IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WINSTON LABORATORIES, INC., a Delaware corporation,	)	
Plaintiff,	)	
v.	)	**Case Number: 09 CV**
KATHLEEN SEBELIUS, as Secretary and Senior Officer of United States Department of Health and Human Services; and MARGARET HAMBURG, M.D., as Commissioner and Senior Officer of United States Food and Drug Administration,	)	**Judge**
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Winston Laboratories, Inc. ("Winston Labs"), by its attorneys Barnes & Thornburg LLP, for its Verified Complaint for Declaratory and Injunctive Relief ("Complaint") against the United States Food and Drug Administration; Kathleen Sebelius, in her official capacity as the Secretary of United States Department of Health and Human Services; and Margaret Hamburg, M.D., in her official capacity as the Commissioner of the United States Food and Drug Administration (collectively, "FDA"), alleges as follows:

NATURE OF ACTION

1. Winston Labs respectfully brings this action for declaratory and injunctive relief challenging FDA's unlawful refusal to grant Winston Labs' May 21, 2008 application for waiver of an application user fee under the small business waiver provision, section 736(d)(1)(D) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 379h(d)(1)(D), for new drug

application ("NDA") 22-403 for Civanex® (civamide (zucapsaicin)) cream 0.075% ("Civanex® cream") for the treatment of osteoarthritis.

2. Winston Labs has satisfied all substantive requirements for approval of a small business waiver for its Civanex® cream product. Winston Labs' product is not subject to any stays of approval, nor has any court decision of patent infringement been rendered, or injunction been entered, against Winston Labs in any action to which Winston Labs is a party.

3. FDA has no lawful basis or authority to deny Winston Labs' request for a small business waiver of the prescription drug user fee.

4. FDA nonetheless has withheld approval of a small business waiver in clear contravention of Section 736(d)(4) of the FFDCA, 21 U.S.C. § 379h(d)(1)(D).

5. Pursuant to the Administrative Procedure Act ("APA"), FDA's actions are arbitrary, capricious, and abuse of discretion, contrary to law, and in excess of statutory authority.

6. To prevent devastating and irreparable harm to Winston Labs, the Court should enter immediate injunctive relief requiring FDA to grant final, effective approval of Winston's Labs' request for waiver of the application user fee under the small business waiver provision, section 736(d)(1)(D) of the FFDCA, 21 U.S.C. § 379h(d)(1)(D), for NDA 22-403 for Civanex® cream.

PARTIES

7. Winston Labs is a Delaware corporation with its principal place of business in Vernon Hills, Illinois, located here within the Northern District of Illinois.

8. Defendant Kathleen Sebelius is the Secretary of Health and Human Services ("HHS"), and the official charged by law with administering the FFDCA. She is sued in her

official capacity. Secretary Sebelius maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

9. Defendant Margaret Hamburg, M.D., is the Commissioner and senior official of FDA. She is sued in her official capacity. Commissioner Hamburg has been delegated the authority to administer the waiver approval provisions of 21 U.S.C. § 379h(d)(1)(D) through FDA. She maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

JURISDICTION AND VENUE

10. Winston Labs' cause of action arises under Section 736(d)(1)(D) of the FFDCA, 21 U.S.C. § 739h(d)(1)(D), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1361.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

13. This Court has personal jurisdiction over the federal Defendants because they conduct substantial business in, or have regular and systematic contact with, this District.

14. FDA's agency action and/or inaction constitutes an actual controversy, for which Winston Labs is entitled to review and relief under 5 U.S.C. §§ 702, 704-706.

15. Winston Labs has standing to maintain this action, pursuant to the APA, as a legal entity that has been adversely affected by final agency action and/or agency action unlawfully withheld.

16. There exists an actual, substantial, and continuing controversy between the parties regarding FDA's application of section 736(d)(4) of FFDCA, 21 U.S.C. § 379h(d)(1)(D), and, in particular, the Agency's refusal to grant Winston Labs a small business waiver of application user fee for Civanex® cream product. This Court may declare the rights and legal relations of the parties under 28 U.S.C. §§ 2201, 2202.

FACTS

17. On May 21, 2008, Winston Labs filed a request for waiver of an application user fee under the small business waiver provision, section 736(d)(1)(D) of the FFDCA, 21 U.S.C. § 379h(d)(1)(D), for NDA 22-403 for Civanex® cream (Exhibit A).

18. Under section 736(d)(4) of the FFDCA, a waiver of the application user fee shall be granted to a small business for the first human drug application that it or its affiliate submits to the FDA for review.

19. Section 736(d)(4) of the FFDCA entitles a small business to a waiver of the new drug application user fee when the business meets the following criteria:

A. The business must employ fewer than 500 persons, including employees of its affiliate;

B. The business does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce;

C. The marketing application must be the first human drug application that a company or its affiliate submits to the FDA.

20. 21 U.S.C. 379g(11) states, "The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly – (A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has the power to control, both of the business entities."

21. On June 26, 2008, the Small Business Administration's Office of Government Contracting in Chicago, Illinois ("SBA") received a request from the FDA for an employee count of Winston Labs (Exhibit B).

22. In a letter dated August 13, 2008, the SBA concluded that Winston Labs qualified as a small business (Exhibit C).

23. On December 1, 2008, Jane A. Axelrad, Associate Director for FDA Policy, Center for Drug Evaluation and Research, denied Winston Labs' request for waiver of the small business application user fee (Exhibit D).

24. In the letter dated December 1, 2008, the FDA denied Winston Lab's May 21, 2008 request for waiver of the application user fee claiming that Winston's request failed because the third criteria of 736(d)(4) of the FFDCA (Exhibit D).

25. In the December 1, 2008 letter, FDA also stated that it considers all business affiliates, even those that are no longer in existence, when determining whether to grant a small business waiver under 736(d)(4) of the FFDCA (Exhibit D).

26. In the December 1, 2008 letter, FDA also stated that GenDerm Corporation ("GenDerm") and Northbrook Testing Co., Inc. ("Northbrook") were once affiliates of Winston Labs and both companies had previously submitted new drug applications to the FDA (Exhibit D).

27. On December 9, 2008, Winston Labs submitted a request to FDA for reconsideration of the FDA's decision to deny its request for small business user fee waiver (Exhibit E).

28. On February 2, 2009, the FDA denied Winston Lab's request for reconsideration, once again stating the reason for its denial is based on the determination that GenDerm and Northbrook are business associates of Winston Labs (Exhibit F).

29. On April 8, 2008, Winston Labs submitted an appeal of the FDA's denial of its request for application of the small business waiver of user fees for its Civamide cream (Exhibit G).

30. On June 18, 2009, Murray M. Lumpkin, M.D., Deputy Commissioner for International Programs at the FDA denied Winston Labs' request for fee waiver claiming that GenDerm and Northbrook are business affiliates of Winston Labs and both had filed a NDA with the FDA (Exhibit H).

31. Northbrook was an Illinois corporation that was dissolved in 1984, approximately nine (9) years before the FDA even initiated the requirement of user fees under the FFDCA, and twenty-four (24) years before Winston filed its request for a waiver. Before Northbrook's dissolution in 1984, Dr. Joel Bernstein owned a majority of the shares of Northbrook and was its President.

32. GenDerm was originally an Illinois corporation, incorporated in 1983. Dr. Joel Bernstein was a 27% minority shareholder and Chairman and CEO of GenDerm until 1997 when all of GenDerm's stock was sold to Medicis Pharmaceutical Corporation, and was merged into Medicis ("Medicis"). Prior to the sale to Medicis, Dr. Bernstein did not control or have the ability to control GenDerm, and after GenDerm's merger into Medicis in 1997, Dr. Bernstein had no ownership or management position with GenDerm.

33. Winston Labs was incorporated in Delaware in 1998. Its CEO is Dr. Joel Bernstein and Dr. Bernstein and his immediate family own indirectly approximately 60% of Winston.

34. At no time did Winston Labs ever control, or have the power to control, Northbrook or GenDerm.

35. At no time did a third party, including Dr. Bernstein, control, or have the power to control, both Winston Labs and Northbrook, or Winston Labs and GenDerm.

36. As of May 21, 2008, Winston Labs employed eleven (11) persons.

37. As of May 21, 2008, Winston Labs did not have a prescription drug product introduced or delivered for introduction into interstate commerce, and did not expect to introduce a prescription product within the following twelve (12) months.

38. NDA 22-403 for Civanex® cream was Winston Labs' first human drug application submitted to FDA for review.

39. Under 21 U.S.C. § 379h(a)(1)(B), if Winston Labs is not granted the requested application fee waiver, an application fee of $1,247,200 will be due upon submission of the Civamide cream NDA.

40. Winston Labs does not have the ability to pay the substantial application fee and, as a consequence, Civamide cream will not be introduced into the market and will not benefit patients.

41. Winston Labs has exhausted its administrative appeals, and has no adequate remedy at law.

COUNT I
(Declaratory and Injunctive Relief)

42. Winston Labs realleges and incorporates by reference paragraphs 1 through 41 as paragraph 42 of Count I.

43. The statutory language of 21 U.S.C. 379g(11) is plainly and unambiguously in the present tense.

44. On May 21, 2008, Winston Labs neither controlled nor had the power to the control Northbrook, which has not existed since 1984, or GenDerm.

45. On May 21, 2008, no third party controlled, or had the power to control, Winston Labs and Northbrook, or Winston Labs and GenDerm.

46. Under the plain and unambiguous language of 21 U.S.C. 379g(11), neither Northbrook nor GenDerm is a Winston Labs affiliate.

47. Accordingly, FDA has no lawful basis or authority to deny Winston Labs' May 21, 2008 request for a small business waiver of the prescription drug application user fee.

48. FDA nonetheless has withheld approval of a small business waiver in clear contravention of Section 736(d)(4) of the FFDCA, 21 U.S.C. § 379h(d)(1)(D).

49. Pursuant to APA, FDA's actions are arbitrary, capricious, and abuse of discretion, contrary to law, and in excess of statutory authority.

WHEREFORE, Plaintiff Winston Labs respectfully requests that the Court enter a judgment declaring the following:

A. That FDA's refusal to grant a small business waiver of user fees is arbitrary, capricious, and an abuse of discretion, contrary to law, and in excess of statutory authority;

B. Entry of an injunction requiring FDA to immediately award approval for Winston Lab's application for small business user fee waiver;

C. Entry of an order awarding Winston Labs its reasonable attorneys' fees and costs of prosecuting this action; and

D. Any such other relief the Court deems proper and equitable.

Dated: July 29, 2009

Respectfully submitted,

WINSTON LABORATORIES, INC.

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