

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question about a medical food in research proposal
Date: Saturday, January 31, 2015 10:22:28 AM

Sorry there was an extra "r" included in the email address. Try this druginfo@fda.hhs.gov

-----Original Message-----

From: [REDACTED]
Sent: Friday, January 30, 2015 2:50 PM
To: OC GCP Questions
Subject: RE: Question about a medical food in research proposal

Hi Doreen,

I tried the email you provided and it immediately bounced back. Is there another email I could try?

Thanks,

[REDACTED]

From: OC GCP Questions [gcp.questions@fda.hhs.gov]
Sent: Friday, January 30, 2015 9:26 AM
To: [REDACTED]
Subject: Question about a medical food in research proposal

Good morning [REDACTED] --

Sorry for the run-around. Try to email the folks in the Center for Drugs (CDER). They determine when an IND is needed. Please see the email below.

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.

-----Original Message-----

From: [REDACTED]
Sent: Thursday, January 29, 2015 3:16 PM
To: OC GCP Questions
Subject: RE: Question about a medical food in research proposal

Hi Doreen,

Thanks for your quick reply. I have spoken with CFSAN and unfortunately they were unable to provide me with the guidance about whether an IND is needed or not and referred me to the good clinical practice office. This was after speaking with Dr. Brian Strongin at the FDA who referred me to CFSAN.

Is there someone specifically at CFSAN whom I should be contacting?

Thanks again,

[REDACTED]

From: OC GCP Questions [gcp.questions@fda.hhs.gov]
Sent: Thursday, January 29, 2015 2:34 PM
To: [REDACTED]
Subject: Question about a medical food in research proposal

Good afternoon --

You will need to contact someone in the Center for Food Safety and Nutrition (SFSAN). Please see their web link below. Please look at the bottom of the right side of the page. There is an email address and phone number.

Foods<https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fda.gov_Food_default.htm&d=AwMFAG&c=2rxEOw2KLbNB-I14iNYDhE3HM0YsihWt2FDmep0EPOI&r=zmroD-3eCDPWgeer71NDjUbWhJyrNu7DvKh3dBs4VKM&m=O4-HkYIEYnSVS6hPOD_c9Wc0MuD23sr0aB4RLUH6nxvs&s=hVBI4tOwDSnvD_iCq-wFfiESsxAZ2E1D8YFBVHmGbKI&e=>>

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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-----Original Message-----

From: [REDACTED]
Sent: Thursday, January 29, 2015 2:27 PM
To: OC GCP Questions
Subject: Question about a medical food in research proposal

Hello,

My name is [REDACTED] and I am a medicine resident at [REDACTED]. I have a question relating to the use of a medical food ([REDACTED]) in a research study involving patients with ulcerative colitis who are now status post ileal pouch anal-anastomosis (IPAA)

and assessing nutritional status, basically using it as a nutritional supplement. I have spoken with other people within the FDA and have been redirected to your office. Would someone be willing to take a look at our proposal and offer guidance if you feel it would be exempt from needing an IND?

Thank you for helping me with this matter and I look forward to your response.

[REDACTED]