

From: [Kezer, Doreen M](#)
To: [REDACTED]
Cc: [REDACTED]
Subject: Guidance for Industry Pharmacokinetics in Pregnancy
Date: Monday, June 09, 2014 2:14:46 PM

Good afternoon ŽŮ^å&Ů^åå–

I work for Joanne Less and she asked me to follow-up on your email question. I reached out to CDER's Maternal Health Team and they stated that they are working on revising the draft. At this point this guidance has not been pulled.

Please let me know if we can assist you in any other way.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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From: [redacted]
Sent: Saturday, June 07, 2014 11:19 PM
To: Less, Joanne
Subject: FDA 2004 draft guidance, "Guidance for Industry Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling"

Hello Joanne,

By any chance, do you know if this guidance was ever finalized or pulled? It came up as a point of discussion and I was a little worried about how old it is. Guidance for Industry Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling, online at <http://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm133348.htm>.

I look forward to hearing about anything you know.

Sincerely,

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