## 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

ne: 301-796-1160 ax: 301-796-9842

email: jacqueline.ware@fda.hhs.gov

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## Ware, Jacqueline H

From: Ware, Jacqueline H

Sant: 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

May 12,

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
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Spring, MD 20993-0002

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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,

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

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## Ware, Jacqueline H

From: Ware, Jacqueline H

Sant: 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

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ja. ne.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

Importance: High

May 12, 2008

b(4)

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. -

b/d

-May 12, 2008

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 <u>at entry</u> or to medications <u>taken during</u> 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

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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,

May 12, 2008

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

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