IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	**MDL No. 1871** **07-md-01871**
THIS DOCUMENT APPLIES TO ALL ACTIONS	:	

PRETRIAL ORDER NO. 96
SUPPLEMENTARY PROTECTIVE ORDER: CLINICAL TRIAL DATA

In order to facilitate production of the Clinical Trial Datasets (as defined in paragraph 1 below), the parties agree that the Clinical Trial Datasets produced in this litigation shall receive protections from disclosure in addition to those provided in Pretrial Order No. 10. Accordingly, the Court enters this Supplementary Protective Order pursuant to Rule 26 of the Federal Rules of Civil Procedure.

1. **Clinical Trial Datasets**

For purposes of this Order, "Clinical Trial Datasets" shall mean electronic derived datasets in SAS format relating to Avandia® to be produced by GlaxoSmithKline LLC ("GSK") to the Plaintiffs' Steering Committee (the "PSC") in the above-captioned litigation.

2. **Applicability of Pretrial Order No. 10 (Protective Order)**

This Order supplements Pretrial Order No. 10 ("PTO 10"), dated June 11, 2008. The Clinical Trial Datasets shall be deemed Confidential Discovery Materials pursuant to PTO 10 and all terms of PTO 10 shall apply to the production of the Clinical Trial Datasets. To the extent that the requirements of this Order differ from those of PTO 10, the terms of this Order shall govern.

3. **Format of Production**

a. The Clinical Trial Datasets shall be produced on a portable external hard drive as industry standard SAS files. To protect the Clinical Trial Datasets during transport, the

Clinical Trial Datasets shall be produced in encrypted format. When the PSC notifies GSK that it has received the Clinical Trial Datasets, GSK shall provide the PSC with instructions for opening the files. GSK will redact from the Clinical Trial Datasets information protected by applicable privacy laws.

b. The production media containing the Clinical Trial Datasets shall be marked with a short description of the data contained on the media, together with a legend substantially similar to the following:

In re Avandia MDL 1871 – Highly Confidential – Subject to Protective Order.

4. Confidentiality Protections

The production of the Clinical Trial Datasets shall be subject to the following confidentiality provisions:

a. Except as provided below, GSK shall produce only two copies of the Clinical Trial Datasets, which copies shall be produced to the PSC.

b. Except as provided below, the PSC may maintain the external portable hard drives containing the Clinical Trial Datasets produced by GSK at the offices of Aylstock, Witkin, Kreis & Overholtz LLP in Pensacola, FL (the "Aylstock Offices") and Reilly Pozner LLP in Denver, CO (the "Zonies Offices"). The Clinical Trial Datasets may be loaded onto the computer networks at the Aylstock and Zonies Offices, but shall be segregated and secured on such computer networks, and shall not be commingled with any other data. The Aylstock and Zonies Offices shall restrict access to the Clinical Trial Datasets to only those persons permitted access to Confidential Discovery Materials pursuant to PTO 10. The Clinical Trial Datasets shall be kept isolated in a manner that prevents any access to the Clinical Trial Data from a location other than the Aylstock and Zonies Offices, whether by Internet, wide area network, virtual private network, or other remote access technology.

c. The PSC may provide one working copy of the Clinical Trial Datasets to a consultant or expert retained for the purpose of assisting the PSC in this litigation. Such outside consultant or outside expert may maintain only one copy of the Clinical Trial Datasets, which

copy shall be maintained at the outside consultant's or outside expert's principal office. A consultant or outside expert may load the Clinical Trial Datasets onto the computer network at its principal office, but the Clinical Trial Datasets shall be segregated and secured on such computer network, and shall not be commingled with any other data. The outside consultant or outside expert shall restrict access to the Clinical Trial Datasets to only those of its employees who are working with the PSC on this litigation. A consultant or outside expert shall keep the Clinical Trial Datasets isolated in a manner that prevents any access to such data from a location other than such consultant's or expert's principal office, whether by Internet, wide area network, virtual private network, or other remote access technology.

d. The PSC shall be permitted to provide access to the Clinical Trial Datasets to any plaintiff's lawyer with a case pending in MDL 1871 for the purpose of preparing their case(s) for trial. Such access, however, must take place at the Aylstock or Zonies Offices. Subject to the provisions of paragraph 4(e) below, the PSC shall be able to provide copies of its own work product derived from the Clinical Trial Datasets to any plaintiff's lawyer with a case pending in MDL 1871 without violating this Order.

e. Any analyses or printouts created from the Clinical Trial Datasets shall be deemed Confidential Discovery Materials pursuant to PTO 10, and all terms of PTO 10 shall apply to such analyses and printouts. All analyses and printouts created from the Clinical Trial Datasets shall be marked "In re Avandia MDL 1871 – Highly Confidential – Subject to Protective Order."

f. The Clinical Trial Datasets shall not be duplicated except as provided above.

g. The Clinical Trial Datasets shall be used by the plaintiffs solely for the prosecution of the above-captioned litigation, to the extent reasonably necessary to accomplish the purpose for which disclosure is made, and not for any other purpose, including any other litigation or judicial proceeding, or any business, competitive, governmental, commercial, or administrative purpose or function.

h. Nothing in this Order shall be construed as granting to or permitting the plaintiffs and their counsel an implied license in, or right or option to license or use, any intellectual property rights relating to the Clinical Trial Datasets, or any other rights to use the Clinical Trial Datasets other than in the above-captioned litigation.

i. The plaintiffs and their counsel are prohibited from publishing any analysis or work product based, in whole or in part, on the Clinical Trial Datasets. Nothing in this Order shall be construed as granting to or permitting the plaintiffs and their counsel an implied license in, or right or option to publish any analysis or work product based, in whole or in part, on the Clinical Trial Datasets.

5. Certifications

a. Any outside consultant or outside expert consultant who receives Clinical Trial Datasets pursuant to the provisions of paragraph 4 above shall sign, prior to such disclosure, a copy of the Endorsement of Protective Order pursuant to PTO 10. In addition, an outside consultant or outside expert shall sign a copy of the Endorsement of Supplementary Protective Order, attached as Exhibit A. Aylstock, Witkin, Kreis & Overholtz LLP shall retain copies of the executed Endorsement(s) of Supplementary Protective Order. Any party seeking a copy of an Endorsement of Supplementary Protective Order may make a demand in writing setting forth the reasons therefore, to which the opposing party shall respond in writing. If the dispute cannot be resolved, the demanding party may move the Court for an order compelling production upon a showing of good cause. For experts who will testify regarding the Clinical Trial Datasets, a copy of the Endorsement of Supplementary Protective Order executed by the testifying expert shall be furnished to counsel for GSK at the time the expert's designation is served, or at the time the Clinical Trial Datasets are provided to the testifying expert, whichever is later.

b. Any outside consultant or outside expert consultant who loads Clinical Trial Datasets onto a computer network shall sign a copy of the Confirmation of Supplementary Protective Order, attached as Exhibit B, and provide it to Aylstock, Witkin, Kreis & Overholtz

LLP within 7 days of loading such data. Aylstock, Witkin, Kreis & Overholtz LLP shall retain copies of the executed Confirmation(s) of Supplementary Protective Order. Any party seeking a copy of a Confirmation of Supplementary Protective Order may make a demand in writing setting forth the reasons therefor, to which the opposing party shall respond in writing. If the dispute cannot be resolved, the demanding party may move the Court for an order compelling production upon a showing of good cause. For experts who will testify regarding the Clinical Trial Datasets, a copy of the Confirmation of Supplementary Protective Order executed by the testifying expert shall be furnished to counsel for GSK at the time the expert's designation is served, or at the time the Clinical Trial Datasets are provided to the testifying expert, whichever is later.

6. Return of Clinical Trial Datasets

Within 15 days of the final conclusion of this litigation, the PSC shall return to counsel for GSK all copies of the Clinical Trial Datasets that reside on external hard drives and certify to counsel for GSK in writing that all copies of the Clinical Trial Datasets previously loaded onto computer systems, including computer systems of any outside consultant or outside expert, have been securely erased and that the data cannot be recovered.

7. Improper Disclosure

Disclosure of the Clinical Trial Datasets other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate.

8. Modification of this Order

Any party may seek modification of this Order upon motion to the Court and proper notice to the other party.

SO ORDERED BY:

March 16th, 2010

Cynthia M. Rufe

Rufe, J.

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	**MDL No. 1871** **07-md-01871**
THIS DOCUMENT APPLIES TO ALL ACTIONS	:	

ENDORSEMENT OF SUPPLEMENTARY PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to PTO __ (Supplementary Protective Order: Clinical Trial Datasets) ("Order") dated _____ in the above-captioned litigation ("Litigation"); that I have been given a copy of and have read the Order; and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Supplementary Protective Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any Clinical Trial Datasets.

I further agree that I shall not disclose to others, except in accord with the Order, any Clinical Trial Datasets, in any form whatsoever, and that such Clinical Trial Datasets and the information contained therein may be used only for the purposes authorized by the Order.

I further agree to return all copies of any Clinical Trial Datasets I have received to counsel who provided them to me within a reasonable time following the completion of the purpose for which they were provided and no later than 15 days following the conclusion of the Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United Stated District Court for the Eastern District of Pennsylvania, for the purposes of any proceedings relating to enforcement of the Order.

I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _____

Signature: _____

Printed Name: _____

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	**MDL No. 1871** **07-md-01871**
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CONFIRMATION OF SUPPLEMENTARY PROTECTIVE ORDER

I have loaded or caused to be loaded a copy of the Clinical Trial Datasets onto my computer network in accordance with the terms of the Supplementary Protective Order, PTO __.

Date: _____

Signature: _____

Printed Name: _____