IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. ACINO PRODUCTS, LLC, a limited liability company and RAVI DESHPANDE, an individual, Defendants.	Civil Action No.: 3:15-cv-3769 CONSENT DECREE FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a Complaint for Permanent Injunction against Acino Products, LLC, a limited liability company currently operating a drug manufacturing facility at 9B South Gold Drive, Hamilton, New Jersey, and Ravi Deshpande, an individual (hereinafter, collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

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

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or 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) or (j), nor exempt from approval under 21 U.S.C. § 355(i), specifically hydrocortisone acetate 25 mg suppositories.

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into

interstate commerce articles of drugs, prescription hydrocortisone acetate 25 mg suppositories, 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 21 U.S.C. § 331(k) by causing articles of drugs, prescription hydrocortisone acetate 25 mg suppositories, that they hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

6. 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 or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise are permanently restrained and enjoined under 21 U.S.C. § 332(a) from:

A. introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce, manufacturing, processing, packaging, labeling, holding, or selling any hydrocortisone acetate 25 mg suppositories, including but not limited to those labeled as Rectacort-HC and GRx HiCort 25; any product labeled similarly to such products and containing the same active ingredients; or any other product that is a new drug within the meaning of 21 U.S.C. § 321(p) that lacks an approved new drug application or abbreviated new drug application under 21 U.S.C. § 355 unless the drug is: (1) exempt from the Act's approval requirements pursuant to an effective investigational new drug ("IND") exemption held by Defendants under 21 U.S.C. § 355(i); or (2) the drug is used by Defendants in a manner that conforms with 21 C.F.R. § 312.160. Under no circumstances shall drugs covered by exceptions (1) and (2) of this subparagraph be distributed for commercial marketing. FDA reserves the right to decide whether any particular drug(s) qualifies for any of the exceptions listed in this subparagraph, which decision shall be final. The parties agree that

any such decision shall be subject to judicial review in accordance with paragraph 18 of this Decree; and

B. introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce, manufacturing, processing, packing, labeling, holding, or selling 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, including but not limited to hydrocortisone acetate 25mg suppositories, or causing the misbranding of any drugs within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

C. violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce new drugs that are neither approved under 21 U.S.C. §§ 355(a) or (j), nor exempt from approval under to 21 U.S.C. § 355(i);

D. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or directly or indirectly 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;

E. violating of 21 U.S.C. § 331(k) by, directly or indirectly, 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) in that their labeling fails to bear adequate directions for use; and

F. directly or indirectly causing to be done any act that results in the failure to implement and continuously maintain the requirements of this Decree.

7. Within twenty (20) business days after entry of this Decree, Defendants shall give written notice to FDA that, at its own expense and under FDA's supervision, it is prepared to destroy all hydrocortisone acetate 25 mg suppositories, including but not limited to those labeled as Rectacort-HC and GRx HiCort 25, and any product labeled similarly to such products and containing the same active ingredient(s) in their custody, control, or possession (hereinafter, "Violative Drugs"). Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall not commence or permit any other person to commence destruction until it has received written authorization from FDA to commence the destruction.

8. Defendants shall at all times, until all of the Violative Drugs have been destroyed in accordance with this Decree, retain the Violative Drugs in its custody intact for examination or inspection by FDA at their facility, located at 9B South Gold Drive, Hamilton, New Jersey, and shall maintain all records or other proof necessary to establish the identity of the Violative Drugs to FDA's satisfaction. Defendants shall not cause the Violative Drugs to be disposed of in a manner contrary to the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed.

9. Within fifteen (15) business days after receiving authorization from FDA to commence destroying the Violative Drugs, Defendants shall, under FDA supervision, complete the destruction in compliance with this Decree. Defendants shall reimburse FDA, at the rates set forth in Paragraph 13, for the supervision of the destruction within ten (10) business days after receiving notice of such costs from FDA.

10. FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of the Defendants' place(s) of business, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations. During inspections, FDA shall be permitted to have

immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials therein; take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials; and examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all drugs and their respective components. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, selling, and/or distributing any or all drugs;

B. Recall, at Defendants' expense, any drug products that are unapproved, misbranded in that their labeling fails to bear adequate directions for use, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations. The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

12. Upon receipt of any order issued by FDA pursuant to Paragraph 11, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA's inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 11 shall be borne by Defendants at the rates specified in Paragraph 13.

13. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $89.35 per hour or fraction thereof per representative for inspection and investigative work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 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 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.

14. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree in a common area at Defendants' drug manufacturing facility at 9B South Gold Drive, Hamilton, New Jersey, and at any other location at which defendants conduct

business, and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

15. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, customers (including, but not limited to, all parties for whom Defendants contract manufacture drugs and private label distributors with whom Defendants are affiliated), and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

16. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time Defendants become associated with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

17. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of its business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution,

bankruptcy, assignment, sale, or any other change in the structure or identity of Acino Products, LLC, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

18. Defendants shall abide by the decisions of FDA and its representatives, which shall be final. All decisions specified in this Decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this Decree shall be based exclusively upon the written record before FDA at the time of the decision. No discovery shall be taken by either party.

19. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall reference the case name and civil action number , be prominently marked "Decree Correspondence" and "Acino Products, LLC," and be addressed to:

District Director
New Jersey District Office
U.S. Food and Drug Administration
10 Waterview Blvd.
Parsippany, New Jersey 07054

20. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, it shall pay to the United States of America the sum of five thousand dollars ($5,000) in liquidated damages for each day such violation continues and an additional sum of one thousand five hundred dollars ($1,500) in liquidated damages for each violation of this Decree, the Act, or its implementing regulations, and an additional sum equal to five (5) times the retail value of each shipment of an unapproved new drug and/or a misbranded drug in liquidated damages for each such unlawful shipment. Defendants understand and agree

that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

21. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and court costs or any other fees relating to such contempt proceedings.

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

SO ORDERED.

Dated this 30 day of June 2015.

UNITED STATES DISTRICT JUDGE

Entry consented to

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