

## APPENDIX A

to

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

### DEFINITIONS

“Adverse Events” are unfavorable and undesired effects observed in patients during a Clinical Study. “Serious” Adverse Events are those that, at any dose, are fatal, life-threatening, disabling or incapacitating; result in hospitalization; prolong a hospital stay; or are associated with congenital abnormality, cancer or overdose (whether accidental or intentional). In addition, any event not meeting the above criteria may still be deemed Serious by the Investigator if such an event jeopardizes the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

“Assurance Date” means the date on which the parties sign this Assurance.

“Clinical Study” means a research investigation on human subjects to answer specific questions about a GSK drug. The term “Clinical Study” is not limited to a research study that is randomized, controlled, or blinded.

“Clinical Study Report” of a Clinical Study means a description of the Protocol, all the Data, and the clinically relevant conclusions drawn from the Data, including the answers to the questions posed in the Protocol.

“Data” means all the results and outcome measurements obtained from a Clinical Study. This includes a description and the results of any planned statistical analysis of the Data, as well as a listing of the common Minor Adverse Events and a more detailed listing of Serious Adverse Events.

“GSK Drug” is a prescription pharmaceutical product that is currently sold for human consumption in the United States by GSK, for which GSK has both the clinical development responsibility and the legal right to use or disclose such product’s Data.

“GSK-Sponsored Clinical Studies” means Clinical Studies of a GSK Drug where GSK is ultimately responsible for regulatory approvals, site selection, Protocol development, initiation, monitoring, safety reporting, and Data analysis, even if some or all of these activities are transferred to another party (e.g., Clinical Research Organization). “GSK-Sponsored Clinical Studies” excludes studies initiated by a third party for which GSK provides some support, for example by way of a grant or supply of medication, but with sponsor responsibilities for study initiation and management agreed in writing to reside with the third party.

“GSK Web Site” refers only to GSK’s main corporate Internet site, currently [www.gsk.com](http://www.gsk.com).

“Off-Label Use” means the use of a GSK Drug to treat a condition, disease or population not listed as an indication on the U.S. Prescribing Information (labeling) for the GSK Drug.

“Peer Reviewed Journal” refers to a professional periodical that, before accepting an original article for publication, has it reviewed, at minimum for scientific merit, by relevant experts selected by the journal. A “Peer Reviewed Journal” does not include a supplement of a professional periodical that is sponsored or supported in any way by or on behalf of GSK or any other manufacturer, seller or promoter of prescription pharmaceutical products.

“Post” information means to provide access to the information on an Internet site that provides no-cost and unrestricted access to both the site and the information GSK has provided through the site. GSK does not fulfill a requirement to Post information under this Assurance if

it does so on an Internet site, other than the GSK Web Site, that contains any advertising by any pharmaceutical company or for any pharmaceutical product.

“Protocol” means the investigational plan used to conduct the Clinical Study. The Protocol for an acute phase of a Clinical Study is separate from the Protocol for a continuation or extension phase of the Clinical Study.

“Study Completion Date” is the date on which the last observation is made either of the last patient who remains enrolled in the Clinical Study or following a decision to terminate the Clinical Study early, whichever happens first.

“Summary of Clinical Study Report” refers to the brief presentations of Clinical Study Reports that are required by this Assurance and that comply with Appendix B.