

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Inquire about using a potential new food ingredient in clinical trials
Date: Thursday, June 04, 2015 11:39:11 AM

Good morning –

You will need to send your question to the Center for Foods. Please see their website below. At the bottom right hand area of the page there are contact numbers and email addresses.

[Foods](#)

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

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From: [REDACTED]
Sent: Thursday, June 04, 2015 11:12 AM
To: OC GCP Questions
Cc: [REDACTED]
Subject: Inquire about using a potential new food ingredient in clinical trials

Dear Sir/Madam,

I am [redacted]. We are interested in using **whole and defatted microalage [redacted]** for human studies. However, currently we do not know if the whole and defatted [redacted] have been approved for human trials. We are unsure about the regulations of using algae as supplement or feeding people with algae-derived food products as well.

1) Are whole and defatted [redacted] considered two separate ingredients?

2) May I know if the whole and/or defatted [redacted] *has been approved* for human trials?

3) If currently this microalgae has not been approved for human use and we would like to use it for different human studies:

- a) Directly give human subjects microalgae as a supplement**
- b) Give human subjects food with microalgae ingredient (*i.e.* algae fortified milk)**
- c) Give subjects food products from animals that are fed with microalgae (*i.e.* eggs**

from chickens that are fed with microalgae)

What regulations and documentations shall we go through for each purpose?

Thank you very much for your time and look forward to your reply,

