APPENDIX B

to

Assurance of Discontinuance
In the Matter of
GlaxoSmithKline, plc, d/b/a/ GlaxoSmithKline and
SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline

The People of the State of New York, by their Attorney General Eliot Spitzer, and GlaxoSmithKline, plc, d/b/a/ GlaxoSmithKline and SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline (collectively "GSK"), agree that the Summaries of Clinical Study Reports, the Posting of which is the subject of the Assurance of Discontinuance in the above-referenced matter, shall each contain all of the categories of information listed herein (first and second pages of the attached templates for Phase 1 Clinical Studies; third through fifth pages of the attached templates for Phase 2, 3 or 4 Clinical Studies). The following list of categories of information that the parties agree shall be included in the Summaries of Clinical Study Reports does not restrict GSK from including in such Summaries any other information that meets the requirements of the Assurance of Discontinuance:

Use subject not patient throughout (except for the title which should be verbatim from the report)

Study No: study number as in report		
Title : Enter title as in report		
Rationale: Not always available in report. May have to be extracted from introduction		
Phase: Enter phase as in the synopsis of the report		
Study Period: As in the synopsis		
Study design: Enter list of descriptive terms		
Centres: Summarised by region/county		
Indication: Enter indication as in the synopsis of the report, enter none if its not applicable.		
Treatment: # Denotes treatment regimens approved in the US and at least one country in the European Union. Summarised from synopsis		
Objectives: Objectives as written in synopsis/report		
Statistical Methods: : As in the study synopsis. .Add definitions of the populations included in the CTR summary for the assessment of efficacy and safety if not included in the synopsis stats section. Make it clear if the populations for efficacy and safety are not the same		
Study Population: Extracted from synopsis.		
Number of Subjects: Adjust according to study	**Group A**	**Group B**
Planned N	From synopsis or body of the report	
Dosed N		
Completed n (%)		
Total Number Subjects Withdrawn N (%)		
Withdrawn due to Adverse Events n (%)		
Withdrawn due to Lack of Efficacy n (%)		
Withdrawn for Other Reasons n (%)	Add-up ALL other reasons for withdrawal	
Demographics	**Group A**	**Group B**
N (ITT)	From synopsis	
Females: Males		
Mean Age in Years (sd)		
Mean Weight in Kg (sd)		
Race, n (%) Substitute the name of the predominant race(s) studied for the word "Race"		

Pharmacokinetics (PK),pharmacodynamics (PD), PK/PD Endpoints:
Amend heading as necessary eg remove PK or PD if not applicable to the study. Present outcome variable(s) with statistical annotation from synopsis/report. Format and presentation indication/study dependent. Use tables from report if available otherwise use text

Safety results:
Define the period for the collection of 'on therapy' AEs and SAEs as given in the methodology section of the report e.g ., An on therapy adverse event (AE) was defined as an AE with onset on or after the start date of study medication but not later than one day after the last date of study medication. An on therapy serious adverse event (SAE) was defined as a SAE with onset on or after the start date of study medication and up to 30 days after the last dose of medication.

Summarise Adverse events as follows:

30 subjects or less /treatment group: any AE that occurs in more than one patient in any group

More than 30 subjects per treatment group and<= 3 groups: the most frequent 10 events in each group

More than 30 subjects/treatment group and > 3 groups: the most frequent 5 events in each treatment group

The Numerator, denominator and the % will all be given

Adverse Events:	**Group A**	**Group B**
N (ITT)		
No. subjects with AEs n (%)		
Most Frequent AEs		

Serious Adverse Events, n (%) [# considered by the investigator to be related, possibly related, or probably related to study medication]:
Summarise SAEs. Table preferred (if available), otherwise use text/list. In square brackets, indicate the number of specific SAEs considered by the investigator to be related/possibly related/probably related.

Format of presentation is: n (%) [n (%)]

Publications: Add citations

Study No.: As on the report cover		
Title: As on the report cover. Trade name may be used if was included in the report title. All other sections of the CTR summary MUST use the generic name (not the trade name).		
Rationale: From synopsis OR extracted from introduction of report. Do not include information about mode of action. Do not use any trade name(s).		
Phase: As in the synopsis		
Study Period: As in the synopsis		
Study Design: List of descriptive terms taken from appropriate section of synopsis		
Centres: Summarised by region/county		
Indication: As agreed by MDC		
Treatment: # Denotes treatment regimens approved in the US and at least one country in the European Union. Summarised from synopsis (exclude batch numbers) using generic name		
Objectives: Primary objective as written in synopsis		
Primary Outcome/Efficacy Variable: Either from synopsis or body of report		
Secondary Outcome/Efficacy Variable(s): From the body of the report. List only the variables that were prospectively defined in the report not any post hoc analysis. Exclude pharmacoeconomics variables (may need to be taken out of secondary objectives list)		
Statistical Methods: As in the study synopsis. .Add definitions of the populations included in the CTR summary for the assessment of efficacy and safety if not included in the synopsis stats section. Make it clear if the populations for efficacy and safety are not the same.		
Study Population: Extracted from synopsis using key inclusion exclusion criteria		
	A	**B**
Number of Subjects: Adjust layout according to study design		
Planned, N	From body of report	
Randomised, N Note: for non-randomised studies, substitute the number of subjects entered into the study and replace the heading with "Entered, N"	From synopsis	
Completed, n (%)	ditto	
Total Number Subjects Withdrawn, N (%)	ditto	
Withdrawn due to Adverse Events n (%)	From synopsis or body of the report	
Withdrawn due to Lack of Efficacy n (%)	ditto	
Withdrawn for other reasons n (%)	Add-up ALL other reasons for withdrawal	
Demographics	**A**	**B**
N (ITT)	From synopsis	
Females: Males If only one gender was studies, just give information for the one gender and modify the heading accordingly.	ditto	
Mean Age, years (SD)	ditto	
Race, n (%) Substitute the name of the predominant race(s) studied for the word "Race"	ditto	
Include any other relevant demographic criteria, e.g., Children:adolescents	ditto	

Primary Efficacy Results:
Primary outcome variable(s) with statistical annotation must be presented in tabular format. Include p-values, if available. Format and presentation will be indication/study dependent. **No text or contextual statements are to be included.** An example is shown in the instruction text below.

	A	B
Mean Baseline (SE)	From synopsis or report	
Difference between treatments (as appropriate to endpoint)		
95% Confidence Interval		
p-value		

Secondary Outcome Variable(s):

Summarise all variables **in tabular format**. Group similar variables. Use 95% CI when appropriate. **Do not include p-values for secondary endpoints.** The analyses presented should be on the primary of population of interest, as presented in the CSR (for example, ITT or ITT LOCF). Quality of life and population pK endpoints should also be added when included in secondary endpoints. **Do not summarise Pharmacoeconomics or tertiary endpoints.** . No text or contextual statements are to be included.

	A	B
Secondary endpoint	From synopsis or report	
Difference between treatments (as appropriate to endpoint)		
95% CI (if appropriate)		

Safety Results: Define the period for the collection of 'on therapy' AEs and SAEs as given in the methodology section of the report e.g ., An on therapy adverse event (AE) was defined as an AE with onset on or after the start date of study medication but not later than one day after the last date of study medication. An on therapy serious adverse event (SAE) was defined as a SAE with onset on or after the start date of study medication and up to 30 days after the last dose of medication.

Summarise Adverse events as follows:

30 patients or less /treatment group: any AE that occurs in more than one patient in any group

More than 30 patients per treatment group and <= 3 groups: the most frequent 10 events in each group

More than 30 patients/treatment group and > 3 groups: the most frequent 5 events in each treatment group

The Numerator, denominator and the % will all be given

	A	B
Most Frequent Adverse Events – On-Therapy	**n (%)**	**n (%)**
Subjects with any AE(s), n(%)		
List specific AEs according to guidance above		

Serious Adverse Events - On-Therapy
n (%) [n considered by the investigator to be related to study medication] Information on **all** on-therapy SAEs by preferred term will be provided. Format will vary, depending on how non-fatal and fatal SAEs were tabulated in the CSR. The table will indicate the number of subjects with specific SAEs, the percentage, and the number considered by the investigator to be related/possibly related/probably related to study medication.

Format of presentation of individual SAEs by preferred term is: n, (%) [n considered "related"]

If the report presents SAEs as "non-fatal SAEs" and "fatal SAEs" (or "deaths") separately, the CTR summary first presents the tabulations of "non-fatal" SAEs and then presents the tabulations of "fatal" SAEs.

If the report presents an all-inclusive SAE (both non-fatal and fatal), then the CTR summary first presents a tabulation of SAEs and then presents a tabulation of fatal SAEs. The heading for the "all SAEs" table should read:

Subjects with any SAEs, n (%)
-Includes both fatal and non-fatal events

	A	B
Subjects with non-fatal SAEs, n (%)		
	n (%) [related]	**n (%) [related]**
Present a table of all on-therapy SAEs using this format: Event A, n (%) [number of subjects who had "related" events]		
Subjects with fatal SAEs, n (%)		
	n (%) [related]	**n (%) [related]**
Event 1, n (%) [number of subjects who had events considered "related"]		

Conclusion:
Within 1 year after study completion this section will either refer you to a publication or contain text interpreting the trial results.

Publications: Add citations