

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: definition of "consumption" - 21 CFR 56.104
Date: Thursday, April 23, 2015 12:09:58 PM

Good morning --

FDA regulations do not define "consumption" and we have not addressed this specific question in past GCP queries. I did find a FDA guidance on Alcoholism. You might want to review this guidance. Also see Appendix 1 on page 10.

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm433618.pdf>

You also might want to contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov as they wrote the guidance.

Additionally you might want to contact NIH's National Institute on Alcohol Abuse and Alcoholism.

[National Institute on Alcohol Abuse and Alcoholism \(NIAAA\)](#)

Sorry I could not be more helpful.

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: Wednesday, April 22, 2015 7:18 PM
To: OC GCP Questions
Subject: FW: definition of "consumption" - 21 CFR 56.104

Good Afternoon,

I posed a question to OHRP regarding §46.101(b)(6) and §56.104(d). OHRP recommended that I reach out to the FDA instead.

IRB Management & Function (Bankert & Amdur, 2006) indicates that, "studies that involve consumption of alcohol... should not qualify for exempt status" (p. 95). I would appreciate some clarification on the definition of "consumption" in this category (§56.104(d)). Specifically, whether or not studies limited to taking alcohol into the mouth and then spitting it out (rather than ingesting) or aroma/odor studies (sniffing alcoholic beverages) are considered "consumption" and should be reviewed by a non-exempt procedure.

We would be grateful for any guidance that you can provide.

Kind regards,

[REDACTED]

"