UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 2:17-CV-14038-ROSENBERG/LYNCH

UNITED STATES OF AMERICA,

Plaintiff,

v.

SYFRETT FEED COMPANY, INC. *et al.*,

Defendants.
_____/

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunctive relief against Syfrett Feed Company, Inc. ("Syfrett Feed"), a corporation, and Charles B. Syfrett I, Melissa S. Montes De Oca, and Charles B. Syfrett II, individuals (collectively, "Defendants"), and the Defendants, having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, 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 and over all parties to this action.

2. The Complaint for Injunction states a claim for relief against the Defendants under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 301 et seq.

3. The complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing the articles of drug, medicated animal feeds, to become adulterated within the meaning

of 21 U.S.C. § 351(a)(2)(B) while holding such feeds for sale after shipment of one or more of their components in interstate commerce. The complaint alleges that Defendants also violate 21 U.S.C. § 331(k) by misbranding medicated animal feeds, which are drug products within the meaning of 21 U.S.C. § 321(g), held for sale after incorporation of components shipped in interstate commerce. The complaint alleges that Defendants misbrand the medicated feeds by failing to include the name of the active ingredient on the label, in violation of 21 U.S.C. § 352(e)(1)(A)(ii). The complaint alleges Defendants also misbrand their medicated feeds by failing to include adequate directions for use on the labels, in violation of 21 U.S.C. § 352(f)(1).

4. The Defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing the manufacture, processing, packing, labeling, holding, and distribution at their facilities located at 3079 NW 8th Street, Okeechobee, Florida (Syfrett Feed) (and any other locations, now or in the future, at which the Defendants manufacture, process, pack, label, hold, or distribute medicated feeds), of any article of medicated feed unless and until:

A. The Defendants establish, operate, and administer their feed manufacturing methods, facilities, and controls in conformity with the general current good manufacturing practice ("CGMP") regulations for medicated feeds set forth in 21 C.F.R. §§ 225.1 and 225.120 through 225.202;

B. The Defendants retain a person (qualified person) who is without any personal or financial ties other than the consulting agreement to the Defendants and their families

and who, by reason of background, training, and experience, is qualified to make inspections of medicated feed manufacturing mills to determine whether the established methods, facilities, and controls are operated and administered in conformity with the Act and its implementing regulations, including, but not limited to the CGMP requirements found in 21 C.F.R. §§ 225.1 and 225.120 through 225.202; the Defendants notify the FDA in writing of the qualified person's identity and qualifications as soon as they retain the person; the qualified person inspects Syfrett Feed and the manner of operating Syfrett Feed, and any new locations at which the Defendants may manufacture medicated feeds; and the qualified person certifies in writing to FDA that the requirements set forth in paragraph 4(A) of this Decree have been met;

C. The Defendants report in writing to FDA all actions they have taken to ensure that the requirements in paragraph 4(A) of this Decree have been met;

D. FDA, as it deems necessary to evaluate the Defendants' compliance with the terms of this Decree, conducts inspections of the Defendants' facilities within twenty-five (25) calendar days of receiving notice from the Defendants pursuant to paragraph 4(C);

E. The Defendants pay the costs of any supervision, inspection, analyses, examination, and review that FDA deems necessary to evaluate the Defendants' compliance with the terms of this Decree; and

F. FDA notifies the Defendants in writing that the Defendants appear to be in compliance with the requirements in paragraphs 4(A)-(E), FDA regulations, and the Act. Under no circumstances shall FDA’s silence be construed as a substitute for written notification.

5. Paragraph 4 does not prohibit Defendants from transporting and delivering medicated feed that is manufactured and labeled by unaffiliated feed mills to Syfrett Feed

customers so long as such medicated feed is not further manufactured, processed or relabeled by Defendants.

6. Paragraph 4 does not prohibit Defendants from holding medicated feed inventory in their possession at the time of entry of the Decree. The Expert must certify in his report required by paragraph 4B that each lot of medicated feed in this inventory was manufactured and labeled in conformity with the Act and its implementing regulations, including, but not limited to the CGMP requirements found in 21 C.F.R. §§ 225.1 and 225.120 through 225.202. Following FDA's written notification pursuant to paragraph 4F, Defendants may distribute the medicated feed inventory in their possession at the time of entry of the Decree. Should the Expert determine in his report required by Paragraph 4B, or should FDA determine through its review of the Expert's report or its inspection of Defendants' facility pursuant to Paragraph 4D, that any lot of the medicated feed in Defendants' inventory was not manufactured and labeled in conformity with the Act and its implementing regulations, including, but not limited to the CGMP requirements found in 21 C.F.R. §§ 225.1 and 225.120 through 225.202, then Defendants shall destroy, at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted to and approved by FDA in writing prior to implementation, the non-compliant lot(s) of medicated feed.

7. Upon resumption of operations after completion of the requirements of paragraph 4, Defendants shall collect a sample of the first lot of medicated feed made with each individual drug used in the feed mill, and submit each sample to a qualified laboratory for analysis. Two additional samples of medicated feed containing each drug shall be collected over the course of the first year and submitted to a qualified laboratory for analysis. Defendants shall conduct an investigation of and take corrective action, pursuant to 21 C.F.R. § 225.158, for any lot of

medicated feed determined by laboratory testing to be outside the permissible assay limits set forth in 21 C.F.R. § 558.4(d). Defendants shall send copies of the lab reports, as well as records generated subsequent to 21 C.F.R. § 225.158 in response to out-of-limits assays, to the Florida District Office, at the address listed in paragraph 18, on a quarterly basis for the first year following the resumption of operations.

8. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $90.65 per hour and fraction thereof per representative for inspection work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 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 representative per day 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.

9. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Defendants' facilities at 3079 NW 8th Street, Okeechobee, Florida, or any other locations, now or in the future, at which the Defendants manufacture medicated feeds and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, FDA regulations, and the Act. During inspections, the Defendants shall cooperate fully with FDA by, among other things, promptly providing FDA investigators with requested documents and material and

making employees readily available to FDA investigators. The costs of all such supervision, inspections, analyses, examinations, and reviews are to be paid by the Defendants at the rates specified in paragraph 8 of this Decree. 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 make inspections under the Act, 21 U.S.C. § 374.

10. After the requirements of paragraph 4(A)-(E) have been met, the Defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of this Decree, 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(k) by causing medicated feed to become adulterated, within the meaning of 21 U.S.C. § 351(a)(2)(B), while such feed is held for sale after shipment of one or more of its components in interstate commerce; or

B. violates 21 U.S.C. § 331(k) by misbranding an article of drug, medicated feed, within the meaning of 21 U.S.C. § 352(e)(1)(A)(ii) while such feed is held for sale after shipment of one or more of its components in interstate commerce; or

C. violates 21 U.S.C. § 331(k) by misbranding an article of drug, medicated feed, within the meaning of 21 U.S.C. § 352(f)(1) while such feed is held for sale after shipment of one or more of its components in interstate commerce.

11. If, at any time after entry of this Decree, FDA determines, based on the results of

an inspection, analysis of a sample or samples, or other information, that the Defendants have failed to comply with any provision of this Decree, have violated FDA regulations or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, FDA regulations, or the Act, FDA may, as and when it deems necessary, notify the Defendants in writing of the noncompliance and order the Defendants to take appropriate action, including, but not limited to, ordering the Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any medicated feeds;

B. Recall all articles of medicated feed manufactured by Defendants, including feed distributed to the Defendants' agents, distributors, customers, or consumers; or

C. Take any other corrective actions as FDA deems necessary to bring the Defendants into compliance with this Decree, FDA regulations, and the Act, including, but not limited to, requiring that the Defendants re-institute or re-implement any of the requirements in paragraphs 4 and 7 of this Decree.

Upon receipt of such notification, the Defendants shall immediately and fully comply with the terms of the notice. The Defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph 8 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

12. Any cessation of operations described in paragraph 11 shall continue until the Defendants receive written notification from FDA that the Defendants appear to be in compliance with this Decree, FDA regulations, and the Act.

13. 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 at 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 that was before FDA at the time the decision was made. No discovery shall be taken by either party.

14. Within ten (10) calendar days from the date of entry of this Decree, the Defendants shall provide a copy of this Decree, by personal service or certified mail return receipt requested, to each and all of the Defendants' officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them; and, in the case of future manufacture of medicated feeds at locations other than Syfrett Feed, within ten (10) calendar days of beginning to manufacture such feeds. In addition, after entry of this Decree, and within ten (10) calendar days from the date of employment of any new employee, the Defendants shall provide a copy of this Decree, by personal service or certified mail return receipt requested, to all new employees hired by the Defendants.

15. Within ten (10) calendar days from the date of entry of this Decree, the Defendants shall post a copy of this Decree on a bulletin board in an employee common area at Syfrett Feed and shall ensure that the Decree remains posted for a period of not less than six (6) months.

16. Within thirty (30) calendar days from the date of entry of this Decree, the Defendants shall provide FDA with an affidavit signed by the Defendants attesting to their compliance with paragraphs 14 and 15 of this Decree, stating the fact and manner of compliance, and identifying the names and positions of all persons so notified.

17. The Defendants shall notify FDA in writing at least thirty (30) calendar days before any change in ownership, name, or character, including reorganization, relocation, dissolution, assignment, lease, or sale of the business or any assets connected to the business such as buildings or equipment, that may affect compliance with the obligations arising from this Decree. The Defendants shall serve a copy of this Decree on any prospective successor or assign no later than thirty (30) calendar days before such sale or change in business, and shall furnish FDA with an affidavit of compliance with this paragraph within fifteen (15) calendar days of such service on a prospective successor or assign.

18. Any notices, correspondence, reports, or other information required by the terms of this Decree to be given to FDA shall be submitted in writing to the District Director of the Florida District Office, United States Food and Drug Administration, Department of Health and Human Services, 555 Winderley Place, Suite 200, Maitland, Florida, 32751.

19. The parties may at any time petition each other in writing to modify any deadline provided herein and if the parties mutually agree in writing to modify a deadline, such modification may be granted and may become effective without leave of the Court.

20. If the Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, the Defendants shall pay to the United States of America the sum of two hundred dollars ($200.00) in liquidated damages per day, and per violation, for as long as such violations occur.

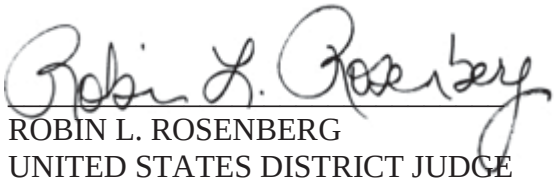
21. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, the Defendants agree to pay attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs,

investigation and analytical expenses incurred in bringing such action, and any other costs or fees related to such enforcement proceedings.

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

23. No sooner than five (5) years after entry of this Decree, Defendants may petition this Court for an order dissolving this Decree. If Defendants have maintained, to FDA's satisfaction, a state of compliance with this Decree, the Act, and all applicable regulations for five (5) years preceding Defendant's petition, the United States will not oppose such petition.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 4th day of May, 2017.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of record