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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

The United States of America, Plaintiff, by Robert J.

Cleary, United States Attorney for the District of New Jersey, respectfully represents to this Honorable Court as follows:

STATUTORY VIOLATIONS

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), 21 U.S.C. § 301 et seq., to enjoin defendants Schering-Plough Corporation and Schering-Plough Products, LLC, a subsidiary of Schering-Plough Corporation, corporations; 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"), from:

a. violating the FDC Act, 21 U.S.C. § 331(a), by directly or indirectly causing the introduction or delivery for introduction into interstate commerce of any human or veterinary drug, as defined by 21 U.S.C. § 321(g), that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice ("CGMP") to assure

that the drug meets the requirements of the FDC Act as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; and

b. violating the FDC Act, 21 U.S.C. § 331(k), by directly or indirectly manufacturing, processing, or packing articles of human or veterinary drug, as defined by 21 U.S.C. § 321(g), after shipment of one or more of the articles' components in interstate commerce, or the doing of any other act, that results in such article(s) being adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

JURISDICTION

2. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a). Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

3. Defendant Schering-Plough Corporation is incorporated under the laws of the State of New Jersey, with its headquarters offices located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, within the jurisdiction of this Court. Defendant Schering-Plough Products, LLC is a subsidiary of Defendant Schering-Plough Corporation and is

incorporated under the laws of the State of Delaware. From its headquarters location, Defendant Schering-Plough Corporation manages and controls the manufacture of prescription and non-prescription, human and veterinary, drugs at facilities located worldwide, including facilities located at 1011 Morris Avenue, Union, New Jersey 07083-7120 and 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 ("New Jersey facilities"); and at facilities owned by Defendant Schering-Plough Products LLC located at State Road No. 686, Km 0.5, Manati, Puerto Rico 00674 and State Road 183 PRIDCO Industrial Park, Las Piedras, Puerto Rico 00771 ("Puerto Rico facilities").

4. Defendant Richard J. Kogan is the Chief Executive Officer and Chairman of the Board of Schering-Plough Corporation. Mr. Kogan is responsible for worldwide management of Schering-Plough Corporation, which includes Schering-Plough Products, LLC. He performs his duties at Schering-Plough Corporation's worldwide headquarters offices in Kenilworth, New Jersey, within the jurisdiction of this Court.

5. Defendant Steven C. Chellevold is the Senior Vice-President of Schering-Plough Corporation, Worldwide Technical Operations as well as Vice-President of Schering-Plough

Products, LLC, and assumed these positions on July 30, 2001. Mr. Chellevold is responsible for the management of Schering-Plough Corporation's pharmaceutical manufacturing operations at all Schering-Plough Corporation pharmaceutical manufacturing facilities located throughout the world. Mr. Chellevold performs his duties at Schering-Plough Corporation's worldwide headquarters offices located in Kenilworth, New Jersey, within the jurisdiction of this Court.

DEFENDANTS' HISTORY OF VIOLATIONS

6. Defendants have a history of failing to comply with CGMP requirements during their manufacture of drugs at their New Jersey and Puerto Rico facilities. Most recently, in May 2001, FDA conducted four inspections of Defendants' New Jersey and Puerto Rico facilities.

7. FDA's inspections of Defendants' New Jersey facilities were conducted from May 7, 2001, through June 13, 2001, and revealed significant CGMP violations, including, but not limited to, violations of 21 C.F.R. §§ 211.22, 211.110, and 211.63.

8. FDA's inspection of Defendants' Manati, Puerto Rico facility, conducted from May 1, 2001, through June 13, 2001, also revealed significant CGMP violations, including, but not

limited to, violations of 21 C.F.R. §§ 211.22, 211.110, 211.113(b), 211.192, 211.160, 211.165, 211.25, and 211.198.

9. FDA's inspection of Defendants' Las Piedras, Puerto Rico facility, conducted from May 1, 2001, through June 5, 2001, revealed similar significant CGMP violations.

10. Most of the same significant CGMP violations identified above, as well as others, have been found during thirteen previous FDA inspections of these facilities

11. FDA notified Defendants in writing of their failure to comply with the CGMP violations identified above, as well as at meetings that occurred in 1998-2001.

12. Defendants have violated the FDC Act, 21 U.S.C. § 331(a), by directly or indirectly causing articles of drug, as defined by 21 U.S.C. § 331(a), to be introduced or delivered for introduction into interstate commerce that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities or controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated or administered in conformity with current good manufacturing practice ("CGMP") to assure that the articles of drug meet the requirements of the FDC Act as to safety, and have the identity and strength, and meet the quality and purity characteristics that they purport or are

represented to possess.

13. Defendants have violated the FDC Act, 21 U.S.C. § 331(k), by directly or indirectly manufacturing, processing, and packing articles of drug, as defined by 21 U.S.C. § 321(g), after shipment of one or more of their ingredients in interstate commerce, which acts result in the articles of drug being adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

14. Based on Defendants' continuing failure to adhere to CGMP requirements during the manufacture, processing, packing, and holding of drugs, it is evident that, unless and until restrained by this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and 331(k).

WHEREFORE, PLAINTIFF PRAYS:

I. That Defendants and each and all of their officers, agents, representatives, employees, successors or assigns, attorneys, and all other persons, including subsidiaries, in active concert or participation with any of them, be perpetually restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. introducing and causing the introduction or delivery for introduction into interstate commerce of any drug, as

defined by 21 U.S.C. § 321(g); and

B. manufacturing, processing, and packing, or doing and causing any other act with respect to any article of drug, as defined by 21 U.S.C. § 321(g), while the article is held for sale by defendants after shipment of one or more of its components in interstate commerce;

UNLESS AND UNTIL Defendants satisfy FDA that the methods, facilities, processes, and controls used for the manufacture, processing, packing, and holding of drugs are established, operated, and will be continuously administered, in compliance with 21 U.S.C. § 351(a)(2)(B) and the CGMP requirements as set forth at 21 C.F.R. Parts 210 and 211.

II. That FDA be authorized pursuant to this injunction to inspect Defendants' places of business to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

III. That the plaintiff be granted judgment for its costs herein, including the costs of FDA's inspections of Defendants' facilities conducted (a) after Defendants' facilities were sent FDA letters warning of possible enforcement actions if CGMP violations were not corrected, and (b) to monitor Defendants' compliance with any order of

injunction entered by this Court; that Defendants be ordered by this Court to disgorge the profits they have earned on past sales of all adulterated drugs; and that this Court grant such other and further relief as it deems just and proper.

Date: _____ Respectfully submitted,

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