IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. WEST DULUTH DISTRIBUTION COMPANY, a corporation doing business as CHK NUTRITION, NEURORESEARCH CLINICS, INC., a corporation, and MARTIN C. HINZ and AMY M. GUNTHERT-HINZ, individuals, Defendants.	)	Civil No. 11-2590 (PJS/LIB)

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against West Duluth Distribution Company, a corporation doing business as CHK Nutrition, NeuroResearch Clinics Inc., a corporation, and Martin C. Hinz and Amy M. Gunthert-Hinz, individuals, and Defendants, without admitting or denying the allegations in the Complaint, having appeared and consented to the entry of this Consent Decree of Permanent Injunction ("Decree"), without contest 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 that:

1. This Court has jurisdiction over the subject matter of this action, and personal jurisdiction over all parties, pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332.

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 et seq. (the "FDC Act").

3. The Complaint alleges that Defendants violate the FDC Act, 21 U.S.C. § 331(d), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate the FDC Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

5. The Complaint alleges that Defendants violate the FDC Act, 21 U.S.C. § 331(k), by doing or causing to be done any act with respect to a drug, while the drug is held for sale after shipment in interstate commerce, that results in the drug being misbranded within the meaning of 21 U.S.C. § 352(f)(1).

6. Upon entry of this Decree, Defendants and each and all of their officers, agents, employees, attorneys, successors, assigns, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined from introducing and delivering for introduction into interstate commerce, causing to be introduced and delivered for introduction into interstate commerce, and holding for sale after shipment in interstate commerce, NeuroReplete, Neuro-R, Replete Extra, Neuro-RE, D5, Neuro-D, D5 Extra, Neuro-DE, D5 Mucuna, Neuro-M, 5-HTP, Neuro-5, Tyrosine Replete, Neuro-T, CysReplete, Neuro-C, and the same or similar products designated by any other name or referred to by any

ingredient combination, unless and until Defendants complete to FDA's satisfaction the requirements in paragraph 6(A) or 6(B), as follows:

A. Defendants have an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(a) that is effective with respect to each product or, alternatively, an investigational new drug application ("IND") filed pursuant to 21 U.S.C. § 355(i) that is in effect for the product, which is to be distributed and used solely for the purpose of conducting clinical investigations in strict accordance with a protocol authorized in the IND; or

B. (1) Defendants remove from their product labels, labeling, promotional material, and websites and other media used by any of them (a) all representations that their products or the ingredient combinations in their products cure, mitigate, treat, or prevent disease, and all representations that otherwise cause any product to be a drug within the meaning of the FDC Act, and (b) all links and references, direct or indirect, to other websites or other sources that contain representations that their products or the ingredient combinations in their products cure, mitigate, treat, or prevent disease, and representations that otherwise cause any product to be a drug within the meaning of the FDC Act;

(2) Defendants send a letter to all persons who are or have been, at any time since January 1, 2010, involved in the promotion, sale, or distribution of any of the products described in the introduction to paragraph 6, notifying those persons that, pursuant to an order of this Court, the products should not have been and may no longer be promoted, sold, or distributed for use in the cure, mitigation, treatment, or prevention of disease and that continued promotion, sale, or distribution of the products for the cure, mitigation, treatment, or prevention

of disease is a violation of the FDC Act. Within the notification, Defendants shall request that all recipients of the letter who are health care providers give a copy of the notification to each of their patients/clients who have used any of the products described in the introduction to paragraph 6. The notification shall also request that, upon receipt, each health care provider post a copy of the notification in a conspicuous place in the patient/client waiting areas, and request that the notification remain posted for a period of no less than twelve (12) consecutive months. In advance of its distribution, the notification shall be submitted to, and approved in writing by, FDA. After Defendants have completed distributing the notification as required by this paragraph, they shall provide FDA with an affidavit stating the fact and manner of compliance with this paragraph, including the names and addresses of each recipient so notified.

(3) Defendants select a person or persons (the "expert") having no personal or financial ties (other than a consulting agreement) to Defendants who, by reason of background, education, training, and experience, is qualified to review Defendants' labels, labeling, promotional material, and websites and other media used by Defendants, to assess compliance with the FDC Act;

(4) The expert performs a review of all of the materials described in paragraph 6(B)(3);

(5) The expert provides to FDA (a) a written certification that, in the expert's opinion, Defendants' labels, labeling, promotional material, and websites and other media, (i) comply with the FDC Act, and (ii) do not contain, or link or refer to other websites or other sources that contain, representations that their products or the ingredient combinations in their products cure, mitigate, treat, or prevent disease, or representations that otherwise cause any

product to be a drug within the meaning of the FDC Act, and (b) a written report describing the actions Defendants have taken to ensure ongoing compliance;

(6) FDA, in its discretion and without prior notice, inspects Defendants' facilities, including the buildings, equipment, in-process and finished articles, labels, labeling, promotional materials, containers, packaging materials, and other documents and things therein;

(7) Defendants pay the costs of the inspections described in paragraph 6(B)(6); and

(8) FDA notifies Defendants in writing that they appear to be in compliance with the requirements of paragraph 6(B) of this Decree.

7. After receiving notification from FDA described in paragraph 6(B)(8), Defendants shall:

A. Notify FDA in writing, at least two (2) business days before the creation of a new website or link or reference, direct or indirect, to another website or other source that conveys information about Defendants' products or the ingredient combinations in their products; and

B. Retain the expert described in paragraph 6(B)(3) (or a similarly qualified expert), on an annual basis, to:

(1) Review all current versions of the materials described in paragraph 6(B)(3);

(2) Certify to FDA, within thirty (30) calendar days after commencing the review, whether, in the expert's opinion, the materials described in paragraph 6(B)(3) comply with the FDC Act and, along with the certification, provide a written report describing in detail the deviations, if any, from the FDC Act and identifying the corrective measures that Defendants have taken, and plan to take, to ensure compliance.

8. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' facilities and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the FDC Act, and applicable regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, in-process and finished articles, labels, labeling, promotional materials, containers, packaging materials, and other documents and things therein; to take photographs and make video recordings; to take samples of Defendants' in-process and finished articles, labels, labeling, promotional materials, containers, and packaging materials; and to examine and copy all records related to the receipt, packing, labeling, promoting, holding, and distribution of any and all of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to conduct inspections under the FDC Act, 21 U.S.C. § 374.

9. Defendants shall pay all costs of FDA's inspections, investigations, supervision, review, examinations, analyses, and other work that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time that the activities are accomplished. As of the date of entry of this Decree, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour and fraction thereof per representative for analytical or review work; $0.51 per mile for travel by automobile; the government rate or 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 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.

10. Defendants and each and all their officers, agents, employees, attorneys, successors, assigns, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined from directly and indirectly:

A. Violating the FDC Act, 21 U.S.C. § 331(d), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce a new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating the FDC Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce a drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that its labeling fails to bear adequate directions for use;

C. Violating the FDC Act, 21 U.S.C. § 331(k), by doing and causing to be done any act with respect to a drug, while the drug is held for sale after shipment in interstate commerce, that results in the drug being misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

D. Failing to implement and continuously maintain the requirements of this Decree.

11. If, based on the results of any inspection, analysis, or any other information, FDA finds that Defendants are not in compliance with the requirements of this Decree, the FDC Act, or applicable regulations, FDA may, as and when it deems necessary, issue a directive notifying Defendants in writing of the noncompliance and ordering Defendants to take immediate action, including but not limited to one or more of the following actions:

A. Cease receiving, packing, labeling, promoting, holding, and distributing in interstate commerce all products described in the introduction to paragraph 6, and any other product that is a drug within the meaning of the FDC Act;

B. Submit additional reports or information to FDA;

C. Recall any and all products at Defendants' expense; and

D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the FDC Act, and applicable regulations.

Upon receipt of such directive, Defendants shall immediately and fully comply with the terms of the directive. Any cessation of operations ordered by FDA as described above shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the terms of this Decree and may resume operations.

12. Defendants shall provide notice of this Decree in the following manner:

A. Within ten (10) calendar days after the entry of this Decree, Defendants shall: (1) provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of Defendants' officers, agents, employees, attorneys, successors, assigns, and all persons in active concert or participation with any of them; and (2) explain the terms of the Decree to each employee;

B. Within twenty (20) calendar days after the entry of this Decree, Defendants shall provide to FDA an affidavit from a person with personal knowledge of the facts, stating the fact and manner of Defendants' compliance with paragraph 12(A) and identifying the names and positions of all persons who were notified pursuant to paragraph 12(A); and

C. After entry of the Decree, Defendants shall, within five (5) calendar days after employment of any new employee: (1) provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to all such employees; and (2) explain the terms of the Decree to all such employees.

13. Defendants shall notify FDA at least thirty (30) calendar days before any change in ownership, name, or character of the business, such as dissolution, reorganization, relocation, assignment, or sale of the business that may affect compliance obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assignee at least thirty (30) calendar days prior to such sale or transfer of business, and shall furnish to FDA an affidavit of compliance with this paragraph within fifteen (15) calendar days after such sale or transfer of business.

14. If any Defendant fails to comply with this Decree, then Defendants shall pay to the United States liquidated damages in the sum of seven thousand five hundred dollars ($7,500.00) per day per violation that any Defendant fails to comply with this Decree, the FDC Act, or applicable regulations, and an additional fifteen thousand dollars ($15,000.00) for each shipment (of any size) that fails to comply with this Decree, the FDC Act, or applicable regulations. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil contempt penalties based on conduct that may also be the basis for the payment of liquidated damages.

15. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys'

fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigational and analytical expenses, and any other costs or fees relating to the contempt proceedings.

16. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the 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.

17. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

18. All notifications, correspondence, and communications to FDA required by this Decree shall be submitted to the Director, Minneapolis District Office, U.S. Food and Drug Administration, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota 55401, and shall reference this civil action by case name and civil action number in such communications.

19. No sooner than sixty (60) months after entry of this Decree, Defendants may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the FDC Act, and applicable regulations for at least sixty (60) months, Plaintiff will not oppose the petition, and Defendants may request the Court to grant such relief.

20. This Court retains jurisdiction of 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.

Dated: September 13, 2011

s/Patrick J. Schiltz
Patrick J. Schiltz

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of this Decree:

For Defendants:

s/ Martin C. Hinz
MARTIN C. HINZ

s/ Martin C. Hinz
MARTIN C. HINZ, on behalf of
NEURORESEARCH CLINICS, INC.

s/ Amy M. Gunthert- Hinz
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