From:
Sent: Friday, June 15, 2007 10:44 AM
To:
Subject: RE: Good Reprint Practices

Would you send me a list of the guidances/regulations you are working on or would like to work on. I'll send that list to the who, in turn, will send it back to the FDA as his list of priority projects. That will ensure that our projects are moved in a timely fashion. Thanks.

From:
Sent: Friday, June 15, 2007 10:40 AM
To:
Cc:
Subject: RE: Good Reprint Practices

Here it is.

<< File: Draft -Guidance- Sec401-- 6-11-07.doc >>

From:
Sent: Friday, June 15, 2007 10:38 AM
To:
Cc:
Subject: Good Reprint Practices

Would you please send the most recent version of the draft guidance. Thanks.

From:
Sent: Friday, June 15, 2007 11:02 AM
To:
Subject: List

let's talk about this:

- Proposed amendment to FDA regulations regarding submission of CBE-30 supplments for safety issues
- Guidance document on good reprint practices for the distribution of medical journal articles and medical or scientific reference publications on unapproved new uses
- Guidance document on manufacturer responses to unsolicited requests for information concerning off-label uses of approved drugs and medical devices
- Guidance document on intended use with respect to drug and cosmetic claims
- Guidance document on the provision of information by drug and device manufacturers concerning off-label uses to consultants

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From:
Sent: Friday, June 15, 2007 11:24 AM
To:
Subject: List

- Proposed amendment to FDA regulations regarding submission of CBE-30 supplements addressing labeling changes under 21 C.F.R. 314.70(c)(6)(iii)
- Guidance document on good reprint practices for the distribution of medical journal articles and medical or scientific reference publications on unapproved new uses
- Guidance document on off-label promotion and manufacturer dissemination of off-label information
- Guidance document on intended use with respect to drug and cosmetic claims
- Proposed amendment to FDA regulations interpreting express preemption clause in the FDCA for medical devices (21 C.F.R. 808.1(d))
- Final Guidance Document: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms
- Final Guidance Document: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements
- Final Guidance Document: Consumer-Directed Broadcast Advertising of Restricted Devices

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