

**Assurance of Discontinuance Between Forest Laboratories and the
Attorney General of the State of New York**

WHEREAS, pursuant to N.Y. Executive Law § 63(12), Eliot Spitzer, the Attorney General of the State of New York, opened an inquiry into whether pharmaceutical companies, including Forest Laboratories, Inc. (“Forest”), disclosed the results of clinical studies of their drugs; and

WHEREAS, Forest cooperated with the Office of the Attorney General (“OAG”) in this inquiry by producing certain documents on or about August 20, 2004. Before the OAG completed its review of these documents, Forest informed the OAG that it intended to create a Clinical Trial Registry (“CTR”) that will provide physicians and patients with information regarding its Clinical Studies, and after discussions, the parties agreed that Forest’s CTR will be implemented in accordance with the standards for disclosure of Clinical Studies (which is attached hereto as Appendix A), and the templates for the Summaries of Clinical Study Reports which will appear in the CTR (which are attached hereto as Appendices B & C); and

WHEREAS, Forest asserts that its past disclosures of Clinical Studies have fully complied with all laws of the State of New York, and all other laws or regulations, but has decided to provide broader disclosure of the results of its Clinical Studies of Forest Drugs; and

WHEREAS, the OAG has reviewed the standards and templates and finds that the information to be provided on Forest's proposed CTR would disclose useful information to the medical community;

IT IS HEREBY AGREED by Forest, its agents, employees, and subsidiaries, that:

DEFINITIONS

1. The following definitions apply to the following terms as used throughout this Assurance, including in any Appendices. Any terms which are not defined in this section shall be interpreted to have the same meaning as they have in ICH's *Guidelines for Industry: Structure and Content of Clinical Study Reports* (July 1996):

a. "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.

b. "Assurance Date" means the date on which the parties sign this Assurance.

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

d. “Clinical Study Report” means a report describing (i) the investigational plan and Protocol used to conduct the Clinical Study, (ii) all the data developed during the Study, and (iii) the clinically relevant conclusions drawn from the data, including the answers to the questions posed at the outset of the Study and the results of the Protocol-defined outcomes.

e. “Forest Drug” is a prescription pharmaceutical product that Forest is selling for human consumption in the United States following FDA approval (including a Forest investigational product once it receives FDA approval and is sold by Forest), for which Forest has both the clinical development responsibility and the legal right to use or disclose such product’s Clinical Study data.

f. “Forest-Sponsored Clinical Studies” means Clinical Studies of a Forest Drug where Forest 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). “Forest-Sponsored Clinical Studies” excludes studies initiated by a third party for which Forest provides some support, for example, by way of grant or supply of

medication, but with sponsor responsibilities for study initiation and management agreed in writing to reside with the third party.

g. “Forest Web Site” refers only to Forest’s main corporate Internet site, currently www.frx.com, or any sites which one can access through a link from that site.

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

i. “On-Label Use” means the use of a Forest Drug to treat a condition, disease or population listed as an indication on the U.S. Prescribing Information (labeling) for the Forest Drug.

j. “Peer Reviewed Journal” refers to a professional periodical that, before accepting an original article for publication, has it reviewed, at a 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 Forest or any other manufacturer, seller or promoter of prescription pharmaceutical products.

k. “Post” means to provide access to information on an Internet site that provides no-cost and unrestricted access to both the site and the information Forest has provided through the site. Forest does not fulfill a requirement to Post information under this Assurance if it does so on an Internet site, other than the Forest Web Site, that

contains any advertising by any pharmaceutical company or for any pharmaceutical product.

1. "Protocol" means the investigational plan used to conduct the Clinical Study.

m. "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.

n. "Summary of Clinical Study Report" refers to the brief presentations of Clinical Study Reports that are required by this Assurance and that provide the information pursuant to the templates set forth in Appendix B or Appendix C, whichever is applicable.

FOREST'S CLINICAL TRIAL REGISTRY

2. Forest shall Post on the CTR Summaries of Clinical Study Reports for Forest-Sponsored Clinical Studies involving Forest Drugs in accordance with Appendix A. The Summaries shall conform to the ICH E3 principles articulated in ICH's *Guidelines for Industry: Structure and Content of Clinical Study Reports* (July 1996) and to the templates set forth in Appendix B or Appendix C, whichever is applicable.

3. For (i) studies in which Forest had significant participation but did not sponsor which are initiated after the Assurance Date, or (ii) studies conducted by Forest's licensing partners which are initiated after the Assurance Date, Forest will also make reasonable efforts to encourage the publication of, or in the alternative, secure the right to publish on the CTR. Forest will use reasonable efforts to exclude from future contracts or licensing agreements any provisions limiting the publication of Summaries of Clinical Study Reports for all future Clinical Studies of Forest Drugs.

4. Forest will Post on the CTR Summaries of Clinical Study Reports for Clinical Studies of the use of Celexa and Lexapro in the pediatric population, including the Clinical Study conducted by its licensor.

The Summaries of Clinical Study Reports that Forest Posts on the CTR shall accurately reflect the methodology used to conduct the Clinical Study and the data obtained during the Clinical Study.

6. Forest shall clearly and conspicuously state the location of the CTR (URL, and where relevant, a link) on the Home Page of the Forest Web Site.

OTHER PROVISIONS

7. This Assurance shall constitute a full resolution of any claims that the Attorney General could assert relating to the past disclosure of Clinical Studies of the use of Celexa and Lexapro in the pediatric population.

8. Nothing in this Assurance shall in any way limit the right of the Attorney General to request information from Forest regarding any matter relating to Clinical Studies, and subject to a reasonable confidentiality agreement, Forest shall cooperatively respond to such requests.

9. Nothing contained in this Assurance shall in any way limit the Attorney General's right to obtain, by subpoena or any other means permitted by law, documents, testimony or other information.

10. Nothing contained in this Assurance shall be construed to deprive any individual of any private right of action under the law.

11. This Assurance shall not be admissible in any other case for any purpose.

12. The execution of this Assurance by the Attorney General shall not be deemed or construed as an approval by the Attorney General of any of Forest's actions, and Forest shall not make any representation to the contrary.

13. The execution of this Assurance by Forest shall not be deemed or construed to be an admission of liability by Forest or a waiver of any defense which Forest has or may have in any dispute with the OAG or any other person or entity, including but not limited to, the defense of federal preemption.

14. This Assurance shall not be construed to preclude Forest from complying with any Federal legal or regulatory requirement to which Forest is, or in the future will be, subject. Any Federal legal or regulatory requirement which conflicts with the provisions of this Assurance shall supercede the provision of this Assurance with which it conflicts, but only if the conflict is such that compliance with the Federal legal or regulatory requirement could not be achieved without modification of a provision of this Assurance.

15. Forest may make changes to the standards for disclosure, as set forth in Appendix A, and its templates, as set forth in Appendix B and Appendix C, so long as such changes would not diminish the data Posted pursuant to the terms of this Assurance. Further, other than the changes covered by the preceding sentence (*i.e.*, changes that would not diminish the data Posted pursuant to the terms of this Assurance) or covered by paragraph 14 above, if Forest believes that any material modifications to Appendix A, Appendix B, or Appendix C, or any modification of any other term of this Assurance, are necessary in light of changed circumstances, including changes in the environment in which Forest operates, Forest may request that the OAG modify Forest's obligations

under this Assurance, and the OAG shall promptly respond reasonably to any such requests, giving due consideration to such changes.

16. This Assurance shall remain in effect for seven years following the Assurance Date.

17. Forest will, in its sole discretion, make Clinical Study Reports and related data available to bona fide researchers who are preparing scholarly work for publication in Peer Reviewed Journals.

WHEREFORE, the following signatures are affixed hereto on the specified dates:

AGREED TO by the parties:

Dated: New York, New York
September 7, 2004

Dated: New York, New York
September 7, 2004

ELIOT SPITZER
Attorney General of the
State of New York

FOREST LABORATORIES, INC.

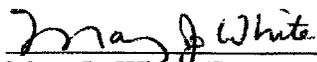
DEBEVOISE & PLIMPTON LLP

By:

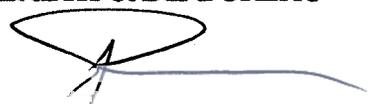
By:

BUREAU OF CONSUMER
FRAUDS AND PROTECTION

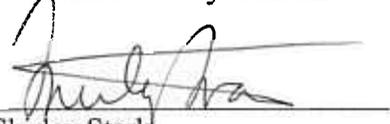

Thomas G. Conway
Assistant Attorney General in Charge


Mary Jo White, Esq.

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Assistant Attorney General in Charge


Rose E. Firestein
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APPENDIX A TO ASSURANCE BETWEEN THE OAG AND FOREST

Standards For Disclosures of Clinical Studies

I. Ongoing Studies. When Forest initiates a phase III or phase IV Forest-Sponsored Clinical Study, the unique study number, study title, study start date and key objectives will be Posted to an online Clinical Trials Registry (“CTR”) to be maintained by Forest and located on Forest’s Web Site. In addition, Forest will Post the same information for phase III studies conducted on Forest investigational products for which Forest is planning on seeking FDA approval.

II. Studies Concluded After the Assurance Date. For all Forest-Sponsored Clinical Studies of Forest Drugs completed after the Assurance Date, Forest will Post Summaries of Clinical Study Reports (regardless of outcome) to the CTR according to the following time schedule:

a) Phase III Studies. Summaries of Clinical Study Reports of Forest-Sponsored phase III Clinical Studies shall be Posted when a Forest investigational product first becomes commercially available following FDA approval (identified by the study numbers assigned previously when listed as ongoing trials). The Summaries of these phase III Clinical Study Reports will include the data set forth in the template attached as Appendix B.

b) Phase IV Studies. Summaries of Clinical Study Reports of Forest-Sponsored phase IV Clinical Studies shall be Posted within one year of their Study Completion Date (identified by the study numbers assigned

previously when listed as ongoing trials). All Summaries of these phase IV Clinical Study Reports covered by this paragraph will include the data set forth in the template attached as Appendix B.

c) Phase I and II Studies. Summaries of safety data from Clinical Study Reports of Forest-Sponsored phase I and phase II Clinical Studies shall be Posted within one year of their Study Completion Date (but in no event shall Forest be required to Post such Clinical Studies before a Forest investigational product first becomes commercially available following FDA approval) if those safety results are material to the clinical use of these drugs or the care of patients. The Summaries of these phase I and phase II Clinical Study Reports will include the data set forth in the template attached as Appendix C.

d) All Studies. When the results of a Forest-Sponsored Clinical Study are submitted to a Peer Reviewed Journal whose editorial policy prohibits any prior disclosure of study results, the results will be Posted to the CTR at the time of publication. Similarly, in some instances, there may be a delay in Posting to the CTR because Forest must seek intellectual-property protection. In such instances, Forest shall make reasonable efforts to seek intellectual property protection as quickly as practicable.

III. Studies Concluded Between January 1, 2000 and the Assurance Date: For all Forest-Sponsored Clinical Studies of Forest Drugs completed after January 1, 2000 and before the Assurance Date, Forest will Post to the CTR Summaries of Clinical Study Reports

according to the same standards (other than the timing provisions) for each of the different phases of Clinical Studies set forth in Section II. All of these Summaries of Clinical Study Reports shall be Posted by December 31, 2005.

IV. Studies Concluded Prior to January 1, 2000: For all Forest-Sponsored Clinical Studies of Forest Drugs which are actively promoted by Forest completed before January 1, 2000, Summaries of Clinical Study Reports shall be Posted in accordance with the following terms:

a) Clinical Studies of On-Label Uses: Summaries of safety data from Clinical Study Reports of Forest-Sponsored phase I, II, III and IV Clinical Studies for an On-Label Use shall be Posted by December 31, 2005 if those safety results are material to the clinical use of the drugs or the care of patients. The Summaries of these Clinical Study Reports will include the data set forth in the template attached as Appendix C.

b) Phase I and Phase II Clinical Studies of Off-Label Uses: Summaries of safety data from Clinical Study Reports of Forest-Sponsored phase I and phase II Clinical Studies for an Off-Label Use shall be Posted in accordance with the standards and time periods set forth in subparagraph IV(a) above.

c) Phase III and Phase IV Clinical Studies of Off-Label Uses: Summaries of Clinical Study Reports of Forest-Sponsored phase III and phase IV Clinical Studies for an Off-Label Use shall be Posted by December 31 2005 if those safety or efficacy results are material to the clinical use of

the drugs or the care of patients. The Summaries of these phase III and phase IV Clinical Study Reports shall include the data set forth in the template attached as Appendix B, which contains both safety and efficacy data.

V. All information provided to the CTR will comply with all relevant FDA regulations.

APPENDIX B

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/country		
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	
	A	B
Demographics		
N (ITT)	From synopsis	
Females: Males If only one gender was studied, 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		
<p>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.</p> <p>Format of presentation of individual SAEs by preferred term is: n, (%) [n considered "related"]</p> <p>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.</p> <p>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:</p> <p>Subjects with any SAEs, n (%) -Includes both fatal and non-fatal events</p>		
	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"]		
<p>Conclusion: Within 1 year after study completion this section will either refer you to a publication or contain text interpreting the trial results.</p>		
<p>Publications: Add citations</p>		

APPENDIX C

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/country		
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 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"		

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