

[REDACTED]

From: Autor, Deborah
Sent: Thursday, August 10, 2006 4:38 PM
To: Axelrad, Jane A
Subject: FW:

FYI

From: Autor, Deborah
Sent: Thursday, August 10, 2006 4:28 PM
To: Gottlieb, Scott
Cc: Anderson, Kathleen R; Nasr, Samia; Silverman, Steven
Subject: RE:

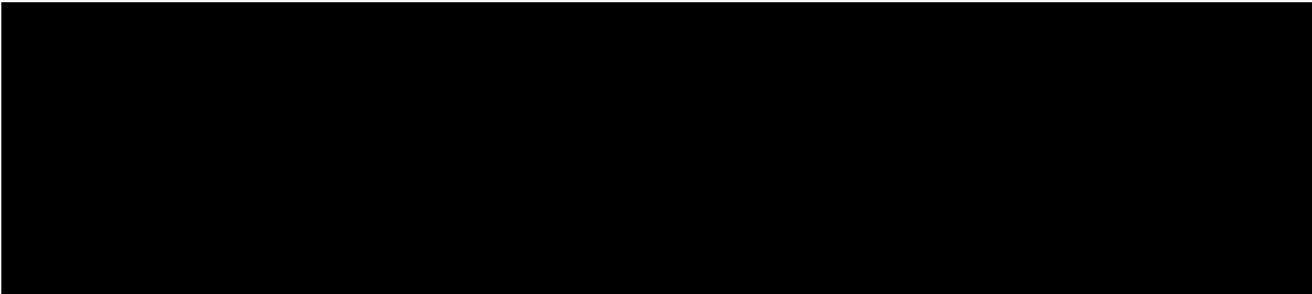
Thanks, Scott. Many people, especially the ccs on this e-mail, put a tremendous amount of effort into this, and they deserve the congratulations and will appreciate your words. This is a highly visible area with extensive attention from compounders, approved drug manufacturers, consumer groups, and the Hill. We're invested in and focused on enforcement initiatives that best respond to the compounding practices of greatest concern. I'm glad that today's action allowed us to have an impact, and your support has been invaluable in that regard.

We also very much appreciate your offer of help. Below is a list of all of our compounding actions that are pending at OGC. We have been told by OGC that they will clear 5 pending letters soon. But, even if that happens, thirteen will remain pending. Most crucially, our revised draft compounding CPG remains in limbo at OGC, and we are under constant pressure from Congress, the Small Business Administration, and others to get that on the street. Even the draft is not perfect, it's better than the current state of affairs. If there's anything you can do to help us make progress on these matters, we would be very grateful.

Thanks again for all of your support.

-- Deb

[REDACTED]



From: Gottlieb, Scott
Sent: Thursday, August 10, 2006 12:54 PM
To: Autor, Deborah
Subject:

Deb, congrats on getting these out. Were there other letters in OCC pertaining to [redacted] or were these the only 3 pending? let me know how I can be helpful as you move forward on clearign the enforcement actions.



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FOR IMMEDIATE RELEASE
P06-113
August 10, 2006

Media Inquiries: Catherine McDermott
301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Warns Three Pharmacies To Stop Mass-Producing Unapproved Inhalation Drugs

The Food and Drug Administration (FDA) has warned three firms, RoTech Healthcare, Inc., CCS Medical, and Reliant Pharmacy Services, to stop manufacturing and distributing thousands of doses of compounded, unapproved inhalation drugs nation-wide. Responsible officials at firms that do not properly address violations identified in FDA warning letters risk further enforcement, including injunctions that prevent further violations and seizure of their products that violate the law.

The three firms warned by FDA say that they produce inhalation drugs as part of the practice of pharmacy compounding. Traditional pharmacy compounding typically involves pharmacies preparing drugs that are not commercially available, such as a unique medicine for a patient who is allergic to an ingredient in a FDA-approved drug. This kind of compounding follows a physician's decision that his or her patient has a special medical need that cannot be met by FDA-approved drugs. FDA normally permits traditional pharmacy compounding and the agency's action is not targeting this practice.

Inhalation drugs are used to treat diseases including asthma, emphysema, bronchitis, and cystic fibrosis. These are potentially life-threatening conditions for which numerous FDA-approved drugs are available. Compounded inhalation drugs may be distributed to patients in multiple states, and patients and their doctors may not know that they are receiving compounded products. FDA urges consumers using inhalation drugs to discuss their medications with their physicians and verify with their pharmacists that the medications they received are what their physicians ordered.

"Compounded inhalation drugs are not reviewed by the FDA for safety and effectiveness, often are not produced according to good drug manufacturing practice, and typically are not sterile. This may expose

patients to unnecessary risk," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research. "To avoid these risks, we encourage patients to use FDA-approved drugs whenever possible."

FDA believes that, in compounding mass amounts of inhalation drugs, a number of pharmacies go well beyond traditional compounding. FDA is aware of certain pharmacies compounding millions of doses of inhalation drugs per year. These compounded drugs often simply copy FDA-approved, commercially available drugs, and any differences from FDA-approved drugs do not appear to be related to patients' medical needs.

Consumers and health care professionals should notify FDA of any complaints or problems associated with compounded drugs. These reports may be made to MedWatch, FDA's voluntary reporting program, by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm.

Warning Letter to Rotech Healthcare, Inc., Orlando, FL
http://www.fda.gov/foi/warning_letters/g5964d.htm

Warning Letter to CCS Medical, Clearwater, FL
http://www.fda.gov/foi/warning_letters/g5963d.htm

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Ticker, Douglas

From: Autor, Deborah
Sent: Thursday, August 10, 2006 4:46 PM
To: Silverman, Steven
Subject: FW:

FYI

From: Autor, Deborah
Sent: Thursday, August 10, 2006 4:46 PM
To: Axelrad, Jane A
Subject: RE:

Hope springs eternal.

From: Axelrad, Jane A
Sent: Thursday, August 10, 2006 4:45 PM
To: Autor, Deborah
Subject: RE:

Thanks. I talked to [REDACTED] and he thinks he will get the CPG out of OCC soon. Famous last words, but for some reason, I believe him.

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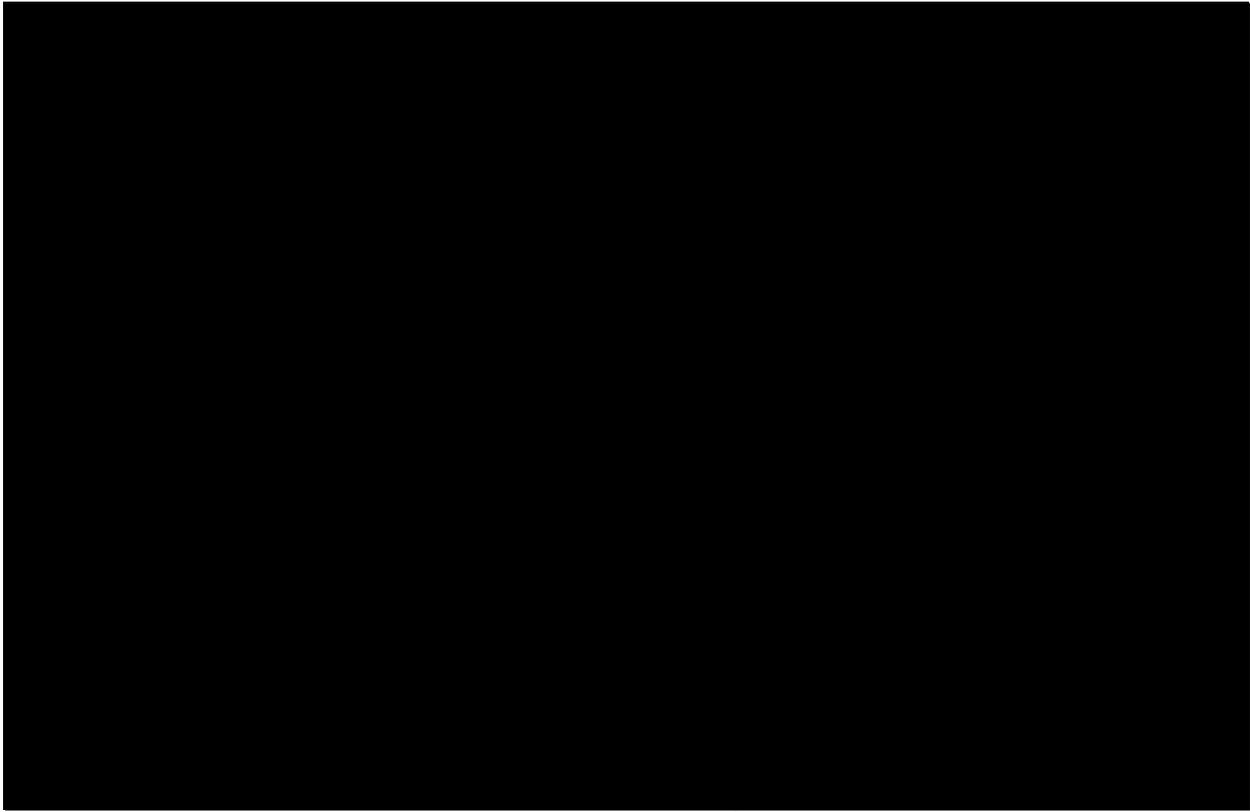
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