From: Toth-Allen, Jean
Sent: Monday, March 06, 2006 9:59 AM
To: [purged]
Subject: RE:

Dear Miss [purged]:

While I am not completely sure what you are referring to as an "ANDA Workshop Handout," information about an abbreviated new drug application (ANDA) can be found at http://www.fda.gov/cder/regulatory/applications/ANDA.htm. This site contains general information about ANDAs as well as links to guidance regarding the content and format of an ANDA application, both paper and electronic, including "An ANDA Checklist for Completeness and Acceptability." The second link at the top of this checklist is to a comprehensive guidance regarding application contents.

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: Friday, March 03, 2006 5:05 PM
To: OC GCP Questions
Subject:

Dear Jean:

Where can i get a Format and Content of an ANDA Workshop Handout? I'm interested in a fomat of cover letter, format of table of contents, forms etc.
Thanks

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