

From: [REDACTED]
To: [REDACTED]
Subject: RE: Draft Compliance Policy Guide Sec. 460.200 Pharmacy Compounding of Human Drug Products under Section 503A
Date: Thursday, May 17, 2012 5:35:21 PM
Attachments: [2012 Compounding CPG 460.200.pdf](#)
[2012 Compounding CPG 460.200 Federal Register.pdf](#)

This CPG has cleared all the necessary offices, although I am still catching up on signatures on a clearance form (versus emails to CDER from the reviewers) for the CPG clearance. The working group has an ambitious deadline and the task is important to the ACRA and Dr Woodcock as well as the Commissioner.

Given that [REDACTED] has been briefed on the issues, and the IO might want to sign this CPG even if the authority is re delegated to OE for other CPGs, do you agree that I can send this to [REDACTED] for signature from the ACRA IO? I have attached the FR notice as well as the CPG. I can send them in paper form in a blue folder if you agree it's ready to proceed.

I am working on a signature for CDER which is already promised, and is non-controversial. OCC likes to sign last, and can sign both forms when the FR goes to that office for final review.

CDER is asking for a response at our earliest convenience.

Thanks for letting me know.

[REDACTED]
Director, Division of Compliance Policy

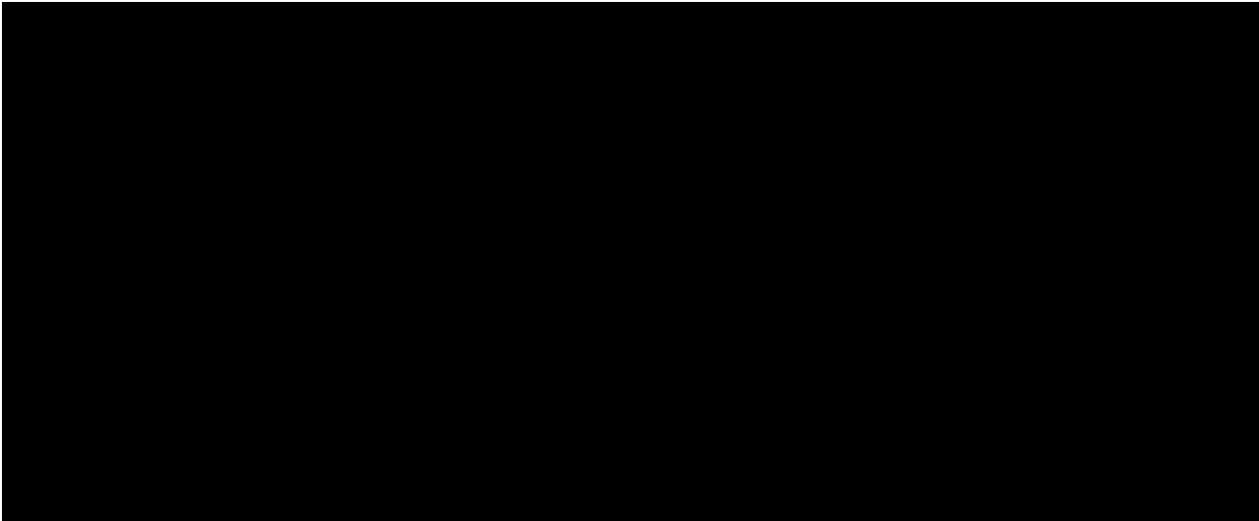
ORA/OE

ELEM Room 4044
[REDACTED]

From: [REDACTED]
Sent: Friday, April 27, 2012 4:25 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: FW: Draft Compliance Policy Guide Sec. 460.200 Pharmacy Compounding of Human Drug Products under Section 503A

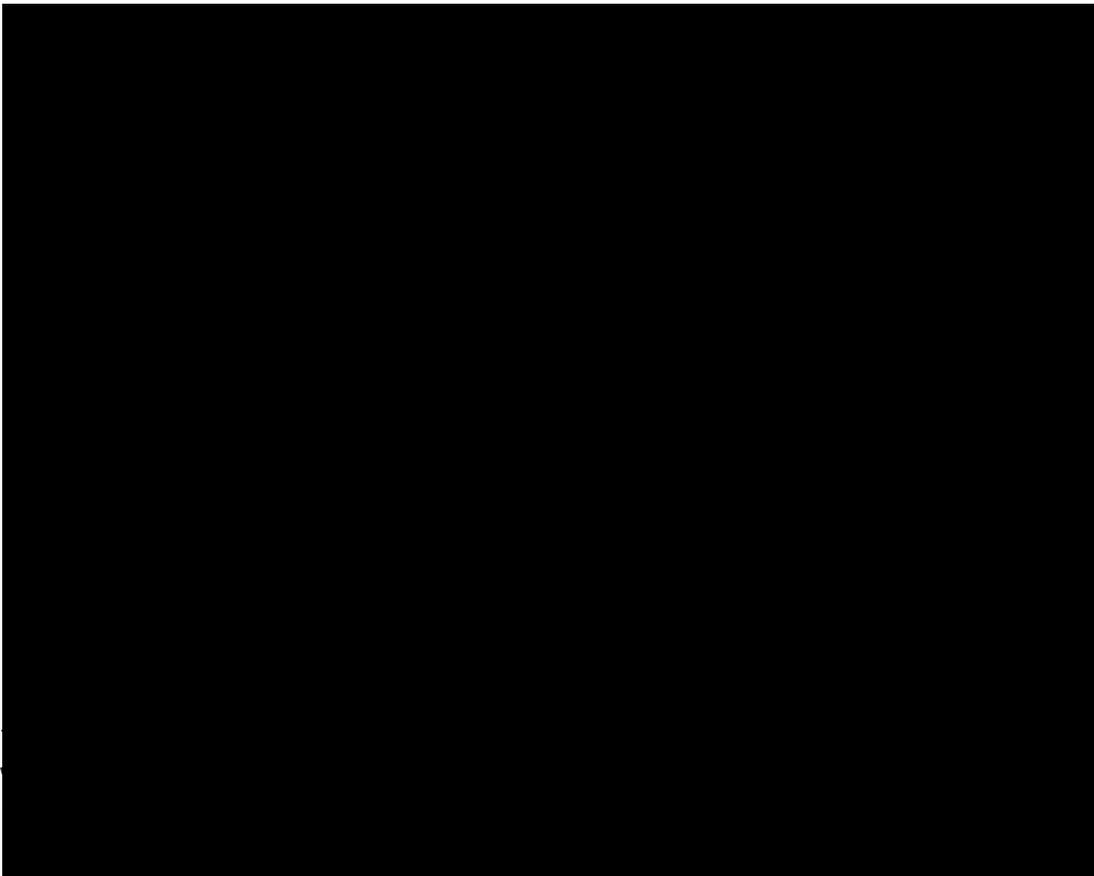
Hi Carol,

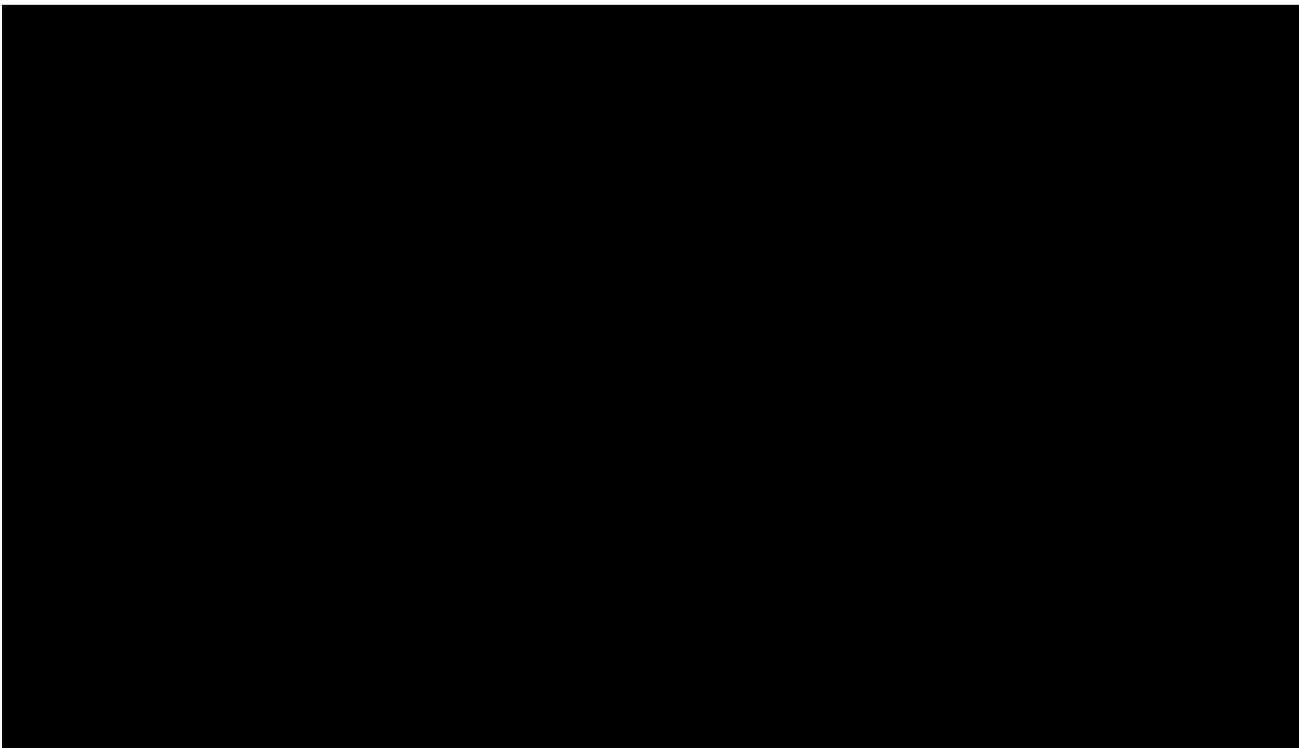
[REDACTED]



From: [REDACTED]
Sent: Thursday, April 26, 2012 2:17 PM
To: [REDACTED]
Subject: FW: Draft Compliance Policy Guide Sec. 460.200 Pharmacy Compounding of Human Drug Products under Section 503A

From: [REDACTED]
Sent: Saturday, April 21, 2012 1:30 PM
To: [REDACTED]
Subject: Draft Compliance Policy Guide Sec. 460.200 Pharmacy Compounding of Human Drug Products under Section 503A





[Redacted]

Director, Division of Compliance Policy

ORA/OE

ELEM Room 4044



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

From: [Redacted]
Sent: Thursday, April 19, 2012 1:40 PM
To: [Redacted]
Subject: Cpg question -

What is the status of the compounding pharmacy CPG? Has it gone back top CDER yet?
Thanks, Carol