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CV 06 3877

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

UNITED STATES OF AMERICA,

Plaintiff,

v.

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

Defendants.

Civil No.

CONSENT DECREE OF PERMANENT INJUNCTION

BIANCO, J.
ORENSTEIN, M

The United States of America, Plaintiff, having filed its Complaint for Injunctive Relief against Syntho Pharmaceuticals, Inc. ("Syntho"), and Intermax Pharmaceuticals, Inc. ("Intermax"), corporations, and Muhammed Malik and Hosneara Malik, individuals, and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), without contest and without admitting any allegation of the Complaint or any liability, 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 of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. Except as provided in Paragraph 3(H), upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any article of drug within the meaning of 21 U.S.C. § 321(g)(1) at or from Defendants' facilities located at 228 and 230 Sherwood Avenue, Farmingdale, New York, or at any new facility, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with current good manufacturing practice ("CGMP"). See 21 C.F.R. Parts 210 and 211;

B. Defendants make inspections of their drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall:

(i) perform a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs to determine whether they are in compliance with CGMP;

(ii) when appropriate, certify in writing to FDA the Defendants' facilities, methods, and controls are in compliance with CGMP; and

(iii) submit to FDA as part of the certification a full and complete written report of the results of their inspection;

C. Defendants cease manufacturing, processing, packing, labeling, holding, and distributing COLDEC TABLETS; COLDEC D TABLETS; COLDEC TR TABLETS; DYPHYLLINE & GUAIFENESIN TABLETS, USP; GUAIDEX PD TABLETS; GUAIDEX D TABLETS; CRANTEX LA TABLETS; USEPT TABLETS; and MIGRAZONE CAPSULES; and any other new drug, as defined in 21 U.S.C. § 321(p), which lacks an approved new drug application or approved abbreviated new drug application under 21 U.S.C. § 355(a), unless the drug is exempt from the approval requirements pursuant to an effective exemption under 21 U.S.C. § 355(i);

D. Defendants cease manufacturing, processing, packing, labeling, holding, and distributing all drugs that are misbranded under 21 U.S.C. §§ 352 or 353;

E. Defendants report to FDA in writing the actions they have taken to: (1) correct the CGMP deviations set forth in the Complaint and all FDA Lists of Inspectional Observations ("Forms FDA-483") and ensure that the methods used in, and the facilities and controls used to manufacture, process, pack, label, hold, and distribute drugs are operated and administered in conformity with CGMP; (2) ensure that their new drugs are the subject of approved new drug applications or approved abbreviated new drug applications under 21 U.S.C. § 355(a) or are exempt from the approval requirements pursuant to an effective exemption under 21 U.S.C. § 355(i); and (3) correct the misbranding violations set forth in the Complaint;

F. Defendants submit a written request for an FDA inspection of their facilities, and FDA representatives inspect Defendants' facilities, including buildings, equipment, finished and unfinished materials, containers, and labeling, and all records relating to the manufacturing, processing, packing, labeling, holding, and distributing of drugs, to determine whether the requirements of the Act and applicable regulations and this Decree have been met; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 3(A)-(E). If Defendants submit a request for an inspection under Paragraph 3(F) and FDA determines that Defendants do not appear to be in compliance with the requirements set forth in Paragraphs 3(A)-(E), FDA shall notify Defendants in writing of the reasons for such determination.

H. The provisions in this Paragraph shall not prohibit Defendants from manufacturing, processing, packing, labeling, holding, or distributing any article of drug for purposes of performing validation of manufacturing processes or conducting stability studies, provided, however, that such drug(s) shall not be commercially distributed.

4. Within fifteen (15) days from the date of entry of this Decree, Defendants, under FDA supervision, shall:

A. Initiate recalls of all drugs manufactured and/or distributed by Defendants that are identified by FDA as adulterated drugs, unapproved new drugs, and/or misbranded drugs. Defendants shall bear all costs of such recalls, including FDA's supervisory costs; and

B. Destroy, under FDA's supervision, all drugs, except for SYNTEST TABLETS, that are in Defendants' possession, custody, or control which are unapproved new drugs or misbranded and/or adulterated drugs, including, but not limited to, the drugs listed or described in Paragraph 3(C) and all components of such drugs, and drugs recalled pursuant to Paragraph 4(A). All costs of destruction shall be borne by Defendants. The costs of FDA's supervision of the destruction shall be borne by Defendants, at the rates specified in Paragraph 11. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws and any other applicable federal and state laws.

C. Within sixty (60) days from the date of entry of this Decree, Defendants shall, under FDA's supervision, either destroy or submit a plan to recondition ("reconditioning plan") SYNTEST TABLETS that are in Defendants' possession, custody, or control to bring them into compliance with the law. FDA's determination of the adequacy of the reconditioning plan shall be final. If FDA determines that the reconditioning plan is inadequate, Defendants, shall, under FDA supervision, destroy the SYNTEST TABLETS within fifteen (15) days from the date of Defendants' receipt of FDA's determination that the reconditioning plan is inadequate. Any destruction under this Paragraph shall comply with the provisions in Paragraph 4(B).

5. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive

actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs within the meaning of 21 U.S.C. § 321(g)(1) that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violates 21 U.S.C. § 331(k), by causing drugs within the meaning of 21 U.S.C. § 321(g)(1) 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. Violates 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. Violates 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs within the meaning of 21 U.S.C. § 321(g)(1) that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) or 353(b)(4)(B); and

E. Violates 21 U.S.C. § 331(k), by causing drugs within the meaning of 21 U.S.C. § 321(g)(1) 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).

6. After Defendants receive written notice from FDA pursuant to Paragraph 3(G) that they appear to be in compliance with Paragraphs 3(A)-(E), Defendants shall retain an independent person or persons (the "auditor"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training, is qualified to assess Defendants' compliance with CGMP, to conduct audit inspections of their drug manufacturing operations. The auditor shall conduct these inspections at least once every six (6) months for a period of three (3) years and, for the following two (2) year period, at least once every twelve (12) months.

A. At the conclusion of each audit inspection, the auditor shall prepare a written audit report analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP and the Act. Beginning with the second audit report, the auditor shall assess the adequacy of any actions taken by Defendants to correct all previously observed CGMP deviations, and include this information in the audit report. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the inspections are completed. In addition, Defendants shall maintain the audit reports in a separate file at their facility and shall make the audit reports available to FDA upon request.

B. If an audit report notes any CGMP deviations or other violations of the Act, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those deviations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the

deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, propose a schedule for completing corrections. The proposed schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, or within the time period otherwise approved by FDA, the auditor shall review the actions taken by Defendants to correct the CGMP deviations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the CGMP deviations has been corrected.

7. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by Defendants, the expert, the auditor, or any other information, that additional corrective actions are necessary to achieve compliance with the Act, the CGMP regulations, or this Decree, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate action, including, but not limited to, one or more of the following:

A. Cease manufacturing, processing, packing, labeling, holding, and distributing any or all drug(s);

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

C. Submit additional reports or information to FDA;

D. Recall specified drugs manufactured and/or distributed by Defendants. Defendants shall bear the costs of such recall(s); or

E. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants into compliance with the Act, the regulations, or this Decree.

8. Any order issued pursuant to Paragraph 7 shall specify the deficiencies or violations giving rise to the order.

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving an order pursuant to Paragraph 7, Defendants shall notify FDA in writing either that: (a) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or to be taken and the schedule for completing the action; or (b) Defendants do not agree with FDA's order.

B. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and specific time frames for achieving FDA's objectives.

C. If Defendants advise FDA in writing that they do not agree with FDA's order, FDA will review Defendants' written material and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable). Defendants may appeal to this Court and shall continue to immediately and fully comply with the order unless and until the order is modified or overturned by the Court.

9. Any cessation of operations as described in Paragraph 7 shall continue until FDA notifies Defendants in writing that Defendants appear to be in compliance with the Act, the regulations, and the requirements of this Decree, and that Defendants may, therefore, resume operations.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and without prior notice take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receiving, manufacturing, processing, packing, labeling, holding, and distributing of any and all drugs, including components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

11. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $76.10 per hour and fraction thereof per

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representative for inspection work; $91.18 per hour or fraction thereof per representative for analytical or review work; $0.445 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; 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. 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.

12. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, and post a copy of this Decree in the employee common areas at their manufacturing facilities. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree.

13. Defendants shall notify FDA at least fifteen (15) calendar days before any change in ownership or character of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor business, the creation of subsidiaries, or any other change in the business structure of Defendants' facilities or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this

Decree to any potential successor or assign at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

14. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, FDA New York District Office, 158-15 Liberty Avenue, Jamaica, New York 11433.

15. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants agree to pay attorney fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

16. Defendants shall abide by all decisions of FDA under this Decree, which decisions shall be final. FDA decisions under this Decree shall be reviewed by the Court, if necessary, under the arbitrary and capricious standard, 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be conducted without any discovery by either party and shall be based exclusively on the written record before FDA at the time the decision was made.

17. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

18. If Defendants maintain a state of continuous compliance with the Decree for sixty (60) months following entry of this Decree, Defendants may, upon notice to

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FDA, petition the Court for an order dissolving this Decree, and FDA will not object to that petition. The Clerk of the Court shall close the case.

IT IS SO ORDERED:

Dated this 15th day of August, 2006.

/s/
UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS

Muhammed Malik, President,
on behalf of Syntho Pharmaceuticals, Inc., and
Intermax Pharmaceuticals, Inc.

Muhammed Malik, in his
individual capacity

Hosneara Malik, in her
individual capacity

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