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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff	)	
	)	
v.	)	No.
	)	
SCHERING-PLOUGH CORPORATION, and	)	
SCHERING-PLOUGH PRODUCTS, LLC,	)	
corporations, and	)	
	)	
RICHARD J. KOGAN, and	)	
STEVEN C. CHELLEVOLD,	)	
individuals,	)	
	)	
Defendants.	)	
	)	

CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, plaintiff, having filed a Complaint for Injunction against Schering-Plough Corporation and Schering-Plough Products, LLC, a subsidiary of Schering-Plough Corporation; and Richard J. Kogan, Chief Executive Officer and Chairman of the Board, Schering-Plough Corporation and Steven C. Chellevold, Senior Vice-President, Worldwide Technical Operations, Schering-Plough Corporation and Vice President, Schering-Plough Products, LLC, individuals (hereinafter, collectively, "Defendants"), and Defendants having appeared and having consented to entry of this Decree, without contest, solely for the purpose of settling this case, without admitting or denying the allegations of the Complaint and disclaiming any liability in connection herewith, and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter herein, and has personal jurisdiction over all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

2. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c).

3. The Complaint for Injunction states a cause of action against the Defendants under the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 301 et seq.

4. Except as provided in paragraph 7, Defendants, and each and all of their subsidiaries, officers, agents, employees, representatives, successors, assigns, and attorneys, and those persons in active concert or participation with any of the Defendants, are permanently enjoined under 21 U.S.C. § 332(a) from directly or

indirectly doing or causing the manufacture, processing, packing, and distribution of any article of human or veterinary drug (as defined by 21 U.S.C. § 321(g); hereinafter, collectively, "drug(s)") at Defendants' facilities located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, and 1011 Morris Avenue, Union, New Jersey 07083 (hereinafter, "New Jersey facilities"), and at State Road No. 686, Km 0.5, Manati, Puerto Rico 00674-0486, and State Road No. 183 Pridco Industrial Park, Las Piedras, Puerto Rico 00771 (hereinafter, "Puerto Rico facilities"), unless and until, for Defendants' New Jersey and Puerto Rico facilities subparagraph (A) has been satisfied, for the Manati facility subparagraphs (B)-(E) have been satisfied, and for the Las Piedras and New Jersey facilities subparagraph (F) has been satisfied.

NEW JERSEY AND PUERTO RICO FACILITIES

A. For Defendants' New Jersey and Puerto Rico facilities, Defendants have selected and retained one or more expert consultants (hereinafter, "expert consultant(s)") who are qualified by education, training, and experience to inspect and to determine whether the methods, procedures, and controls used to manufacture, process, pack, and hold drug(s) at Defendants' New Jersey and Puerto Rico facilities are in compliance with the requirements of 21 U.S.C. § 351(a)(2)(B), the current good manufacturing practice ("CGMP") regulations set forth at 21 C.F.R. Parts 210 and 211, and 21 U.S.C. § 355 (b)(1)(B)-(D). Each such expert consultant shall be retained at Defendants' expense and shall be without personal or financial ties (other than consulting agreements between the parties or indirect ownership of Schering-Plough Corporation or Schering-Plough Products, LLC, or their subsidiaries, e.g., through

diversified mutual funds or pension funds) to Defendants, Defendants' subsidiaries, or their immediate families.

MANATI FACILITY

B. For Defendants' Manati facility, Defendants have caused their expert consultant(s) to inspect the facility in accordance with the CGMP Protocol for the facility concurred with in writing by FDA on March 6, 2002 ("the March 6 CGMP Protocol"), which identifies specific systems and processes that FDA believes require review by the expert consultant(s) for compliance with CGMP;

C. Defendants have caused their expert consultant(s) to concurrently provide to Defendants and FDA a final detailed written report of all results of the expert consultant(s)'s evaluation of whether the Manati facility complies with all the requirements of the March 6 CGMP Protocol;

D. (i) Defendants' expert consultant(s) has found that the Manati facility is in compliance with the requirements of the March 6 CGMP Protocol; (ii) Defendants' expert consultant(s) has certified such compliance in writing to Defendants; and (iii) Defendants have sent a copy of the written certification to FDA. Defendants' expert consultant(s) may certify the Manati facility in its entirety or on a building-by-building basis, or it may certify the part(s) of the facility used to manufacture sterile drug(s) separately from the part(s) of the facility used to manufacture non-sterile drug(s), provided that, in the professional opinion of Defendants' expert consultant(s), it is appropriate to do so. Beginning sixty (60) days after receipt of the expert consultant(s)'s written report submitted pursuant to paragraph 4(C), Defendants shall submit reports to FDA describing (a) the status of the implementation of the corrective actions identified in

the expert consultant(s)'s written report, and (b) the impact on current production and marketed drug(s) of the deficiencies noted in the expert consultant(s)'s written report. Defendants shall submit such status reports every 60 (sixty) days until the date of the first yearly inspection of the Manati facility has commenced pursuant to paragraph 26. Defendants shall cause the expert consultant(s) conducting this first yearly inspection of the Manati facility to take into account the expert consultant(s)'s initial report and the Defendants' subsequent status reports; and

E. The drug product(s) or active pharmaceutical ingredient(s) (hereinafter, "API(s)") manufactured by Defendants at the Manati facility meets the requirements of clause (i) or (ii) or, in the case of the active pharmaceutical ingredients alclometasone dipropionate, netilmicin sulfate, and isepamicin sulfate, such API meets the requirements of clause (iii) of this subparagraph:

i. FDA has received a written certification from Defendants' expert consultant(s) that the production equipment and processes that are used to manufacture the drug product(s) have been, respectively, qualified and validated, in accordance with paragraphs 9-13; or

ii. FDA has received a final written certification by Defendants' expert consultant(s) that: (a) a product quality review was performed in accordance with the product quality review protocol and the first, second, and third addenda concurred with in writing by FDA on February 14, 2002, April 25, 2002, May 15, 2002, and May 16, 2002, respectively, ("the product quality review protocol"), under which the review of a drug product(s) is sufficient to cover its API(s); and (b) the manufacturing process is in control and produces a drug product(s) that consistently meets all applicable approved

specifications described in the product quality review protocol through the labeled expiration period of the drug product(s); or

iii. With respect to the APIs alclometasone dipropionate, netilmicin sulfate, and isepamicin sulfate, FDA has received a final written certification by Defendants' expert consultant that: (a) a product quality review was performed in accordance with the product quality assessment protocol for the designated Manati active pharmaceutical ingredients concurred with in writing by FDA; and (b) the process for the API is in control and produces API that consistently meets approved specifications through its retest or expiration date.

LAS PIEDRAS AND NEW JERSEY FACILITIES

F. The drug product(s) manufactured by Defendants at the Las Piedras and New Jersey facilities meets the requirements of either paragraph 4(E)(i) or 4(E)(ii).

PUERTO RICO AND NEW JERSEY FACILITIES

5. For Defendants' Puerto Rico and New Jersey facilities:

A. Within ninety (90) days of the entry of this Decree, Defendants shall submit to FDA: (i) a written comprehensive CGMP Workplan for each of Defendants' Puerto Rico and New Jersey facilities designed to ensure that the methods, facilities, and controls used to manufacture drug(s) at each of these facilities are, and will be continuously maintained, in compliance with 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210 and 211, and 21 U.S.C. § 355(b)(1)(B)-(D) (except for equipment qualification and process validation, which are subject to paragraphs 9-13 rather than this paragraph); and (ii) a timetable for completion of each significant step in the CGMP Workplan for each facility. Defendants shall obtain written FDA concurrence of the CGMP Workplans and

timetables. FDA shall respond to Defendants within sixty (60) days of the receipt of any CGMP Workplan and timetable or revised CGMP Workplan or timetable.

B. Defendants shall promptly notify FDA in writing as and when Defendants complete each step identified in the CGMP Workplans for which a deadline has been established in the timetables submitted to FDA pursuant to paragraph 5(A)(ii).

C. Until Defendants' expert consultant(s) has certified that the CGMP Workplan described in paragraph 5(A) for a facility has been fully and satisfactorily completed, Defendants shall cause an expert consultant(s) to review each report of an investigation of an out-of-specification (OOS) laboratory test result for a batch of any drug(s), and any Material Review Board ("MRB") investigation (as defined by Defendants), relating to the manufacture of any batch of any drug(s) at such facility, and shall cause the expert consultant(s) to certify in writing prior to the release of such batch whether Defendants' investigation complies with the requirements of 21 C.F.R. § 211.192. Defendants may not release for distribution any batch of a drug(s) associated with an OOS laboratory test result or MRB investigation (as defined by Defendants) until Defendants' expert consultant(s) has certified in writing that the investigation complies with all requirements of the foregoing regulation.

D. Defendants' expert consultant(s) shall conduct monthly audits of Defendants' log(s) of all variances to ensure that any variance(s) that may adversely affect the safety, identity, strength, quality, or purity of a batch of drug(s) has been investigated by Defendants' MRB. If Defendants' expert consultant(s) identifies a variance that may adversely affect the safety, identity, strength, quality, or purity of a batch of drug(s) that has not been investigated by Defendants' MRB, Defendants shall immediately

designate the variance as requiring review by Defendants' MRB, and the certification requirements of this paragraph shall apply.

E. After review by the MRB, if Defendants' expert consultant(s) does not certify that Defendants' investigation complied with all requirements of 21 C.F.R. § 211.192, and the batch has been released for distribution, Defendants shall immediately notify FDA in writing, and shall immediately recall the batch unless FDA determines in its sole and unreviewable discretion that a recall is not required. The requirements of this paragraph do not affect Defendants' obligations to send product defect reports to FDA as required by 21 C.F.R. §§ 314.81 and 510.300, or to take any other action required by law or regulation.

6. Defendants represent that, as of the date of entry of this Decree, they have voluntarily discontinued manufacturing the following drug products at Defendants' Puerto Rico and New Jersey facilities. Defendants shall not resume the manufacture of any of these drug products at their Puerto Rico or New Jersey facilities unless and until: (A) Defendants have fully and satisfactorily completed the CGMP Workplan for the applicable facility as evidenced by certification by Defendants' expert consultant(s); (B) Defendants have provided FDA with thirty (30) days prior written notice of their intention to resume the manufacture of such drug products; and (C) the drug(s) meets the requirements of paragraphs 10-13 of this Decree.

Product	Manufacturing Site
Aclovate Cream 15 gm, 45 gm, 60 gm	New Jersey
Aclovate Ointment 15 gm, 45 gm, 60 gm	New Jersey

A&D Personal Care Lotion	New Jersey
Celestone Tablets 100s & 21s	New Jersey
Coricidin Night Time Tablet Coricidin High Blood Pressure Night Time Cold/Flu Tablets 24s	New Jersey
Correctol 50 Tablets Correctol 50 Tablets 24s	New Jersey
Correctol Caplets/Bisacodyl Correctol Caplet 30s	New Jersey
Diprolene Gel (Samples) 18 x 1.8 gm	New Jersey
Diprosone Lotion 20ml & 60ml	New Jersey
Doral Tablets (IVAX) 15 mg & 7.5 mg bulk	New Jersey
Estinyl Tablets Estinyl 0.02mg 100s Estinyl 0.02mg 250s Estinyl 0.05mg 100s Estinyl 0.05mg 250s	New Jersey
Etrafon Tablets Etrafon 2/10mg 100s Etrafon 2/10mg Hospital Unit Dose Etrafon 2/25mg 100s Etrafon 2/25mg Hospital Unit Dose Etrafon 4/25mg 100s Etrafon 4/25mg Hospital Unit Dose	New Jersey
Fulvicin P/G (Griseofulvin) (Human Rx) Tablets Fulvicin P/G 125mg 100s Fulvicin P/G 165mg 100s Fulvicin P/G 250mg 100s Fulvicin P/G 330mg 100s Griseofulvin P/G 125mg 100s Griseofulvin P/G 250mg 100s Griseofulvin P/G 330mg 100s	New Jersey

Fulvicin U/F (Griseofulvin) New Jersey
(Human Rx) Tablets
Fulvicin U/F 250mg 60s
Fulvicin U/F 250mg 250s
Fulvicin U/F 500mg 60s
Fulvicin U/F 500mg 250s

Gyne-Lotrimin 3-Day Combination Pack New Jersey
(Cream and Inserts)
Gyne-Lotrimin 3-Day Combination Pack
Gyne-Lotrimin 3-Day Combination Pack
with electronic article surveillance tag

Gyne-Lotrimin 3-Day Inserts New Jersey
Gyne-Lotrimin 3-Day Inserts 200mg
Gyne-Lotrimin 3-Day Inserts 200mg
with electronic article surveillance tag

Gyne-Lotrimin 7-Day Insert New Jersey

Intron A Powder 3 MIU 1ml/vial New Jersey

Lotrimin Lotion New Jersey
Lotrimin Creamy Lotion 20ml (OTC)
Lotrimin Lotion 30ml (Human Rx)

Lotrimin Solution (Human Rx) New Jersey
10 ml bottle, 30 ml bottle

Lotrisone Cream (Samples) 18x1.8gm New Jersey

Metricorten Tablets New Jersey
1mg 100s
2.5 mg 30s

Miradon Tablets 50mg 100s New Jersey

Naqua Tablets 4 mg 100s New Jersey

Optimine Tablets 1mg 100s New Jersey

Oreton Methyl Tablets New Jersey
Oreton Methyl Tablets 10mg 100s
Oreton Methyl Tablets 10mg bulk

Oreton Methyl Tablets 25mg 100s

Oreton Methyl Buccal Tablets — New Jersey
10mg x 100s, 30s

Permitil Oral Concentrate 5mg 4oz. — New Jersey

Permitil Tablets — New Jersey
Permitil Tablets 2.5mg 100s
Permitil Tablets 5mg 100s
Permitil Tablets 10mg 1000s

Polaramine Tablets 2mg 100s — New Jersey

Polaramine Repetab Tablets & Cores — New Jersey
4mg 100s & 6mg 100s

Polaramine Syrup 16oz — New Jersey

Proglycem Oral Suspension 30ml — New Jersey

Proventil Repetab Tablets 4 mg — New Jersey
100s, 500s, Hospital Unit Dose
18x2 samples

Proventil Syrup 16oz — New Jersey

Proventil/Albuterol Tablets — New Jersey
Proventil Tablets 2mg 100s
Proventil Tablets 2mg 500s
Proventil Tablets 4mg 100s
Proventil Tablets 4mg 500s
Albuterol Tablets 2mg 100s
Albuterol Tablets 2mg 500s
Albuterol Tablets 4mg 100s
Albuterol Tablets 4mg 500s

Sodium Sulamyd Ophthalmic Solution & Ointment — New Jersey
Solution 10% 25x5ml
Solution 10% 25x15ml
Solution 30% 15ml
Ointment 1/8oz

Trilafon Concentrate 4 oz New Jersey

Trilafon Tablets/Perphenazine New Jersey
Perphenazine Tablets 2mg 100 Warrick
Perphenazine Tablets 4mg 100 Warrick
Perphenazine Tablets 8mg 100 Warrick
Perphenazine Tablets 16mg 100 Warrick
Trilafon Tablets 2mg 100s
Trilafon Tablets 4mg 100s
Trilafon Tablets 8mg 100s
Trilafon Tablets 16mg 100s

Valisone Lotion 20ml & 60 ml New Jersey

Vancenase Aqueous Nasal New Jersey
Spray 42mcg 25gm Pump

Vanceril Double Strength Aerosol New Jersey
12.2gm & Convenience Package 3x5.4gm

Ventolin Syrup (Proventil Syrup) New Jersey
Ventolin Syrup 16oz
Ventolin Syrup 72x1oz

Afrin Allergy 4 hr Nasal Spray 15ml Manati

Afrin Menthol Saline Nasal Spray Manati
15ml, 30ml, 45 ml
45 ml with coupon

Azium IV Solution Manati

Betasone Aqueous Suspension 5ml Manati

Celestone Phosphate Injection Manati
2.5mg/3ml

Diprosone Cream 15gm & 45gm Manati

Diprosone Ointment 15gm & 45gm Manati

Garacin Piglet Injection Manati
250ml, 250ml Durvet

Garamycin Cream 15gm Manati

Garamycin Ophthalmic Ointment Manati

Garamycin Ophthalmic Solution 3mg/ml Manati

Garamycin Topical Ointment Manati

Gentocin Sterile Solution (Injection) Manati
100 mg 100 ml & 250 ml
50 mg 50 ml, 100 ml

Lotrimin Cream (Human Rx) Manati
15gm, 30gm & 45 gm

Clotrimazole Cream 1%
15 gm, 30 gm 45 gm, 2x45gm

Metimyd Ophthalmic Ointment 1/8oz Manati

Metimyd Ophthalmic Suspension 5 ml Manati

Netromycin Injection Manati
Solution/Netromycin Disc
Netromycin Injection 10x1.5ml

Ocuclear Opthalmic Solution, 30 ml Manati

Otobiotic Otic Solution, 15 ml Manati

Solganal Suspension 50mg/ml Manati

Trilafon Injection 5mg 1ml Ampul x 100 Manati

Valisone Cream Manati
Valisone Cream 0.1% 15gm
Valisone Cream 0.1% 45gm
Valisone Cream 0.1% 110gm
Valisone Cream 0.1% 430gm jar (government)
Valisone Cream 0.01% 15gm
Valisone Cream 0.01% 60gm

Valisone Ointment 15gm, 45gm, & 110gm Manati

Vancenase Aqueous Nasal Spray 84 mcg Manati

Normodyne/Labetalol Tablets Las Piedras

- Normodyne Tablets 100mg 100s
- Normodyne Tablets 100mg 500s
- Normodyne Tablets 100mg 1000s
- Normodyne Tablets 100mg Hospital Unit Dose
- Normodyne Tablets 200mg 100s
- Normodyne Tablets 200mg 500s
- Normodyne Tablets 200mg 1000s
- Normodyne Tablets 200mg Hospital Unit Dose
- Normodyne Tablets 300mg 100s
- Normodyne Tablets 300 mg 500s
- Normodyne Tablets 300 mg Hospital Unit Dose
- Labetalol Tablets 100mg 100s
- Labetalol Tablets 100mg 500s
- Labetalol Tablets 100mg 1000s
- Labetalol Tablets 200mg 100s
- Labetalol Tablets 200mg 500s
- Labetalol Tablets 200mg 1000s
- Labetalol Tablets 300mg 100s
- Labetalol Tablets 300mg 500s

Theo-Dur Extended Release Tablets Las Piedras
(Key Pharmaceuticals) (except for 100 mg
and 200 mg bulk packages for shipment to Japan)

- 100mg 100s
- 100mg 500s
- 100mg 1000s
- 100mg 5000s
- 100mg Hospital Unit Dose
- 200mg 100s
- 200mg 500s
- 200mg 1000s
- 200mg 5000s
- 200mg Hospital Unit Dose
- 300mg 100s
- 300mg 500s
- 300mg 1000s
- 300mg 5000s
- 300mg Hospital Unit Dose
- 450mg 100s
- 450mg Hospital Unit Dose

Theophylline Extended Release Tablets Las Piedras

- 100mg 100s
- 100mg 500s

200mg 100s
200mg 500s
200mg 1000s
300mg 100s
300mg 500s
300mg 1000s
450mg 60s Institution
450mg 100s

Uni-Dur/Frivent Theophylline — Las Piedras
Uni-Dur Extended Release Tablets
400mg & 600mg 100s

EXCLUSIONS

7. A. Manufacturing, processing, packing, holding, and distributing the following drugs, all of which have been identified by FDA as being medically necessary, shall be exempt from the requirements of paragraphs 4(B)-(F):

-Albuterol Aerosol Inhalers
-Rebetron
-Ribavarin Capsules
-Celestone Soluspan Injection
-Garamycin Injection
-Hyperstat Injection
-Normodyne Injection
-Integrilin IV Injection
-Ethamolin Injection 5%
-Sterile Bacteriostatic Water for Injection, USP containing 0.9% Benzyl Alcohol for use with Intron
-Sterile Bacteriostatic Water for Injection, USP containing Benzyl Alcohol for use with Etanercept
-Sterile Water for Injection for use with Etanercept.

B. Manufacturing, processing, packing, holding, and distributing investigational new human and animal drugs at Defendants' Las Piedras and New Jersey facilities shall be exempt from the requirements of paragraphs 4(E) and (F), 5(C)-5(E), and 9-13.

Defendants may manufacture, process, pack, hold, and distribute no more than five (5) batches of Ampligen from its Manati facility for use in clinical trials.

C. Manufacturing, processing, packing, holding, and distributing quantities of a drug(s) that are necessary to support or prepare an application, as defined in paragraph 28, or to support the development of a nonprescription drug(s) subject to 21 C.F.R. Part 330, shall be exempt from paragraphs 4, 5(C)-5(E), and 9-13. Such drug(s), however, shall not be commercially distributed unless the drug(s) otherwise complies with this Decree.

D. Manufacturing, processing, packing, holding, and distributing a drug(s) for the sole purpose of conducting non-clinical laboratory studies or other research and testing that does not involve exposure of human subjects shall be exempt from the requirements of this Decree.

E. Manufacturing, processing, packing, holding, and distributing a drug(s) for the purposes of performing qualification of equipment, validation of drug(s) manufacturing processes, or conducting stability studies shall be exempt from paragraphs 4, 5(C)-5(E), 6, and 9-13. Except for a drug(s) approved by FDA after the date of entry of this Decree, as provided in paragraph 42, such drug(s) shall not be commercially distributed unless it meets the requirements of paragraph 4, and, when applicable, paragraph 5(C)-5(E).

F. Assembling Intron Multi-dose Pen, Rebetron Pen, PEG-Intron Pen, and PEG-Rebetron Pen, and packaging, labeling, testing, releasing, holding, and distributing these and any other drug(s) (including, but not limited to, Intron and PEG-Intron, as single ingredient drug(s) or as components of Rebetron or PEG-Rebetron, respectively)

at Defendants' Puerto Rico and New Jersey facilities, provided that the drug(s) was not otherwise manufactured or processed at any of Defendants' New Jersey and Puerto Rico facilities, are exempt from the requirements of paragraphs 4(E)-(F), 8(A), and 9-13.

G. APIs manufactured, processed, packed, and held, at Defendants' New Jersey and Puerto Rico facilities, when used as components of a drug(s) manufactured by Defendants and when not commercially distributed as APIs, are exempt from the requirements of paragraphs 4(E) and 4(F). APIs used to manufacture a drug(s) listed in paragraph 7(A) are exempt from the requirements of paragraph 4(B)-(F). Notwithstanding the foregoing, Batch numbers 2-ALOX-6001 and 2-ALOX-6002 of the API alclometasone dipropionate and Batch number 2-NLMN-6903 of the API netilmicin sulfate manufactured, processed, packed, held at, and distributed from, Defendants' Manati facility, are exempt from the requirements of paragraph 4(E) and (F) provided they are distributed by Defendants prior to June 30, 2002. Defendants may continue to manufacture, process, pack, and hold additional batches of alclometasone dipropionate, netilmicin sulfate, and isepamicin sulfate, at Defendants' own risk, but may not commercially distribute such batches unless the requirements of paragraph 4(E)(iii) or paragraphs 9-13 are satisfied.

H. Manufacturing, processing, packing, holding, distributing for export, and exporting any drug(s) or biological product(s) in compliance with 21 U.S.C. §§ 381(e) or 382, and 21 C.F.R. § 312.110, or 42 U.S.C. § 262(h), as appropriate, or exporting any drug(s) that is eligible for commercial distribution in domestic commerce under the terms of this Decree or that is an export-only version of such a drug(s), are not prohibited by this Decree.

8. A. For each batch of the drug(s) listed in paragraph 7(A), the manufacture of which has commenced after the date of entry of this Decree, and that is not the subject of a validation certification under paragraphs 9-13, Defendants' expert consultant(s) shall, prior to release of a batch for distribution, complete a record review of the complete batch production and control record for each batch approved for release by Defendants and certify in writing whether, based upon the expert consultant(s)'s review (which shall, when applicable, rely in part upon a review and certification of an OOS result or MRB investigation that was the subject of a review and certification pursuant to paragraphs 5(C) or 5(D)), no deviations occurred during the manufacture of the batch that, in the expert consultant(s)'s professional opinion, would, during its labeled expiration period, adversely affect the safety, identity, strength, quality, or purity of the batch or cause the batch to fail to meet any and all applicable approved specifications established in its application. In the absence of such a written certification, Defendants shall not distribute the batch. Defendants shall continue to have their expert consultant(s) perform the batch-by-batch reviews required by this paragraph for each drug(s) listed in paragraph 7(A) until FDA has received from Defendants a copy of Defendants' expert consultant(s)'s final written validation certification for such drug(s) under paragraphs 11 or 13. The foregoing requirements shall not apply to the assembly of Rebetron, but shall apply to all other manufacturing, processing, and control steps associated with the ribavirin component of Rebetron.

B. FDA shall have the sole and unreviewable discretion to add any drug(s) to, and the discretion to delete any drug(s) from, paragraph 7(A), either on its own initiative, after consultation with Defendants, or after consideration of a written request from the

Defendants. Defendants may not discontinue manufacturing and distributing any drug(s) listed in or added to paragraph 7(A), without FDA's prior written approval unless the cessation of manufacture and distribution is not within Defendants' control, the drug(s) is manufactured for another company under contract and the contract has expired, has been terminated or not renewed in accordance with the contract's terms, or has been terminated or breached by the other party, and Defendants provide written notice to FDA within five (5) business days of such discontinuation, or Defendants have provided written notice to FDA at least twelve (12) months prior to discontinuing the manufacture or distribution of the drug(s).

C. If any drug(s) listed in paragraph 7(A) is deemed by FDA, after consultation with Defendants, to be no longer medically necessary, FDA shall notify Defendants in writing. If this notification occurs before the drug(s) has been certified to FDA as validated by Defendants' expert consultant(s)(as described in paragraphs 9-13), Defendants shall immediately cease manufacturing the drug(s) unless and until the drug(s) meets the requirements of paragraphs 4(E) or 4(F), or unless FDA agrees, in its sole and unreviewable discretion, that Defendants may continue to manufacture the drug(s). If any drug(s) is added to paragraph 7(A) that has not yet been certified as validated in accordance with paragraphs 9-13, the batch-by-batch review and certification requirements of subparagraph (A) of this paragraph shall apply.

ADDITIONAL REQUIREMENTS

9. A. Defendants shall conduct and have certified by their expert consultant(s) adequate validation studies, conducted pursuant to paragraphs 10-13, for: (a) each drug product formulation, dosage form, strength, and packaging configuration, identified in

the timetable and list (submitted to and concurred in by FDA on May 2, 2002) of drug(s) that they intend to distribute under paragraphs 4(E)(ii) and 7(A); and (b) each API(s) manufactured by Defendants at its New Jersey or Puerto Rico facilities and identified in the list and timetable that Defendants have agreed to, and shall, submit to FDA in writing for FDA concurrence within sixty (60) days after entry of this Decree.

B. As and when Defendants have fully and successfully complied with the requirements of paragraphs 9(A) and 10-13 for a particular drug(s) or API(s), the certification requirements of paragraphs 9(A) and 10-13 shall no longer apply to the drug(s) or API(s), unless FDA determines, after consultation with Defendants, that the certification was not adequate.

10. In certifying the validation of a drug product(s) or API(s) under paragraphs 4(E)(i), 4(F)(excluding 4(E)(ii)), and 9-13, Defendants' expert consultant(s) shall, using the criteria described in subparagraphs (A)-(E) of this paragraph, review the protocols and reports provided by Defendants, as well as any other information Defendants' expert consultant(s) deems to be appropriate and necessary to evaluate the adequacy of Defendants' validation protocols and reports:

A. whether the process validation protocol clearly states how the validation study was to be conducted, including test parameters, relevant characteristics of the drug(s) or API(s), production equipment used, and decision points on what constitutes acceptable test results;

B. whether the process validation protocol was adhered to during its execution (and if not, what deviations occurred and whether the deviations may have adversely affected the validation study);

C. whether the drug(s) or API(s) is being manufactured in conformity with the equipment operating principles, analytical methods, and formulations described in the current Chemistry Manufacturing Control (CMC) section of the FDA-approved application(s) or, if applicable, in the most recent submission to Defendants' Drug Master File (DMF) for an API;

D. whether the equipment used in the New Jersey and Puerto Rico facilities to manufacture the drug(s) or API, including equipment used to process components, fill product, and in the case of sterile drug(s) also process containers and closures, is qualified and is of appropriate design for each of its intended uses. This analysis shall include whether adequate controls exist to ensure that such equipment is operating within specifications and are sufficient to ensure the safety, identity, strength, quality, and purity of the drug(s) or API(s); and

E. whether the results of the validation study show that the current process used to manufacture the drug product(s) or API(s) is validated and that, in Defendants' expert consultant(s)'s professional opinion, there is reasonable assurance that the drug(s) or API(s) will consistently meet all applicable specifications established in its approved application(s) and, if applicable, Defendants' DMF for an API, or, for a drug(s) or API(s) that does not require an FDA-approved application, that the drug(s) or API(s) meets all applicable specifications established in official compendia, applicable OTC monographs, and by Defendants, when the drug(s) or API(s) is manufactured pursuant to its validated process.

11. A. As the validation of each drug product(s) or API(s) listed in the timetables concurred with by FDA under paragraph 9(A) is completed, Defendants shall

notify Defendants' expert consultant(s). Defendants' expert consultant(s) shall promptly determine whether the current production equipment and manufacturing processes used to manufacture the drug(s) or API(s) have been, respectively, qualified and validated in accordance with the requirements of paragraphs 9 and 10. If Defendants' expert consultant(s) finds that the equipment qualification and process validation for the drug(s) or API(s) is adequate, Defendants' expert consultant(s) shall so certify in writing to Defendants. Defendants shall promptly provide FDA with a copy of the certification.

B. If Defendants' expert consultant(s) is unable to certify that a manufacturing process validation or equipment qualification for a particular drug product(s) or API(s) is adequate, Defendants' expert consultant shall, contemporaneously, provide a complete and detailed written report to the Senior Vice President, Worldwide Quality, Schering-Plough Corporation, and to FDA, identifying all reasons and results found during the review that are the basis for not certifying the validation of the manufacturing process or qualification of the equipment under review (hereinafter, "negative report"). If at any time Defendants become aware that they are or will be unable to validate a drug(s) or API(s) in accordance with paragraphs 9-13, Defendants shall promptly notify FDA in writing.

12. Within thirty (30) days of receiving a negative report, if any, Defendants shall send to FDA a written proposed plan to correct all deviations found by Defendants' expert consultant(s) along with a proposed timetable to complete the corrections. The proposed timetable shall be subject to FDA concurrence in writing. FDA shall concur with or identify any objections it may have to the timetable in writing to Defendants within fifteen (15) business days of its receipt.

13. After all of the findings identified by Defendants' expert consultant(s) pursuant to paragraph 11 have been adequately corrected for a particular drug product(s) or API(s) to the satisfaction of Defendants' expert consultant(s), Defendants' expert consultant(s) shall provide Defendants with a written certification that the production equipment and the manufacturing process currently used for the drug(s) or API(s) is qualified and validated, respectively, in accordance with paragraphs 9-12. Defendants shall promptly provide a copy of the written certification to FDA.

PRODUCT RECALLS

14. Upon entry of this Decree, Defendants shall immediately recall all lots of Theophylline and Proventil Repetabs that are still within their labeled expiration periods from all of their United States wholesale consignees and all other United States direct consignees for destruction.

DISGORGEMENT AND OTHER MONETARY PROVISIONS

15. Schering-Plough Corporation and Schering-Plough Products, LLC (the owner of the Puerto Rico facilities) agree to pay equitable disgorgement to the United States Treasury in the total amount of five hundred million dollars ($500,000,000.00), as follows: Schering-Plough Corporation agrees to pay one hundred seventy-five million dollars ($175,000,000.00) to the United States Treasury no later than ten (10) days after the date of entry of this Decree. Schering-Plough Products, LLC agrees to pay seventy-five million dollars ($75,000,000.00) to the United States Treasury no later than ten (10) days after the date of entry of this Decree. With respect to the remaining two hundred and fifty million dollars ($250,000,000.00), one hundred seventy-five million dollars ($175,000,000.00) shall be paid by Schering-Plough Corporation and seventy-five

million dollars ($75,000,000.00) shall be paid by Schering-Plough Products, LLC, to the United States Treasury no later than three hundred sixty-five (365) days after the date of entry of this Decree.

16. A. In the event that FDA or Defendants' expert consultant(s) determines that Defendants have failed to: (a) submit to FDA a CGMP Workplan in accordance with the time frame specified in paragraph 5(A), or satisfactorily complete a step within a time frame established in such a CGMP Workplan; (b) submit a drug(s) or API(s) validation timetable in accordance with the time frame specified in paragraph 9(A), or validate any drug(s) or API(s) within a time frame established in such timetable; (c) submit a proposed plan and timetable for required corrections in accordance with the time frame specified in paragraphs 12 or 18(D); or (d) submit a copy of the expert consultant(s)'s management report or inspection report in accordance with, respectively, paragraphs 23 and 25(D); and the Defendants are continuing to distribute drugs from the affected New Jersey and/or Puerto Rico facilities after the deadlines set forth above in this paragraph, FDA shall have the sole and unreviewable discretion to order Defendant Schering-Plough Corporation (for the New Jersey facilities), and Schering-Plough Products, LLC (for the Puerto Rico facilities), to pay to the United States Treasury a portion of the proceeds from the sales of such products in the amount of fifteen thousand dollars ($15,000.00) for each business day that Defendants have failed to perform any of the acts described in clauses (a)-(d) of this subparagraph.

B. Payments under this paragraph shall be assessed by FDA on a quarterly basis. Total payments incurred by the corporate Defendants for business days in the calendar year 2002 during which corporate Defendants failed to perform any of the acts

described in clauses (a) through (d) of subparagraph 16(A), or incurred under this paragraph by reason of paragraph 17(C), 18(C) and/or 18(E), shall not exceed twenty-five million dollars ($25,000,000). Total payments incurred by the corporate Defendants for business days in the calendar years 2003, 2004, and 2005 for the failure to perform any of the acts described in clauses (a)-(d) of subparagraph 16(A), or incurred under this paragraph by reason of paragraph 17(C), 18(C), and/or 18(E), shall not exceed fifty million dollars ($50,000,000) in any one calendar year. No payments shall be incurred by the corporate Defendants under this paragraph for Defendants' failure(s) to perform any of the acts described in clauses (a) through (d) of subparagraph 16(A), or incurred under this paragraph by reason of paragraph 17(C), 18(C) and/or 18(E), after calendar year 2005 except by mutual agreement of the parties. Although the corporate Defendants may incur only the foregoing maximum amounts in any calendar year, nothing shall prevent FDA from assessing, and corporate Defendants from being obligated to pay, more than the foregoing maximum amounts in any calendar year for payments incurred in any prior year(s) or in more than a single calendar year. Payments under this paragraph shall be due and owing thirty (30) days after the date of FDA's order to Defendants. No payment shall be due or owing under this paragraph for the failure to validate any drug(s) or API(s), or for the failure to complete a CGMP Workplan step for a drug(s) or API(s), that is not commercially distributed by Defendants. Total payments incurred by Defendants under this paragraph or made pursuant to this paragraph shall not exceed one hundred seventy-five million dollars ($175,000,000) in the aggregate.

17. A. If any drug(s) or API(s) that is scheduled to be validated under paragraph 9(A) has not been certified in writing by Defendants' expert consultant(s) as having been validated as of the date on which the last validation in that timetable is scheduled to be completed (hereinafter, "last validation date"), payments under paragraph 16 shall stop on the last validation date, and FDA shall have the sole and unreviewable discretion to order Defendant Schering-Plough Corporation (for the New Jersey facilities), and Defendant Schering-Plough Products, LLC (for the Puerto Rico facilities), to pay the United States Treasury twenty-four and six-tenths percent (24.6%) of all net sales of each uncertified drug(s) and/or API(s), excluding any drug(s) or API(s) that complies with paragraph 7(H), accruing from the last validation date and continuing until such drug(s) and/or API(s) has been certified as validated by Defendants' expert consultant(s). The amount(s) paid under this paragraph shall be determined by a Certified Public Accountant on a quarterly basis beginning ninety (90) days after the last validation date, and ending on the date that the drug(s) or API(s) is certified by Defendants' expert consultant. Defendants shall cause the Certified Public Accountant to send a determination to FDA in writing within forty-five (45) days of the end of each quarter. Payments under this paragraph shall be due and owing thirty (30) days after the date of FDA's order to Defendants. No payment shall be due or owing with respect to any drug(s) or API(s) that is not commercially distributed by Defendants.

B. The Certified Public Accountant shall: apply Generally Accepted Accounting Principles, be paid by Defendants, and be found acceptable to Defendants and FDA. Defendants shall cooperate in full with the accountant and shall provide all records reasonably requested by the accountant to make the determinations described in this

paragraph. Defendants agree, in the event of a dispute with FDA over any determinations regarding the amounts due and owing under this paragraph, to provide all records reasonably requested, by the accountant or by FDA, to FDA. The accountant and FDA shall treat any such records as confidential proprietary business records and shall not disclose them to any third party.

C. Notwithstanding paragraphs 16 and subparagraph (A) of this paragraph, if Defendants' expert consultant(s) has failed to certify, to FDA's satisfaction, that a drug(s) and/or API(s) (excluding drug(s) listed in paragraph 7(A)) has been validated within six (6) calendar months of the date that the drug(s) or API(s) is scheduled to be validated in the applicable timetable, Defendants shall immediately upon the expiration of such six-month period cease manufacturing and distributing such drug(s) or API(s) until Defendants' expert consultant(s) has certified to FDA's satisfaction that the drug(s) or API(s) is validated. FDA may, in its sole and unreviewable discretion, agree that manufacture and distribution of a drug(s) or API(s) may continue after the foregoing six (6) month period subject to payments described in paragraph 16 or 17(A), as applicable, provided however that no payment shall be required with respect to a drug(s) listed in paragraph 7(A) upon expiration of the twelve (12) month notification period to FDA described in paragraph 8(B), provided that Defendants have complied with paragraph 8(B). Any request by Defendants that FDA exercise its discretion to permit Defendants to continue manufacture and distribution of an uncertified drug(s) or API(s) must be in writing and must be received by FDA no later than sixty (60) days prior to the scheduled certification date for the drug(s) or API(s) unless FDA agrees in writing to a shorter time period.

D. Defendants Schering-Plough Corporation and Schering-Plough Products, LLC shall be jointly and severally liable for any and all amounts due and owing under this Decree.

E. Interest on the second payments described in paragraph 15 and on all other payments that are not made by Schering-Plough Corporation or Schering-Plough Products, LLC within the time frames established in paragraphs 16-19 shall begin to accrue on the day following the date on which payment is due as established in paragraphs 15-19, at a rate equal to the weekly average one-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System.

18. The remedies provided in paragraphs 15-17 shall be in addition to and not in lieu of any action(s) taken under this Decree.

A. The parties shall make a good faith attempt to promptly identify and resolve any issue relating to this Decree, using written communication and, when appropriate, meetings, in order to facilitate compliance with this Decree. FDA and Defendants shall each designate a primary Decree administrator who shall be responsible for implementing this provision.

B. For purposes of paragraphs 16 and 17, if Defendants' expert consultant(s) certifies in writing that a validation study has been satisfactorily completed and the validation study was completed on or before the date in the timetable(s) described in paragraph 9(A) or if Defendants notify FDA that a step identified in a CGMP Workplan has been satisfactorily completed on or before the date in the CGMP Workplan timetable described in paragraph 5(A), it shall, for the purposes of calculating payments under this Decree, be assumed that the validation study or CGMP Workplan step was

satisfactorily completed by the timetable date, unless and until FDA notifies Defendants to the contrary under subparagraph (C) of this paragraph.

C. If at any time Defendants' expert consultant(s) or FDA notifies Defendants in writing that a validation certification of a drug(s) or API(s) was not completed by the scheduled date in the timetable submitted pursuant to paragraph 9(A), or that a validation certification of a drug(s) or API(s) was not adequate, or that a CGMP Workplan step was not satisfactorily completed by the applicable timetable date in the timetable submitted pursuant to paragraph 5(A), payment shall be due and owing as described in paragraph(s) 16 and/or 17, as applicable, for each drug(s) and/or API(s) and each CGMP Workplan step, commencing on the date Defendants' expert consultant or FDA notified Defendants of the failure to meet such scheduled date(s), whichever is earlier, and ending on, and including (for validation studies) the completion date re-certified to by Defendants' expert consultant(s) or (for a CGMP Workplan step) the date on which Defendants' expert consultant certifies that the step has been completed. This process shall continue, and payments under paragraphs 16 and/or 17, as applicable, shall continue until FDA agrees in writing that the drug(s) or API(s) has been satisfactorily validated and/or the CGMP Workplan step(s) has been satisfactorily completed.

D. When making any such determination(s), FDA shall identify in writing the specific deficiencies on which it is relying. Within thirty (30) days of receiving such notification, Defendants shall submit to FDA a written plan and timetable to correct the specified deficiencies. The plan and timetable shall be subject to FDA's written concurrence. FDA shall respond to the submission within thirty (30) days.

E. If Defendants' expert consultant(s) is unable to certify the validation of an API(s) or if FDA should find that a certification of an API(s) is not adequate, Defendants' expert consultant shall determine whether any prior certification by Defendants' expert consultant(s) of any drug(s) that contained such API(s) as an ingredient is, in the expert consultant(s)'s professional opinion, no longer valid. If Defendants' expert consultant(s) or FDA, either as an initial matter or after review of Defendants' expert consultant(s) opinion, determines that the API(s) certification is not adequate and that, as a result, the validation of the drug(s) containing the API(s) is not adequate, payments under paragraph 16 and/or 17, as applicable, shall be due and owing from the date that the drug(s) was certified as validated by Defendants' expert consultant(s) and shall continue until the date that the drug(s) is certified by Defendants' expert consultant(s). If more than six (6) calendar months have passed since the drug(s) (other than those drug(s) listed in paragraph 7 (A)) was initially certified by Defendants' expert consultant, Defendants shall immediately, upon notice from Defendants' expert consultant(s) or written notice from FDA that a drug(s) certification is not adequate, discontinue manufacturing the drug(s) unless FDA, in its sole and unreviewable discretion invokes, in writing, the post-six (6) month payment provision described in paragraph 17(C).

19. Defendants Schering-Plough Corporation and Schering-Plough Products, LLC shall reimburse the United States Treasury within ten (10) days of the date of entry of this Decree for the costs of conducting and reporting FDA's prior inspections of Defendants' New Jersey and Puerto Rico facilities that followed FDA's issuance of Warning Letters to the respective facilities, at the rates applicable at the time of the

inspections. The total cost associated with conducting and reporting these inspections is four hundred seventy-one thousand five hundred dollars ($471,500.00).

20. All FDA orders to Defendants issued under paragraphs 16, 17, and 18 shall be signed by the Director, Office of Compliance, Center for Drug Evaluation and Research.

21. The parties acknowledge that the payment(s) made under paragraphs 15 through 19, 34, and 35 are not a fine, penalty, forfeiture, or payment in lieu thereof. Defendants do not admit any violation of the law that is or may be a ground for the imposition of any fine, penalty, forfeiture, or payment in lieu thereof.

MANAGEMENT CONTROLS

22. Within sixty (60) days after the date of entry of this Decree and for a period of no less than thirty-six (36) months after the date of entry of this Decree, Defendants shall assign no fewer than four individuals reporting directly to the Senior Vice President, Worldwide Quality, Schering-Plough Corporation, who are qualified by education, training, and experience to perform the functions described in this paragraph, to provide full-time on-site coverage, at least one individual per site, at each of Defendants' New Jersey and Puerto Rico facilities. These individuals shall have full-time responsibility for monitoring whether employees in the New Jersey and Puerto Rico facilities are properly performing their functions and the facility and personnel are operating in compliance with the CGMP Workplans, Defendants' approved standard operating procedures ("SOPs"), 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210 and 211, 21 U.S.C. § 355(b)(1)(B)-(D), and this Decree. Each month these individuals shall report findings in writing directly and concurrently to the Chief Executive Officer, the

Senior Vice President, Worldwide Quality, and the Senior Vice President, Technical Operations, Schering-Plough Corporation. The Chief Executive Officer shall take action necessary to ensure that all adverse findings included in these reports are promptly and appropriately addressed by the appropriate personnel in the relevant facilities.

23. Defendants shall retain an expert consultant(s) to prepare a detailed written report on the adequacy of management controls of the manufacturing and laboratory operations at Defendants' New Jersey and Puerto Rico facilities. The report shall be delivered to the Chief Executive Officer within one hundred twenty (120) days after the date of entry of this Decree. This written report shall:

A. describe Defendants' current organizational structure and the specific responsibilities of each of Defendants' organizational units that are involved in manufacturing drug(s) and API(s) at Defendants' New Jersey and Puerto Rico facilities;

B. assess the role and personnel resources of Defendants' quality assurance and quality control units at Defendants' New Jersey and Puerto Rico facilities, including the units' roles in detecting and correcting all deficiencies and noncompliance with the CGMP Workplans, Defendants' SOPs, 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210 and 211, 21 U.S.C. § 355(b)(1)(B)-(D), and this Decree; and

C. evaluate whether personnel responsible for directing and performing the manufacture and quality control of drug(s) at Defendants' New Jersey and Puerto Rico facilities are adequate in number and qualifications (education, training, and experience, or a combination thereof) to ensure compliance with the CGMP Workplans, Defendants' SOPs, 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210 and 211, 21 U.S.C. § 355(b)(1)(B)-(D), and this Decree.

24. The Chief Executive Officer, Schering-Plough Corporation shall, within forty-five (45) days of receipt of the expert consultant(s)'s report under paragraph 22, submit to FDA a copy of the report together with a description of the actions Defendants propose to take in response to the report and a proposed timetable for completing those actions. The timetable shall be subject to FDA written concurrence. FDA shall provide its written response to Defendants within forty-five (45) days.

YEARLY INSPECTIONS BY AN EXPERT CONSULTANT(S)

25. A. Defendants shall retain an expert consultant(s) to inspect Defendants' New Jersey and Puerto Rico facilities, no less frequently than the schedule set forth in paragraph 26, to ensure that the methods, facilities, and controls used to manufacture drug(s) are, and are designed to remain, in compliance with the CGMP Workplans, Defendants' SOPs, 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210 and 211, 21 U.S.C. § 355(b)(1)(B)-(D), and this Decree. As part of these inspections, the expert consultant(s) shall assess the steps that Defendants have taken and need to take to ensure that Defendants' New Jersey and Puerto Rico facilities are in compliance with the requirements described in the preceding sentence.

B. Qualification of equipment and validation of manufacturing processes shall be subject to paragraphs 9-13, rather than this paragraph, except that, after Defendants' expert consultant has certified that the equipment used to manufacture a drug(s) or API(s) has been qualified and its manufacturing process has been validated in accordance with paragraphs 9-13, any and all subsequent qualification of equipment and process validation of the drug(s) or API(s) shall be subject to this paragraph.

C. Defendants' expert consultant(s) shall prepare written reports of the inspections required by this paragraph that set forth their inspectional findings, the progress made by Defendants, and the state of compliance with the CGMP Workplans, Defendants' SOPs, 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210 and 211, 21 U.S.C. § 355(b)(1)(B)-(D), and this Decree, and shall submit these reports to the Chief Executive Officer, Schering-Plough Corporation, no later than forty-five (45) days after the date on which the inspection is completed.

D. Within sixty (60) days of receiving a copy of the expert consultant(s)'s inspection report, the Chief Executive Officer, Schering-Plough Corporation, shall submit to FDA a copy of that report, together with a description of the actions the Chief Executive Officer proposes to take in response to the report, and a proposed timetable for completing those actions. The proposed timetable shall be subject to FDA concurrence. FDA shall concur with or reject the proposed timetable in writing within forty-five (45) days of receipt thereof.

26. The inspections required in paragraph 25 shall commence at Defendants' Manati facility within six (6) months of the date of entry of this Decree. The inspections of Defendants' Las Piedras and New Jersey facilities shall commence within six (6) calendar months of the date of FDA written concurrence with the CGMP Workplan submitted to FDA pursuant to paragraph 5(A) for the applicable facility. These inspections shall thereafter be conducted at each of the four facilities no less frequently than once a year per facility for a period of no less than three (3) years from those dates, for a total of four (4) inspections at each of the four facilities.

27. Defendants may, for good cause shown in writing to FDA, no later than sixty (60) days prior to the expiration of a timetable concurred in by FDA pursuant to this Decree, unless FDA agrees in writing to a shorter time period, request FDA to concur with a reasonable revision of any timetable previously concurred with by FDA. FDA shall concur, or not concur, with such request, in writing, within thirty (30) days. To the extent that any timetable is revised in accordance with this paragraph, the revised timetable shall control for purposes of determining whether any payment(s) may be required under paragraph 16, 17, or 18, and for purposes of calculating the amount of such payment(s).

GENERAL PROVISIONS

28. For purposes of this Decree, unless stated otherwise, any reference to an "application" shall be construed to include a new drug(s) application (NDA), supplemental NDA, abbreviated NDA, supplemental abbreviated NDA, new animal drug(s) application (NADA), supplemental NADA, abbreviated NADA, supplemental abbreviated NADA, biologics license application (BLA), or supplemental BLA; and any reference to qualification or validation shall be construed to include re-qualification or re-validation, as applicable.

29. A. If at any time after this Decree has been entered, FDA determines that, with respect to Defendants' New Jersey or Puerto Rico facilities, and with respect to any drug(s) or API(s) manufactured at Defendants' New Jersey and Puerto Rico facilities, Defendants have failed to fully comply with or have violated 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210 and 211, or 21 U.S.C. § 355(b)(1)(B) and (C), or any provision of this Decree; or that any report, plan, written procedure, or equipment qualification, or

drug(s) or API(s) validation study prepared or submitted by Defendants pursuant to this Decree, or any measure or action implemented by Defendants to comply with this Decree, is inadequate to fully comply with the foregoing statutory and regulatory provisions, or any provision of this Decree, FDA may (except with regard to timetables concurred in by FDA pursuant to this Decree, which shall be presumed, rebuttably, to be appropriate), as and when it deems necessary, after consultation with Defendants, order Defendants in writing to take appropriate corrective action(s) within specified time frames, including but not limited to, immediately taking one or more of the following actions with respect to any of Defendants' New Jersey and Puerto Rico facilities or with respect to any drug(s) and/or API(s) manufactured at these facilities:

i. revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

ii. submit additional reports or information to FDA;

iii. submit any supplement to an existing application to FDA;

iv. cease manufacturing, processing, packing, holding, and/or distributing any drug(s) and/or API(s);

v. recall any drug(s) and/or API(s) as and when FDA deems necessary and in accordance with procedures identified by FDA; and/or

vi. take any other corrective action(s) as FDA, in its discretion, deems necessary to bring any of Defendants' Puerto Rico and New Jersey facilities and any of Defendants' drug(s) and/or APIs that they manufacture at these facilities into compliance with the statutory and regulatory provisions described in this paragraph.

B. Any order issued pursuant to this paragraph shall issue from either FDA's New Jersey District Director or its San Juan District Director, as appropriate, and shall specify the deficiencies or violations giving rise to the order.

30. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving an order pursuant to paragraph 29, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken the action(s), in which event Defendants also shall describe the specific action(s) taken or proposed to be taken and a proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall fully explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives. Defendants need not comply with the order until FDA has issued a final decision pursuant to paragraph 31.

31. If FDA affirms or modifies its order, FDA shall identify in its order that it is FDA's final order. Defendants shall, upon receipt of FDA's final order, immediately implement the final order. If Defendants so choose, they may bring the matter before this Court on an expedited basis; however, Defendants shall continue to diligently and in good faith implement FDA's final order, unless and until the Court issues an order to the contrary.

32. Consistent with this Decree, after Defendants send FDA a copy of Defendants' expert consultant(s)'s certification for Defendants' Manati facility, or any part thereof, pursuant to paragraph 4(D), and from the date of entry of this Decree with respect to Defendants' Las Piedras and New Jersey facilities, Defendants and each and

all of their subsidiaries, officers, agents, employees, representatives, successors, assigns, and attorneys, and those persons in active concert or participation with any of the Defendants shall, with respect to such facilities, be permanently enjoined under 21 U.S.C. § 332(a) from directly or indirectly, doing or causing any and all of the following: introducing or delivering for introduction into interstate commerce, in violation of 21 U.S.C. §§ 331(a) or 331(d), any article of human or veterinary drug(s), as defined by 21 U.S.C. § 321(g), that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) or is an unapproved new human or veterinary drug within the meaning of 21 U.S.C. §§ 355 or 360b, respectively, and from adulterating any article of human or veterinary drug(s) while such drug(s) is held for sale after shipment of one or more of its components in interstate commerce, in violation of 21 U.S.C. § 331(k).

33. All communications required to be sent by Defendants to FDA under this Decree shall be prominently marked "Decree Correspondence." Those communications that pertain in whole or in part to the New Jersey facilities shall be sent to the Director, FDA New Jersey District Office, HFR-CE300, 10 Waterview Boulevard, Parsippany, New Jersey 07054. Those communications that pertain in whole or in part to the Puerto Rico facilities shall be sent to the Director, FDA San Juan District Office, HFR-SE500, 466 FDZ Juncos Avenue, San Juan, Puerto Rico 00901-3223. All notifications and other communication required to be sent by FDA to Defendants under this Decree shall be marked "Decree Correspondence" and shall be sent to Senior Vice President for GMP Compliance Task Force, Schering-Plough Corporation, K-1-4 Ex9, 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

34. Defendants shall reimburse FDA for the costs of all FDA inspections, examinations, analytical work, and review work that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree with respect to a drug(s) and API(s) manufactured at Defendants' New Jersey and Puerto Rico facilities at the standard rates prevailing at the time the activities are accomplished. As of the date that this Decree is signed by the parties, these rates are: $65.14 per hour and fraction thereof per representative for inspection work, $78.07 per hour or fraction thereof per representative for analytical or review work, $0.345 per mile for travel expenses by automobile, government rate or the equivalent for travel by air, and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for subsistence expenses, where necessary. FDA shall submit a reasonably detailed bill of costs to Defendants at the address specified in paragraph 33. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

35. A. FDA shall be permitted to take, without prior notice and at any time, any and all actions necessary to ensure continuing compliance with the provisions of this Decree, including, but not limited to, conducting inspections of the New Jersey and Puerto Rico facilities, taking photographs, collecting samples of any drug(s), and copying records. Such inspections shall include, but not be limited to, any drug(s), API(s), and equipment therein, finished and unfinished materials, containers, labeling, records (including but not limited to, all computer hardware and software, computer printouts, raw data, and laboratory data generated in connection with, and/or in support

of, Defendants' expert consultant(s)'s reports required by this Decree), files, papers, written procedures, and process controls.

B. The costs of all such inspections, record reviews, and sample analyses shall be borne by Defendants at the rates specified in paragraph 34. The inspections described in this Decree shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority described in this paragraph shall be separate and apart from, and in addition to, statutory authority to make inspections under the FDC Act.

36. Within fifteen (15) days after the date of entry of this Decree, Defendants shall deliver copies of this Decree to each of its officers, those employees in a supervisory or managerial position, and all other persons who are in active concert or participation with Defendants with respect to the manufacture of drug(s) at each of the facilities located in New Jersey and Puerto Rico. Within thirty (30) days of the date of entry of this Decree, Defendants shall conduct a training session(s) for all supervisors and managers at Defendants' Puerto Rico and New Jersey facilities who are involved in the manufacture of drug(s) to fully explain the terms and requirements of this Decree. Within ten (10) days after the date of entry of this Decree, Defendants shall prominently post a copy of this Decree in the employee common areas in the New Jersey and Puerto Rico facilities so that it is fully accessible to all employees who are involved in such activities. Defendants shall ensure that the Decree remains prominently posted in the employee common areas for a period of no less than thirty-six (36) months. If any person begins employment in a supervisory or managerial position at Defendants' New Jersey or Puerto Rico facilities involving the activities described, at a time subsequent to

the periods described Defendants shall, within ten (10) days of the commencement of such employment, deliver a copy of this Decree to such person and provide adequate training to the person regarding the terms and requirements of this Decree.

37. Within forty (40) days after the date of entry of this Decree, Defendants shall provide to the District Directors of the New Jersey and San Juan District Offices affidavits stating the fact and manner of their compliance with paragraph 36, identifying the names and positions of all persons receiving copies of the Decree pursuant to the first sentence of paragraph 36 and all supervisors and managers to whom training on the terms and requirements of this Decree was provided. Thereafter, within ten (10) days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with paragraph 36, Defendants shall provide such information or documentation to FDA.

38. A. Defendants shall notify FDA in writing within ten (10) business days of any decision to discontinue manufacturing any drug(s) or API(s) at the New Jersey or Puerto Rico facilities. However, drug(s) listed in paragraph 7(A) shall be subject to the notification requirements described in that paragraph.

B. Defendants shall notify FDA in writing at least fifteen (15) business days before any of the following events, if the event may affect Defendants' obligations arising out of this Decree:

i. reorganization, bankruptcy, dissolution, or assignment or sale resulting in the emergence of a successor;

ii. the creation or dissolution of subsidiaries; or

iii. any other change of the corporate structure or function of Defendants.

39. Defendants shall serve a copy of this Decree on any prospective purchaser or assignee at least thirty (30) business days prior to such an assignment or change in ownership. Defendants shall furnish FDA with an affidavit of compliance with this paragraph sworn to by the Chief Executive Officer no later than fifteen (15) business days prior to such assignment of change in ownership.

40. Whenever this Decree requires an expert consultant(s) to certify to a matter, and the expert consultant(s) is unable to make that certification, the expert consultant(s) shall so notify Defendants and state the reasons therefor in writing. Defendants shall immediately send a copy of the expert consultant(s)'s written notification to FDA. After Defendants have addressed the matters identified in the expert(s)' notification, the same expert consultant(s) shall determine whether the certification can be made. This process shall continue until the certification is made.

41. All destruction of any drug(s) pursuant to this Decree shall be conducted at Defendants' expense and in a manner that complies with the requirements of the National Environmental Policy Act of 1969.

42. FDA review of Defendants' new drug application(s) for any human drug(s) shall be in accordance with 21 U.S.C. § 355(b)(4)(F). The process validation and equipment qualification certification requirements of paragraphs 4(E), 4(F), and 9-13 shall not apply to applications approved by FDA after the date of entry of this Decree. These requirements will be addressed by FDA in accordance with its new drug(s) pre-approval inspection program.

43. All decisions conferred upon FDA in this Decree shall be vested in the sole discretion of FDA. Defendants shall abide by the decisions of FDA, and FDA's decision

shall be final. FDA's decisions under this Decree shall be reviewed by this Court under the standard set forth in 5 U.S.C. § 706(2)(A). Any matter brought before this Court shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

44. Defendants' obligations under this Decree do not modify or absolve Defendants from any obligation to comply with the FDC Act and its regulations, any application, or any other federal statute or regulation. Nothing in this Decree shall affect FDA's authority to suspend or revoke any of Defendants' applications pursuant to 21 U.S.C. § 355(e).

45. This Decree does not in any way limit any administrative, civil, or criminal action that may be deemed appropriate to be taken by any agency or department of the United States.

46. The obligations under this Decree of each individual named herein shall apply only to the extent of his authority, responsibilities, and conduct within Schering-Plough Corporation or any of its divisions, subsidiaries, or affiliates.

47. The execution and entry of this Decree shall not be construed by FDA to mean that Defendants are not responsible government contractors. Except as provided in this Decree, FDA has taken no action to prohibit distribution in United States or foreign commerce of any drug(s) or API(s) manufactured at Defendants' New Jersey and Puerto Rico facilities.

48. All protocols, workplans, and timetables concurred with in writing by FDA shall be deemed to be incorporated by reference in this Decree and fully enforceable in the same manner as any other provision of this Decree.

49. If, during any five year period after the date of entry of this Decree, FDA has not notified Defendants that there has been a significant violation of FDA law and regulations or this Decree during such five year period, Defendants may petition the Court to dissolve this Decree, and FDA will not oppose the petition.

50. This Court shall retain jurisdiction over this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, that Defendant shall, in addition to other remedies, reimburse the United States for its attorney's fees, investigational expenses, and court costs relating to contempt proceedings related to that Defendant.

Dated this _____ day of May, 2002.

_____
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of this Decree:

FOR DEFENDANTS:

_____
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of Schering-Plough
Corporation and Schering-Plough
Products, LLC

FOR PLAINTIFF:

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