From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, July 05, 2006 11:33 AM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged]:

Your question was forwarded to me for a response.

FDA's regulations pertaining to the "Investigator's brochure," (IB) are found at 21 CFR 312.23(a)(5), and describe what the IB must contain. There is a link to FDA's Good Clinical Practice (GCP) regulations on our GCP website: http://www.fda.gov/oc/gcp ; once at the site, click on "Good Clinical Practice/Clinical Trials Regulations" in the middle column and scroll down the list to 21 CFR 312.

The ICH E6 "Good Clinical Practice: Consolidated Guidance," issued in 1997. ICH E6 also contains a fairly detailed discussion of the Investigator's Brochure (Introduction; General Considerations; Contents; and Appendices) in Section 7. There is a also link to ICH E6 on FDA's GCP website, under "Guidances and Information Sheets" in the middle column.

If this isn't what you're looking for, please let me know.

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 14-B17
Rockville, MD 20857

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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: Wednesday, June 28, 2006 1:25 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: This statement appears in the Guidelines for Submission of an IND: "Under the auspices of the International Conference on Harmonization (ICH), a document that provides general guidance on the Investigator's Brochure has been developed and will soon be published in the Federal Register (Good Clinical Practice: Guideline for the Investigator's Brochure). Sponsors are referred to this document for further information on recommended elements of an Investigator's Brochure."

Is this document ready yet? If so, where is it? If not, are there any directions somewhere? I am not finding explicit directions for this part of the submission. Thanks.