

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Who sets the guidelines for the FDA?  
**Date:** Monday, April 27, 2015 10:50:37 AM

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Good morning --

Please see the links below for historical dates at FDA. The regulations are passed by Congress.

[Milestones in U.S. Food and Drug Law History > Significant Dates in U.S. Food and Drug Law History History](#)

<http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm>

Please see the link below to the FDA regulations.

[Clinical Trials and Human Subject Protection > Regulations](#)

Kind regards,

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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: Saturday, April 25, 2015 11:24 PM  
To: OC GCP Questions  
Subject: Who sets the guidelines for the FDA?

Who sets the guidelines for the FDA ?