7173. She will refer the caller to the appropriate DEA registration unit at DEA as necessary.

Hope this information is useful. If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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: [purged]
Sent: Thursday, September 14, 2006 3:17 PM
To: Toth-Allen, Jean
Subject: DEA requirements

I've been in clinical research since the Jurassic Period but this week I'm encountering situations that make me feel like a novice!

We are conducting a trial in which a marketed product (AndroGel) is being used as an active-control. This being a Schedule III (anabolic

steroid) drug, DEA certificates are required by the contract firm in order to ship the supplies. For a number of the investigators, the address on the DEA certificate is their private practice office, not the investigational site/clinic. This may or may not be in the same building. The contract firm has informed us that the study supplies can only be shipped to the address on the DEA certificate. Obviously this presents a problem. Any insight into how this has been handled by others will most definitely be appreciated.

Thanks

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