UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO. 2:17-cv-14038

UNITED STATES OF AMERICA,

Plaintiff,

v.

SYFRETT FEED COMPANY, INC. and
CHARLES B. SYFRETT I,
MELISSA S. MONTES DE OCA,
and CHARLES B. SYFRETT II,
individuals,

Defendants.
_____/

COMPLAINT FOR PERMANENT INJUNCTION

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

INTRODUCTION

1. The United States of America, on behalf of the United States Food and Drug Administration (FDA), brings this statutory injunction proceeding under the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 332(a); and the inherent equitable authority of this Court, to permanently enjoin and restrain Syfrett Feed Company, Inc. (Syfrett Feed), Charles B. Syfrett I, Melissa S. Montes De Oca, and Charles B. Syfrett II, individuals (collectively, Defendants), from violating:

A. 21 U.S.C. § 331(k) by manufacturing medicated animal feeds, held for sale after incorporation of components shipped in interstate commerce, in a manner that results in the feeds being adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. 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; and

C. 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.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

THE DEFENDANTS

3. Defendant Syfrett Feed is a Florida corporation located at 3079 NW 8th Street, Okeechobee, FL 34973, within the jurisdiction of this Court. It was incorporated in 1956. The company manufactures, on average, 69,000 tons of feed annually using 176 different formulas, primarily for food-producing animals and fowl. Approximately 70% of the company's feeds are medicated. In addition to animal feeds, the company also warehouses and distributes bagged pet food.

4. Charles B. Syfrett I is the Owner and President of Syfrett Feed. He is the most responsible person at the company and makes all major financial decisions. He is also involved in day-to-day activities.

5. Melissa S. Montes De Oca is the daughter of Mr. Syfrett I, and the Vice President of Syfrett Feed. She has held her position for seven years and has been with the company since 2001. Her responsibilities include managing inventory, ordering ingredients, paying bills, and handling human resources, such as employee hiring and firing.

6. Charles B. Syfrett II is the son of Mr. Syfrett I, and the Operations Manager of Syfrett Feed. He reports directly to his father. He is responsible for formulating feed for cattle and other ruminants, and for implementing general formulation changes.

7. Defendants receive 80% of the ingredients used to manufacture their animal feeds from suppliers outside of the state of Florida.

MEDICATED ANIMAL FEED

8. A medicated feed is an animal feed that contains at least one new animal drug, as defined by 21 U.S.C. § 321(v). *See also* 21 U.S.C. § 321(w). Medicated feeds are created by adding a new animal drug, or drugs, to grains and other animal feed ingredients.

9. A medicated feed is also a drug within the meaning of 21 U.S.C. § 321(g) because it is intended to prevent or treat disease in animals, or to affect the function or structure of their bodies. The manufacture and distribution of medicated feeds must comply with the Act to ensure, among other things, that animals are not injured by the feed and that humans who ultimately consume the tissues, milk, or eggs of the animals do not ingest unsafe drug residues.

10. A medicated feed is deemed adulterated under the Act if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not administered in conformity with, Current Good Manufacturing Practices (CGMP), 21 U.S.C. § 351(a)(2)(B).

11. A medicated feed is misbranded if its labeling lacks the name of the active drug ingredient, 21 U.S.C. § 352(e)(1)(A)(ii), or if it lacks adequate directions for use, 21 U.S.C. § 352(f)(1).

THE DEFENDANTS' VIOLATIONS

12. Defendants adulterate their medical feeds within the meaning of 21 U.S.C. § 351(a)(2)(B) by manufacturing feeds in a manner that does not conform to the CGMP requirements for medicated feeds, 21 C.F.R. Part 225. For example, Defendants:

a) fail to establish and maintain adequate procedures for the identification, storage, and inventory control of drugs intended for use in medicated feed, in violation of 21 C.F.R. § 225.142;

b) fail to establish and use adequate procedures for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and non-medicated feeds, in violation of 21 C.F.R. § 225.165; and

c) fail to adopt labeling practices that assure that the correct labels are used for the medicated feeds they manufacture, and that all deliveries of medicated feeds, whether bagged or in bulk, are adequately labeled to assure that the feed can be properly used, in violation of 21 C.F.R. § 225.180.

13. Defendants misbrand their medicated feeds by failing to list the name of the active drug ingredient on the label of the medicated feeds, in violation of 21 U.S.C. § 352(e)(1)(A)(ii). For example, Defendants omitted the names and concentrations of the active drug ingredients from the labels of their medicated feeds.

14. Defendants also misbrand their medicated feeds by failing to include adequate instructions for use on the products' labels, in violation of 21 U.S.C. § 352(f)(1). For example,

Defendants did not include adequate instructions for use on the products' labels when they omitted dose administration instructions, feeding limitations and/or cautionary statements for use of the drugs in combination with other drugs on the label of the medicated feeds.

PRIOR WARNING

15. FDA conducted inspections of Defendants' facility located at 3079 NW 8th Street, Okeechobee, Florida in January 2014, June 2015 and June 2016. FDA observed significant CGMP deviations and misbranding violations during all three inspections.

16. Defendants are aware of their ongoing violations of the Act. For example, on July 15, 2014, FDA sent a Warning Letter to Mr. Syfrett I, notifying him of the significant CGMP deviations and misbranding violations observed by FDA during a January 2014 inspection. The letter stated that failure to correct the CGMP deviations and the misbranding of drug products could result in sanctions, including, but not limited to, injunction.

17. In April 2014, Syfrett Feed conducted a recall of its non-medicated horse pellet food when customers complained that their horses were falling ill after consuming Syfrett Feed's horse pellet food. Fifteen horses had to be euthanized. Defendants did not inform FDA of the recall until May 2015, nearly a year after the recall. In September 2014, two more horses had to be euthanized after consuming Syfrett Feed's horse pellet food. Following these events, Defendants discontinued manufacturing medicated and non-medicated feeds for horses.

18. At the close of FDA's 2014 inspection, FDA investigators presented Mr. Syfrett I with List of Inspectional Observations (Form FDA 483) and discussed the documented deviations with Mr. Syfrett I and Ms. Montes De Oca. At the close of FDA's 2015 inspection, FDA investigators presented Mr. Syfrett I with a List of Inspectional Observations (Form FDA 483) and discussed the documented deviations with Mr. Syfrett I, Mr. Syfrett II and Ms. Montes

De Oca. At the close of FDA's 2016 inspection, FDA investigators presented Ms. Montes De Oca with a List of Inspectional Observations (Form FDA 483) and discussed the documented deviations with her. These inspections served as repeated warnings of the violations described in the previous section.

19. In response to these warnings, Syfrett Feed has repeatedly promised corrections. However, at each inspection, FDA has found that Defendants have either failed to implement the promised corrections, or have implemented them inadequately.

20. On September 11, 2015, FDA wrote to Mr. Syfrett I, stating that Syfrett Feed had not taken adequate measures to correct the CGMP deviations and misbranding violations noted in FDA's 2014 Warning Letter and 2015 inspection. The letter stated that failure to correct the CGMP deviations and the misbranding of drug products could result in sanctions, including, but not limited to, injunction. The letter also requested a response to FDA to describe in detail the corrective action plan Syfrett Feed intended to implement.

21. Syfrett Feed did not respond to FDA's September 11, 2015 letter. During FDA's 2016 inspection, Ms. Montes De Oca confirmed that she received the September 11, 2015 letter but decided not to respond.

22. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) by adulterating and misbranding its medicated feed.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin 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 the Court's order from directly or indirectly doing or causing any act which:

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;

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; and

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.

II. Order 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 the Court's order, to cease manufacturing, processing, packing, labeling, holding for sale, and distributing any article of medicated feed unless and until the Defendants bring their facilities into compliance with the law as acceptable to FDA; and

III. Award Plaintiff its costs herein and such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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