IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. FRANCK'S LAB, INC., d.b.a. FRANCK'S COMPOUNDING LAB, a corporation, and PAUL W. FRANCK, an individual Defendants.	Civil Action No. 5:10 CV-147-OC-32GRJ COMPLAINT FOR PERMANENT INJUNCTION INJUNCTIVE RELIEF SOUGHT

The United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Defendants from violating: (a) 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(5) and misbranded within the meaning of 21 U.S.C. § 352(f)(1); and (b) 21 U.S.C. § 331(k) by causing drugs 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)(5) and misbranded within the meaning of 21 U.S.C. § 352(f)(1).

JURISDICTION

2. This Court has jurisdiction over the subject matter and over all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

VENUE

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Franck's Lab, Inc., d.b.a. Franck's Compounding Lab ("Franck's"), has been incorporated under the laws of the state of Florida since 2003, and conducts its business at 1210 SW 33rd Avenue, Ocala, Florida, within this Court's jurisdiction. Franck's markets itself as a compounding pharmacy, and compounds, manufactures, and distributes a wide variety of drugs for both human and animal uses, to customers across the United States. Franck's is licensed in Florida by the State Board of Pharmacy, and holds licenses to distribute drugs in all but three states in the country. Franck's employs approximately 67 people, has annual gross sales of roughly $8 million, $3.5 million from veterinary products, and filled more than 37,600 prescriptions for animal use between February 1 and December 4, 2009.

5. The firm manufactures the vast majority of its animal drugs from active pharmaceutical ingredients ("API"). API are "bulk drug substances" as defined in the Act, 21 C.F.R. § 207.3(a)(4), as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include

intermediates used in the synthesis of such substances." Defendants purchase API from suppliers outside of Florida.

6. Paul W. Franck is the owner and Chief Executive Officer of Franck's. He is involved in the firm's day-to-day activities, and is responsible for providing the final approval on all decisions concerning its operations. He maintains an office and performs his duties at the firm's headquarters, within this Court's jurisdiction, and has participated in each FDA inspection discussed herein.

7. Defendants maintain a website at www.francks.com, from which customers can place orders for compounded products.

8. Defendants have been, and are now engaged in compounding, manufacturing, processing, packing, labeling, holding, and distributing drugs within the meaning of 21 U.S.C. § 321(g), which are new animal drugs within the meaning of 21 U.S.C. § 321(v).

9. Defendants regularly compound and/or manufacture drugs using components they receive from outside Florida and introduce finished drugs into interstate commerce for shipment outside Florida.

10. None of Defendants' compounded animal drugs is the subject of an approved new animal drug application ("NADA"), an abbreviated new animal drug application ("ANADA"), a conditional approval, or a relevant index listing for minor species, and none meets the requirements for the investigational new animal drug exemption. See 21 U.S.C. §§ 360b(a)(1), 360b(j).

COMPOUNDING AND NEW ANIMAL DRUGS

11. "Drug compounding" is "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." Thompson v. Western States Med. Ctr., 535 U.S. 357, 360-61 (2002). In Western States, the Supreme Court explained that "[c]ompounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." Id. at 361. Other traditional uses for compounding include, but are not limited to, flavoring medications and altering dosage strength or dosage form for a particular patient's needs.

12. Defendants' compounded products for animal use are "drugs" within the meaning of the Act, 21 U.S.C. § 321(g)(1), because they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" in animals and/or are "intended to affect the structure or any function" of animals. This is evident by information on Defendants' website, www.francks.com. The website contains a "Product List" consisting of a chart listing four categories: Defendants' "drug name;" the "trade name;" the "drug classification;" and the "dosage forms available," indicating that they are willing to compound commercially available drugs. The "Product List" identifies over 200 products that the firm is willing to compound. The firm's website also claims that "Franck's Pharmacy is the nation's premier veterinary compounder." Further, the website states that "Franck's Compounding Lab specializes in compounded medications."

13. A drug is a "new animal drug" within the meaning of the Act, 21 U.S.C. § 321(v), if it is intended for use in animals and is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.

14. For a drug to be deemed "generally recognized as safe and effective," it must be the subject of published adequate and well-controlled studies showing the drug is safe and effective for the use(s) set forth in its labeling, and be recognized as safe and effective by qualified experts whose opinions are based on the publicized studies. See 21 U.S.C. § 360b(d). Defendants' compounded drugs have not undergone adequate and well-controlled studies, and there are no published data on which experts can base their opinions. Thus, their compounded drugs for use in animals are "new animal drugs."

15. To obtain approval to market a new animal drug, a drug's sponsor must submit to FDA an NADA, which demonstrates, through adequate and well-controlled studies, the safety and efficacy of the drug for particular uses and, among other things, describes its manufacturing process. 21 U.S.C. § 360b(b). As part of a new animal drug approval, FDA approves specified uses for which the drug can be marketed. Manufacturers of approved drugs must meet certain requirements, such as registering with FDA, validating their chemistry and manufacturing processes, and complying with post-approval obligations, including reporting adverse events. See 21 C.F.R. Part 514. A drug without approval, or without an appropriate exception, including a conditional

approval, an index listing for use in minor species, or an exemption for an investigational new animal drug, is unsafe, and therefore adulterated, within the meaning of the Act. See 21 U.S.C. § 351(a)(5).

16. In 2003, FDA promulgated Compliance Policy Guide 608.400, entitled "Compounding of Drugs for Use in Animals" ("CPG"). The CPG makes clear that it does not create or confer any rights for or on any person, but sets out FDA's current interpretation of the law and its thinking on the application of the relevant provisions of the Act. In the CPG, FDA recognizes the use of compounding within certain areas of veterinary practice, while also explaining FDA's concern about the intentional circumvention of the drug approval process and the potential for an unacceptable lack of quality control and appropriate manufacturing standards by compounders. The CPG sets out FDA's position that compounding from bulk substances or unapproved drugs renders the compounded drugs adulterated in violation of 21 U.S.C. § 351(a)(5), and provides a non-inclusive 13-item list of factors which the Agency may consider in deciding whether to exercise its enforcement discretion with regard to compounding animal drugs. One of these factors is the compounding from bulk drug substances or other unapproved drugs.

ADULTERATED NEW ANIMAL DRUGS

17. Failure to have an approval, a conditional approval, or an index listing for use in a minor species to which approved label a drug's use complies, or to meet the requirements for the exemption for an investigational new animal drug, 21 U.S.C.

§§ 360b(a)(1), 360b(j), renders a drug unsafe, and therefore adulterated, within the meaning of the Act, 21 U.S.C. § 351(a)(5).

18. The Animal Medicinal Drug Use Clarification Act of 1994 ("AMDUCA"), offers an additional exemption from the "unsafe" classification for the use in animals of approved animal or human drugs, validly prescribed by veterinarians, for indications that are not listed in the drugs' FDA-approved labeling. 21 U.S.C. §§ 360b(a)(4)(A) and (a)(5). As set out in paragraph 17, the Act provides that a new animal drug is considered unsafe if its use does not conform to its approved, conditionally approved, or indexed indications. Pursuant to AMDUCA and corresponding regulations, an approved new animal drug or human drug intended to be used for an indication not listed in its labeling will not be deemed unsafe under 21 U.S.C. § 360b if the use is "by or on the lawful . . . order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and in compliance with [21 C.F.R. Part 530]." 21 C.F.R. § 530.10.

19. FDA has promulgated regulations implementing AMDUCA, and those regulations apply to compounding. 21 C.F.R. Part 530. Under the regulations, products must be compounded from "approved animal or human drugs." 21 C.F.R. § 530.13 (emphasis added). The regulation states that "[n]othing in this part shall be construed as permitting compounding from bulk drugs." Id. The regulation further states that extralabel use from compounding of approved new animal or human drugs is permitted only when certain criteria are met. 21 C.F.R. § 530.13(b) (the criteria include:

compliance with 21 C.F.R. Part 530; the lack of any approved product to appropriately treat the condition; compounding performed by a licensed veterinarian within the scope of a professional practice; adequate procedures and process are used to ensure safety and effectiveness; the scale is commensurate with the need for products; and all state laws are followed)(emphasis added).

20. Defendants do not have any approvals, or conditional approvals, nor are any of their drugs listed in an index for use in minor species, nor do they meet the requirements for an investigational new animal drug exemption for any of their compounded animal drugs as required by 21 U.S.C. §§ 360b(a)(1), 360b(j). Additionally, a substantial majority of Defendants' compounded new animal drugs, are not compounded from approved drugs, as required by AMDUCA. Therefore, those products are "unsafe" within the meaning of the Act. Because these drugs are unsafe within the meaning of 21 U.S.C. § 351(a)(5), they are adulterated within the meaning of 21 U.S.C. § 360b(a)(1).

MISBRANDED DRUGS

21. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1), unless its labeling bears "adequate directions for use." FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a). Adequate directions for use must be based on animal and clinical data derived from extensive, scientifically controlled testing.

22. Defendants have no animal and clinical data and therefore cannot write adequate directions for use for their compounded drugs. Therefore, their drugs are misbranded, within the meaning of the Act. 21 U.S.C. § 352(f)(1).

INTERSTATE COMMERCE

23. Defendants ship compounded drugs outside the state of Florida to, among other states, Kentucky, Virginia, California, Illinois, Pennsylvania, Texas, Missouri, Tennessee, and New York.

24. Defendants purchase components used to compound their drugs from firms located outside Florida. For example, Defendants receive API from, among other locations, Texas and Minnesota.

VIOLATIVE HISTORY

25. Following the deaths, on April 19, 2009, in Wellington, Florida, of 21 polo horses that received a drug which Defendants admitted to compounding incorrectly, FDA inspected Defendants' facility, located in Ocala, Florida, on May 5 through 20, June 18 through 23, and December 1 through 4, 2009.

26. These inspections revealed that Defendants continue to unlawfully compound drugs from API for use in animals.

27. FDA conducted a previous inspection of Defendants' facility from September 29 through October 4, 2004. The inspection revealed that Defendants compounded drugs for use in animals using API, and distributed those compounded drugs in interstate commerce. Based on this inspection, FDA issued a Warning Letter,

dated January 10, 2005, to Defendants. The violations discussed in the Warning Letter included the following:

(a) Compounding veterinary drugs from API, and distributing them in interstate commerce;

(b) Compounding veterinary drugs outside the context of a valid veterinarian- client-patient relationship;

(c) Not compounding for individual patients, but rather, compounding for third-parties who resell to individual patients; and

(d) Compounding drugs for use when an approved drug, in available dosage form and concentration, exists to treat the animal.

28. Franck's responded to the Warning Letter through counsel in a letter dated January 27, 2005, promising “to comply immediately and completely with any and all FDA and other legal requirements . . . .”

PRIOR NOTICE

29. Defendants are well aware that their practices violate the law, having received notice at the conclusion of an FDA inspection in 2004 through a List of Inspectional Observations, Form FDA 483, and a Warning letter in January 2005. In addition, FDA investigators informed Defendants of their continuing violation during the December 2009 inspection, to which Defendant Paul W. Franck responded that he understood that under FDA’s interpretation of the law, Defendants’ activities are illegal, but disagreed with that interpretation.

30. The United States is informed and believes that, unless restrained by this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and 331(k), in the manner set forth above.

WHEREFORE, the United States respectfully requests that this Court:

I. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a), 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, from compounding, manufacturing, processing, packing, labeling, holding, or distributing articles of drug for use in animals, unless and until Defendants obtain appropriate FDA approvals for their drugs, or meet an appropriate exemption to the approval requirements under the Act; and

II. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a), 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, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(5);

B. Violating 21 U.S.C. § 331(k) by causing drugs 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)(5);

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

D. Violating 21 U.S.C. § 331(k) by 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); and

III. Authorize FDA, pursuant to this injunction, to inspect Defendants' places of business and all records relating to the receipt, compounding, manufacturing, processing, packing, labeling, holding, storing, or distribution of any drug or component to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such equitable relief as this Court deems just and proper.

DATED this 16th day of April, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on (date) , I presented the foregoing to the Clerk of the Court for filing and uploading to the CM/ECF system. I further certify that I mailed the foregoing document and the notice of electronic filing by first-class mail to the following non-CM/ECF participants: FRANCK'S LAB, INC., d.b.a. FRANCK'S COMPOUNDING LAB, a corporation, and PAUL W. FRANCK, an individual, 1210 SW 33rd Avenue, Ocala, Florida, 34474-2853.

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