**Ware, Jacqueline H**

**From:** Ware, Jacqueline H
**Sent:** Monday, May 19, 2008 5:10 PM
'Blumberg Alan'; 'DOttavio Misty'
Sullivan, Matthew; Ware, Jacqueline H
**Subject:** Question about LCM

Dear Alan,
Can you please assist with the following question? If Schwarz has already submitted this information, please just let me know where/when it was submitted.

- Has Schwarz submitted additional information on the nephropathy of subject #588/8061?

We believe this information was requested 2-3 weeks ago. However, I searched Misty's list of requests/responses to see if I could find it and was not successful.

Thanks,
Jackie

**********

Jacqueline H. Ware, Pharm.D., RAC
Commander, United States Public Health Service
Regulatory Project Manager Team Leader

Division of Neurology Products
Center for Drug Evaluation and Research, FDA
10903 New Hampshire Avenue; WO22 Rm. 4348
Silver Spring, MD 20993-0002

one: 301-796-1160
ax: 301-796-9842
email: jacqueline.ware@fda.hhs.gov

## Ware, Jacqueline H

**From:** Ware, Jacqueline H
**Sent:** Monday, May 19, 2008 2:10 PM
'Blumberg Alan'; 'DOttavio Misty'
**Cc:** Sullivan, Matthew; Ware, Jacqueline H
**Subject:** RE: Clarification request RE: FDA Request for Information - NDA 22-253, 22-254, [redacted] May 12, 2008 b(4)

Dear Alan,
The clinical team has considered your proposals and had determined that they would like Option 2.

On a separate note, I believe that I sent a request about the exposure to placebo in the epilepsy population, (including those pts exposed to placebo while randomized to LCM) a couple of weeks ago. Do you recall such a request and, if so, have you sent a response?

Thanks,
Jackie

**********

Jacqueline H. Ware, Pharm.D., RAC
Commander, United States Public Health Service
Regulatory Project Manager Team Leader

Division of Neurology Products
Center for Drug Evaluation and Research, FDA
10903 New Hampshire Avenue; WO22 Rm. 4348
Silver Spring, MD 20993-0002

phone: 301-796-1160
fax: 301-796-9842
email: jacqueline.ware@fda.hhs.gov



---

**From:** Blumberg Alan [mailto:Alan.Blumberg@ucb-group.com]
**Sent:** Friday, May 16, 2008 5:34 PM
**To:** Ware, Jacqueline H; Sullivan, Matthew
**Cc:** DOttavio Misty; Moe Kirsten
**Subject:** Clarification request RE: FDA Request for Information - NDA 22-253, 22-254, [redacted] May 12, 2008

This message contains an encrypted email which can be read by opening the attachment

---

SCHWARZ BIOSCIENCES, Inc.
A Member of the UCB Group
Mail P.O. Box 110167 - Research Triangle Park - NC 27709 - USA
Via Courier 8010 Arco Corporate Drive - Suite 100 - Raleigh - NC 27617 - USA
Phone +1 919 767 2555 - Fax +1 919 767 2570 - E-mail info@schwarzpharma.com

**Ware, Jacqueline H**

**From:** Ware, Jacqueline H
**Sent:** Monday, May 19, 2008 1:38 PM
'Blumberg Alan'; 'DOttavio Misty'
**Cc:** Sullivan, Matthew; Ware, Jacqueline H
**Subject:** FW: Partial Response to FDA Request for Information - NDA 22-253, 22-254 ——— May 12, 2008 b(4)

Dear Alan,
Thanks for clarifying. This response is clear.
Jackie
**********
Jacqueline H. Ware, Pharm.D., RAC
Commander, United States Public Health Service
Regulatory Project Manager Team Leader

Division of Neurology Products
Center for Drug Evaluation and Research, FDA
10903 New Hampshire Avenue; WO22 Rm. 4348
Silver Spring, MD 20993-0002

phone: 301-796-1160
fax: 301-796-9842
email: jacqueline.ware@fda.hhs.gov



---

**From:** Blumberg Alan [mailto:Alan.Blumberg@ucb-group.com]
**Sent:** Monday, May 19, 2008 1:19 PM
**To:** Ware, Jacqueline H; DOttavio Misty
**Cc:** Sullivan, Matthew; Moe Kirsten
**Subject:** RE: Partial Response to FDA Request for Information - NDA 22-253, 22-254 ——— May 12, 2008 b(4)
**Importance:** High

Dear Jackie,
Please see if the attached clarifies the situation for the Clinical Reviewer. If not, perhaps we should set up a short telecom?
Best regards,
Alan

---

**From:** Ware, Jacqueline H [mailto:jacqueline.ware@fda.hhs.gov]
**Sent:** Friday, May 16, 2008 4:12 PM
**To:** Blumberg Alan; DOttavio Misty
**Cc:** Sullivan, Matthew
**Subject:** FW: Partial Response to FDA Request for Information - NDA 22-253, 22-254 ——— May 12, 2008 b(4)

Dear Alan,
The clinical reviewer has asked for clarification regarding your recent partial response to our May 12, 2008 requests. Please see below.

The original request refers to concomitant medications and diseases at baseline before entering the studies. The sponsor's table EP 5.1.1 is entitled:"medications taken during the baseline phase in population pool S1". It is unclear whether this

table refers to medications at entry or to medications taken during the placebo-controlled period ("baseline phase") which (would include baseline plus new medications taken during the placebo-controlled period). Similarly, EP 5.1.2 refers to concomitant diseases.

Please clarify that these tables refer to the baseline use of medications and diseases.

Thanks,
Jackie
**********

Jacqueline H. Ware, Pharm.D., RAC
Commander, United States Public Health Service
Regulatory Project Manager Team Leader

Division of Neurology Products
Center for Drug Evaluation and Research, FDA
10903 New Hampshire Avenue; WO22 Rm. 4348
Silver Spring, MD 20993-0002

phone: 301-796-1160
fax: 301-796-9842
email: jacqueline.ware@fda.hhs.gov



---

**From:** Blumberg Alan [mailto:Alan.Blumberg@ucb-group.com]
**Sent:** Friday, May 16, 2008 2:15 PM
**To:** Ware, Jacqueline H; Sullivan, Matthew
**Cc:** DOttavio Misty; Moe Kirsten
**Subject:** Partial Response to FDA Request for Information - NDA 22-253, 22-254, [redacted] May 12, 2008

b(4)

Dear Jackie,
Please find attached a partial response to the request made on May 12 in a WORD document. Responses to questions 2, 3 and 4 with tables to support the responses 2 and 3 are included.

Best regards,
Alan

APPEARS THIS WAY
ON ORIGINAL

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.