

# **EXHIBIT**

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May 11, 2007

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FRED T. MAGAZINER

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**VIA E-MAIL**

Paul J. Pennock, Esquire  
Weitz & Luxenberg  
180 Maiden Lane  
17th Floor  
New York, NY 10038

Re: Seroquel Litigation

Dear Paul:

We have been trying to piece together the CANDAs story, as you requested, and here is our current understanding.

The term CANDAs (Computer Assisted NDAs) generally refers to an electronic version of an NDA submitted to the FDA in addition to a paper NDA. When AstraZeneca submitted the original Seroquel NDA to the FDA in July 1996, it did so both in hard copy (the NDA) and in electronic format (the CANDAs). The Seroquel CANDAs contained the same information as the Seroquel NDA that was produced to you (including communiqués and amendments thereto), with the exception of Item 12 (Case Report Forms).

Item 12 contains detailed information about participants in clinical trials who either withdrew from the trials due to adverse events or died while the trials were underway. We believe that other parts of the NDA (parts that you already have) summarize the information in Item 12. Each clinical trial report in the original submission reports on withdrawals for that study. In addition, section 5 (and its subparts) of the "Integrated Summary on Safety" reports on the withdrawals, and section 6 (and its subparts) reports on deaths.

The FDA did not require that Item 12 be submitted in hard copy, so AstraZeneca submitted it only as part of the CANDAs. AstraZeneca has preserved the Item 12 Case Report Forms on a DLT tape, but they exist in Interleaf printerleaf format, which is now apparently obsolete. AstraZeneca no longer has the technology to process Interleaf files, and we have not yet been able to locate a vendor who can do so.

There is another problem as well: we believe that it would be illegal to produce the tape to you "as is" without first redacting the patient-specific information that it might contain.

We have two suggestions to offer to you:

First, you might be able to get Item 12 directly from the FDA. We certainly have no objection to your doing so, and if the FDA needs AstraZeneca's consent, we will give it to you.

Second, if you can find a vendor who can open or "read" the Interleaf files, we'll work with you to open them, we'll redact the patient-identifying information, if any, and then we'll give them to you.

We welcome your suggestions. If you have any questions, of course, let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Fred T. Magaziner", followed by a horizontal line.

Fred T. Magaziner  
FTM:jew