From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, October 03, 2005 8:20 AM
To: [purged]
Subject: RE: Completion of the Form FDA 1572

Dear Ms. [purged]:

I cannot open the Form FDA 1572 (1572) that you attached, however, you should not send the form to my office. The information on the form should be submitted to the Center within FDA having jurisdiction over the product that is the subject of the study.

I hope this is helpful.

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: Monday, October 03, 2005 5:54 AM
To: OC GCP Questions
Subject: RE: Completion of the Form FDA 1572

Dear Ms Hommel,

Thank You for such prompt answer.
I am attaching You the sample of completed FDA1572.
The names/ addresses of clinic/ IEC appear exactly like on the official stamp of these institutions.
We thought it was important FDA had the original appear of names/addressees especially that there can always be a difference in translation of individual/ personal names.

I would be very grateful of Your expertise on this

Thank You very much in advance,
Kind Regards,
[purged]

"OC GCP Questions" <GCPQuestions@OC.FDA.GOV>
Sent by: "Hommel, Carolyn - OC" <Carolyn.Hommel@OC.FDA.GOV>
30/09/2005 15:30 To[purged]
cc"CDER DRUGINFO" <DRUGINFO@cder.fda.gov>
SubjectRE: Completion of the Form FDA 1572

Dear Ms. [purged]:

Your question to the CDER DRUGINFO e-mail account was forwarded to me for a response.

In answer to your question, please complete the form to show the names and addresses of the clinics as they appear in the "local language." If your computer/typewriter does not have the letters/symbols you need, you may complete the form by hand.

I hope this is helpful.

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)
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-----Original Message-----
From: CDER DRUGINFO
Sent: Monday, September 26, 2005 5:24 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

Dear GCP,

Can you help us on this one.

Thanks,
DDI

-----Original Message-----
From: [purged]
Sent: Thursday, September 22, 2005 2:39 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Dear Sirs,

I need Your instructions on the proper completion of FDA1572.
Should we write the addressess & names of the clinics in local language as
they appear on the stemps? .
What about the situations when the computer simply does not have such
letters ?

Thank You in advence for answering

Sincerely
[purged]

**********IMPORTANT--PLEASE READ**********
If this electronic message contains a zipped attachment and you do not have
a decompression tool, you can download unZIP (for free) from:
http://www.mk-net-work.com/us/uz/unzip.htm. Alternatively, request
that the attachment be resent in an uncompressed format. This electronic message,
including its attachments, is COMPANY CONFIDENTIAL
and may contain PROPRIETARY or LEGALLY PRIVILEGED information. If you are
not the intended recipient, you are hereby notified that any use, disclosure,
copying, or distribution of this message or any of the information included
in it is unauthorized and strictly prohibited. If you have received this
message in error, please immediately notify the sender by reply e-mail and
permanently delete this message and its attachments, along with any copies
thereof. Thank you. 2.2
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