From: OC GCP Questions
To: [redacted]
Subject: Quality Briefing Book
Date: Wednesday, June 21, 2017 8:23:00 AM
Attachments: ITHS_Template_Pre-IND_Briefing_Packet.pdf

Please see the template above. I am not sure this what you are looking for. If not, please contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, 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: [redacted]
Sent: Monday, June 19, 2017 5:55 PM
To: OC GCP Questions
Subject: Quality Briefing Book

Hi GCP,
I have recently heard that companies are submitting, with their product submissions, a Quality Briefing document. This document covers all the quality activities and actions conducted for that product. Is there a template or table of contents that is used for such, and that FDA expects?
Kind Regards

[redacted]

[redacted]