CV 06 3877

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

NSI

UNITED STATES OF AMERICA,

Plaintiff,

v.

SYNTHO PHARMACEUTICALS, INC., INTERMAX PHARMACEUTICALS, INC., corporations, and MUHAMMED MALIK and HOSNEARA MALIK, individuals,

Defendants.

Civil No.

COMPLAINT FOR PERMANENT INJUNCTION

BIANCO, J.
ORENSTEIN, M

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Syntho Pharmaceuticals, Inc. ("Syntho"), a corporation, Intermax Pharmaceuticals, Inc. ("Intermax"), a corporation, and Muhammed Malik and Hosneara Malik, individuals (hereafter, collectively "Defendants") from:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355, nor exempt from approval pursuant to 21 U.S.C. § 355(i);

D. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1);

E. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B);

F. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

G. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

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

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

The Defendants

4. Defendant Syntho was incorporated in the State of New York in 2001. Syntho is located at 230 Sherwood Avenue, Farmingdale, New York, within the jurisdiction of this Court. The firm has been and is currently manufacturing, processing, packing, labeling, holding, and distributing in interstate commerce prescription and over-the-counter ("OTC") drugs for human use. The firm manufactures solid oral dosage forms of immediate and extended release tablets and immediate release capsules of prescription and OTC drugs including hormone replacements, decongestants/expectorants/bronchodilators, antihistamines, and urinary antiseptics. Syntho manufactures drugs under the Syntho label and also under customer labels.

5. Defendant Intermax was incorporated in the State of New York in 1997. Intermax is located at 228 Sherwood Avenue, Farmingdale, New York, within the jurisdiction of this Court. The firm has been and is currently manufacturing, processing, packing, labeling, holding, and distributing in interstate commerce prescription and OTC drugs for human use. The firm manufactures solid oral dosage forms of immediate and extended release tablets and immediate release capsules of prescription and OTC drugs including hormone replacements, decongestants/expectorants/bronchodilators, antihistamines, urinary antiseptics, and analgesics/sedatives. Intermax manufactures drugs primarily under customer labels.

6. Both Syntho and Intermax are individual corporate entities, but processing of all but one drug is conducted jointly by both facilities. The facilities are connected by a common door that permits the joint production from one facility to the other. The firms also share some employees and other services, such as quality assurance/control

operations, production supervision, and packaging and labeling control. Although they are separate corporations, the nature of these businesses is that one cannot operate without the other.

7. Defendant Muhammed Malik, an individual, is the President/Director of Scientific Affairs and co-owner of Syntho and Intermax. He is the most responsible individual at both firms, and has authority over all operations, including, but not limited to, manufacturing, processing, packaging, labeling, and distributing products at both Syntho and Intermax. Mr. Malik performs his duties at 230 Sherwood Avenue, Farmingdale, New York, but also supervises activities at 228 Sherwood Avenue, Farmingdale, New York, within the jurisdiction of this Court.

8. Defendant Hosneara "Ara" Malik, an individual, is Mr. Malik's wife and the co-owner and Vice President of Operations at Syntho and Intermax. Mrs. Malik maintains control over all batch records, which are kept locked in her office. Mrs. Malik is responsible for payroll and customer orders, supervision of packaging and production, and issuance of components to the packaging and production areas. Mrs. Malik performs her duties at 230 Sherwood Avenue, Farmingdale, New York, but also supervises activities at 228 Sherwood Avenue, Farmingdale, New York, within the jurisdiction of this Court.

9. Defendants manufacture, process, pack, label, hold, and distribute various prescription and OTC products that are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B), because they are intended to be used in the cure, mitigation, treatment, and prevention of diseases in man and/or to affect the structure or function of the human body.

10. The United States Food and Drug Administration ("FDA") has inspected Syntho and Intermax on the following dates: November 16, 2004-February 4, 2005 (concurrent inspection of Syntho and Intermax); June 24-October 17, 2003 (concurrent inspection of Syntho and Intermax); October 22-November 20, 2002 (inspection of Intermax); and October 21-November 20,2002 (inspection of Syntho). The FDA investigators observed that Defendants manufacture and distribute unapproved new drugs in violation of 21 U.S.C. § 331(d), misbranded drugs in violation of 21 U.S.C. § 331(a), and cause drugs to be misbranded in violation of 21 U.S.C. § 331(k). Moreover, in every inspection, FDA has documented numerous violations by Defendants of current good manufacturing practice ("CGMP"), 21 C.F.R. Parts 210 and 211, thereby causing the adulteration of Defendants' drugs within the meaning of 21 U.S.C. § 351(a)(2)(B). Defendants' distribution of these adulterated drugs in interstate commerce violates 21 U.S.C. § 331(a), and their acts in causing the drugs to become adulterated violate 21 U.S.C. § 331(k).

11. Defendants receive components used to manufacture their drugs from firms located throughout the country, including Virginia, New Jersey, North Carolina, Ohio, Kentucky, and Illinois.

12. Defendants deliver their finished drugs in interstate commerce to distributors in Florida and Connecticut.

Adulteration

13. Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their

manufacture, processing, packing, or holding do not conform to CGMP. See 21 C.F.R. Parts 210 and 211.

14. CGMP includes procedures and practices that are intended to ensure that drugs are safe and have the identity and strength, and meet the quality and purity characteristics that they purport or are represented to possess. FDA has promulgated regulations establishing minimum CGMP requirements applicable to human drugs. See 21 C.F.R. Parts 210 and 211. CGMP requires responsible parties to control all aspects of the processes and procedures by which drugs are manufactured to prevent production of unsafe and ineffective products. Drugs not manufactured in conformance with CGMP are deemed to be adulterated as a matter of law. See 21 U.S.C. § 351(a)(2)(B).

15. In FDA's November 2004-February 2005 inspection of defendants' facilities, FDA investigators observed and documented numerous violations of CGMP, including, but not limited to:

A. Failure of the quality control unit to investigate thoroughly unexplained discrepancies or the failure of a batch or any of its components to meet any of its specifications, as required by 21 C.F.R. § 211.192;

B. Failure to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products, as required by 21 C.F.R. § 211.110(a);

C. Failure to record and justify deviations from written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, as required by 21 C.F.R. §§ 211.160(a) and (b);

D. Failure to include reliable, meaningful, and specific test methods as part of the written program for stability testing, as required by 21 C.F.R. § 211.166(a);

E. Failure to have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release, as required by 21 C.F.R. § 211.165(a);

F. Failure to establish and document the accuracy, sensitivity, specificity, and reproducibility of test methods employed, as required by 21 C.F.R. § 211.165(e);

G. Failure to review and investigate any complaint involving the possible failure of a drug product to meet any of its specifications, as required by 21 C.F.R. § 211.198; and

H. Failure to clean and maintain adequately equipment at appropriate intervals to prevent malfunctions or contamination, as required by 21 C.F.R. § 211.67(a).

16. The CGMP violations observed by the FDA investigators during the November 2004-February 2005 inspection of both Syntho and Intermax are the same as, or similar to, violations observed by FDA investigators during inspections conducted in June-October 2003 and October-November 2002. For example, the June-October 2003 inspection of both facilities revealed out-of-specification test results for several lots already in distribution; the failure to have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product; the failure to investigate thoroughly unexplained discrepancies or the failure of a batch to meet any of its specifications; and the failure to validate the performance of those manufacturing

processes that may be responsible for causing the variability in the characteristics of in-process materials and drug products.

17. The October-November 2002 inspections of Syntho and Intermax revealed similar violations as those listed above, including the failure to validate manufacturing processes, establish adequate laboratory controls, and investigate unexplained discrepancies or out-of-specification batches.

18. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth in Paragraphs 13-17 above.

19. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), as set forth in Paragraphs 13-17 above, while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drugs

20. FDA's inspections revealed that Defendants manufacture, process, pack, hold, and distribute unapproved new drugs. They introduce or cause the introduction into interstate commerce of the unapproved new drugs in violation of 21 U.S.C. §§ 331(d) and 355(a). These unapproved new drugs include:

- COLDEC TABLETS
- COLDEC D TABLETS
- COLDEC TR TABLETS
- DYPHYLLINE AND GUAIFENESIN TABLETS, USP
- GUAIDEX PD TABLETS

- GUAIDEX D TABLETS
- CRANTEX LA TABLETS
- USEPT TABLETS
- MIGRAZONE CAPSULES

21. The drugs listed in Paragraph 20 (hereafter, "the Paragraph 20 Drugs") are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

22. There is not now, nor has there ever been, a new drug application ("NDA") or abbreviated new drug application ("ANDA") approved by FDA pursuant to 21 U.S.C. § 355 for any of the Paragraph 20 Drugs. Moreover, the Paragraph 20 Drugs are not exempt under 21 U.S.C. § 355(i) from the Act's pre-market approval requirement.

23. Defendants violate 21 U.S.C. 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from the Act's pre-market approval requirement pursuant to 21 U.S.C. § 355(i), as set forth in Paragraphs 20-22 above.

Misbranding

24. FDA's three most recent inspections also revealed that the Paragraph 20 Drugs are misbranded.

25. A prescription drug that is an unapproved new drug is per se misbranded because it cannot bear adequate directions for use as required by statute, 21 U.S.C. § 352(f)(1), because studies which would support the labeling claims do not exist.

Coldec, Coldec D, Coldec TR, Dyphylline and Guaifenesin, Guaidex PD, Guaidex D, USept Tablets, and Migrazone Capsules are prescription drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

26. One of the drugs, Crantex LA Tablets, is also misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B), because it is an OTC drug that bears the prescription label "Rx only."

27. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth in Paragraph 25 above.

28. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B), as set forth in Paragraph 26 above.

29. Defendants violate 21 U.S.C. 331(k), by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth in Paragraph 25 above.

30. Defendants violate 21 U.S.C. 331(k), by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B), as set forth in Paragraph 26 above.

Prior Warnings To Defendants

31. At the end of each inspection, the FDA investigators issued a List of Inspectional Observations ("Form FDA-483") to Defendants and discussed with them the violative conditions which they had observed. In addition, FDA representatives met with Mr. Malik and his consultants on June 3, 2003, held telephone discussions with defendants on June 20 and July 1, 2003, and March 19 and 22, 2004, and sent Defendant Muhammed Malik Warning Letters dated March 14 and May 13, 2003, regarding the 2002 inspections of Syntho and Intermax.

32. Defendants have submitted to FDA responses to the Warning Letters and the Forms FDA-483 issued to them at the end of each inspection. Defendants' responses have promised to correct the CGMP violations, but serious, significant violations have persisted.

33. The FDA Warning Letter dated March 14, 2003, to Defendant Muhammed Malik emphasized the serious nature of Defendants' violative manufacturing practices observed at Syntho during the October-November 2002 inspection, and alerted Defendants that further regulatory action could result if they did not implement corrections. The FDA Warning Letter dated May 13, 2003, to Defendant Muhammed Malik informed Defendants that they were marketing Guaifenesin Sustained Release Tablets without an approved application as required by the Act, and also explained how Defendants' practices at Intermax violated CGMP.

34. On October 13, 2003, in response to FDA's 2003 inspection, Defendants recalled six lots of Syntest Tablets because the drugs did not meet finished product specifications. Defendants did not recall several other lots of drugs, including Coldec

TR Tablets, Crantex LA Tablets, Syntest Tablets, Migrazone Capsules, and Guaidex D Tablets, even though these lots also failed to meet specifications. FDA's inspections documented that Defendants put approximately thirty-five lots of out-of-specification product on the market; only nine of those lots have been recalled.

35. Defendants have made many promises to correct all of their violations of the Act. Despite FDA's repeated warnings and Defendants' promises, FDA has found little or no improvement. Each inspection reveals Defendants' continued inability or unwillingness to operate in compliance with the Act.

36. Based on the foregoing, FDA believes that Defendants will continue to violate 21 U.S.C. §§ 331(a), 331(d), and 331(k) in the manner set forth above, unless restrained by this Court.

WHEREFORE, Plaintiff respectfully requests:

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

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce "new drugs" within the meaning of 21 U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

D. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) or 353(b)(4)(B); and

E. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) or 353(b)(4)(B).

II. That FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receiving, manufacturing, processing, packing, labeling, holding, and distributing of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the published rates prevailing at the time the inspections are accomplished; and

III. Award plaintiff costs and other such relief as the Court deems just and proper.

Respectfully submitted,

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