From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO; Generic Drugs
Subject: RE: IRB question
Date: Tuesday, December 16, 2014 10:10:00 AM

Dear [Redacted]-

MANY thanks for your continued patience in receiving a response to your question As previously mentioned, I had to forward your question to others within FDA for a response I received a response from the Office of Generic Drugs (OGD), who also consulted others within FDA OGD indicated that, based on the limited information provided, it does not appear that such a study would be exempt from IRB review

With regard to requesting a waiver of the IRB requirement per 21 CFR 56 105, you can submit a request to OGD You can find contact information for OGD at the following web page:

http://www fda gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm142112 htm

I have also copied the "Contact FDA" information for OGD below for reference:

Contact FDA
240-402-7920
301-595-1147 Fax
genericdrugs@fda hhs gov

Office of Generic Drugs
Immediate Office
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have any further questions about this response, need more specific information about how to request a waiver, or need additional assistance regarding this issue, please contact OGD directly using the contact information provided above, as this will be the most efficient way to reach the appropriate staff who can further assist you I also copied the OGD central mailbox on this response

Thank you again and Happy Holidays to you

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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

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From: [Redacted]]
Sent: Friday, November 14, 2014 11:47 AM
To: OC GCP Questions
Subject: FW: IRB question

Hello,

I am reaching out again to ask a more specific question

Is IRB review and approval required for a taste-testing study of a drug product? Assume that the test article is an OTC drug that is marketed under an ANDA, that the study subjects are healthy volunteers, and that the only change being tested is a change in the flavor

If the answer is yes, can you advise on the procedure for seeking a waiver of the IRB requirement under 56 105?

Thank you very much for your help Feel free to call me at the number below

Best regards,
[Redacted]

> **From:** [Redacted]
> **Sent:** Wednesday, November 12, 2014 2:32 PM
> **To:** 'gcp.questions@fda.hhs.gov'
> **Subject:** IRB question
>
> Hello,
>
> I have questions about seeking a waiver of IRB requirement under 21 C F R § 56 105, and was hoping to speak to someone in your office I left a voicemail message as well My direct dial appears below
>
> Thank you,
> [Redacted]