STUART F. DELERY
Assistant Attorney General
Civil Division
MICHAEL S. BLUME
DAVID A. FRANK (Cal. Bar No. 119818)
United States Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044-0386
Telephone: (202) 307-0061
Facsimile: (202) 514-8742
Email: David.Frank@usdoj.gov

Attorneys for Plaintiff United States of America

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

| | |
|---|---|
| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>LACLEDE, INC. and MICHAEL A. PELLICO<br><br>Defendants. | CASE NO.: CV14-04948 - PA(FFMx)<br><br>**COMPLAINT FOR PERMANENT INJUNCTION**<br><br>[21 U.S.C. §§ 331(a), 331(d), and 331(k), and 332(a)] |

Plaintiff, United States of America ("United States"), alleges and complains against defendants Laclede, Inc. and Michael A. Pellico (collectively, the "defendants"), as follows:

## I. INTRODUCTION

1. The United States brings this action under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332(a), to permanently enjoin and restrain the defendants, Laclede, Inc. and Michael A. Pellico, from:

A. violating 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 that are neither approved pursuant to 21 U.S.C. §§ 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(c) and (e); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(c) and (e).

## II. JURISDICTION AND VENUE

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

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

## III. THE PARTIES

4. Plaintiff is the United States of America.

5. Defendant Laclede, Inc. ("Laclede" or "the firm") is a privately-held California corporation. Laclede operates at its headquarters and drug manufacturing facility, located at 2103 East University Drive, Rancho Dominguez, Los Angeles County, California ("Facility"), within the jurisdiction of this Court.

6. Laclede manufactures, processes, packs, labels, holds, and distributes four over-the-counter ("OTC") vaginal health care drug products for human use: Luvena Prebiotic Vaginal Moisturizer & Lubricant ("LPVML"); Luvena Prebiotic Feminine Wipes ("LPFW"); Luvena Prebiotic Enhanced Personal Lubricant ("LPEPL"); and Luvena Prebiotic Daily Therapeutic Wash ("LPTW") (collectively referred to as "Luvena Prebiotic Products"). Within cartons of LPVML that defendants distribute to consumers in interstate commerce, they include product samples of LPFW, LPEPL, and LPTW.

7. Defendant Michael A. Pellico ("Pellico") is Laclede's president, founder, and 50% owner. He is ultimately responsible for, and oversees, all operations at the firm, including research and development, manufacturing, approving master batch

records, and product labeling. He is also responsible for, and has authority over, the labeling and marketing of Laclede's products, including approving the contents of product labels and websites operated and/or controlled by the firm. Defendant Pellico performs his duties at the Facility, within the jurisdiction of this Court.

8. The defendants manufacture their Luvena Prebiotic Products using components received in interstate commerce.

9. The defendants sell their Luvena Prebiotic Products to other distributors and/or retailers outside of California.

10. As of June 12, 2014, the defendants sold their Luvena Prebiotic Products directly to customers through their online store at their website, http://laclede.com (last accessed on June 12, 2014).

11. In addition, the defendants also operate their website www.luvenacare.com (last accessed on June 12, 2014), the link to which is printed on the label of their Luvena Prebiotic Products, and a Twitter feed (https://twitter.com/LuvenaPrebiotic) (last accessed on June 12, 2014), and/or operated a Facebook page (https://www.facebook.com/Luvenaactibiotic, formerly https://www.facebook.com/LuvenaPrebiotic) (last accessed on May 23, 2014). These are or have been used to promote the defendants' Luvena Prebiotic Products. Defendants are responsible for the information and updates provided on http://laclede.com, www.luvenacare.com, and for Laclede's Facebook and Twitter entries.

## IV. DEFENDANTS' VIOLATIONS OF THE ACT

Unapproved New Drugs

12. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C). A product is also a drug if it is "intended for

use as a component of the articles" specified in 21 U.S.C. §§ 321(g)(1)(B) or (C); 21 U.S.C. § 321(g)(D).

13. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held that the term "accompanying" in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue and that physical attachment to the article is not necessary. See Kordel v. United States, 335 U.S. 345, 349-50; 69 S.Ct. 106, 109-111; 93 L.Ed. 52, 57-58 (1948)

14. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1).

15. An OTC drug manufactured and labeled in strict conformance with 21 C.F.R. Part 330 and any applicable monograph is generally recognized as safe and effective and not considered to be misbranded. See 21 C.F.R. § 330.1.

16. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j). It is a violation of the Act to introduce or deliver for introduction, or cause to be introduced or delivered for introduction, into interstate commerce an unapproved new drug. 21 U.S.C. § 331(d).

17. A product that constitutes a combination of a drug, device, and/or biological product is referred to as a "combination product." 21 U.S.C. § 353(g). Combination products include products comprised of two or more regulated

components, i.e., drug/device or drug/device/biologic that are physically, chemically, or otherwise combined or mixed and produced as a single entity. 21 C.F.R § 3.2(e). FDA is required to designate a lead agency center with primary jurisdiction for premarket review and regulation of a combination product based the product's primary mode of action. 21 U.S.C. § 353(g).

18. A "device" is an instrument or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321(h).

19. A "biological product" is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. § 262(i)(1).

20. In accordance with 21 U.S.C. § 353(g) and its implementing regulations at 21 C.F.R. Part 3, FDA, through its Office of Combination Products ("OCP"), has determined that LPVML and LPEPL are combination products for which the Center for Drug Evaluation and Research ("CDER") is the agency center with primary jurisdiction for premarket review and regulation.

21. Laclede's websites (www.luvenacare.com; http://laclede.com; https://www.facebook.com/Luvenaactibiotic, formerly https://www.facebook.com/LuvenaPrebiotic; and https://twitter.com/LuvenaPrebiotic) constitute labeling within the meaning of 21 U.S.C. § 321(m) because they are "written, printed, or graphic matter . . . accompanying such article [of drug]."

22. The claims that the defendants make and/or have made on Laclede's websites (www.luvenacare.com; http://laclede.com; and https://www.facebook.com/Luvenaactibiotic, formerly https://www.facebook.com/LuvenaPrebiotic; and https://twitter.com/LuvenaPrebiotic) demonstrate that the Luvena Prebiotic Products are: (1) intended to mitigate, treat, or prevent vaginal infections; and/or (2) intended to affect the structure or function of the human body by modulating vaginal microflora. These claims include, but are not limited to, the following:

a. "Yes, Luvena Prebiotics absolutely do help dryness, but their enzymes help with pH also. Too alkaline of a pH is a major cause of infections in young women – sexually active or not. 'Friendly' bacteria (flora) need acid and cannot thrive if the pH is too high. If the pH is not between 3.8 – 4.2, there can be Bacterial Vaginosis (BV), Trichomoniasis, Yeast infections, and fishy odor. If a young woman has any of the above, it is possible the pH is too alkaline; the flora is imbalanced . . . . If you have frequent vaginal infections, use Luvena Prebiotic every two weeks -- see if it stops your infections" (Facebook entry dated May 23, 2013, last accessed on March 5, 2014);

b. "Bacteria are sooo good for us . . . The more good bacteria the better to hold off the bad bacteria. Less infection - less disease . . . Killing off bacteria with broad spectrum antibiotics also kills the good bacteria . . . . The vaginal bacterial balance needs the correct conditions: pH, moisture, specific sugars . . . Now, you've got to reset the correct vaginal conditions for the good bacteria to grow. Use Luvena Prebiotics for excellent ingredients" (Facebook entry dated September 19, 2013, last accessed on March 5, 2014);

c. "D-Mannose is a little-known sugar that can help UTIs and Vaginal infections. In LuvenaPrebiotics; say good-bye to antibiotics" (Twitter entry dated March 18, 2013, accessed on March 27, 2014 and June 12, 2014);

d. "If you take antibiotics 'friendly' bacteria are destroyed along with 'harmful' bacteria. Use Luvenaprebiotics prophylactically" (Twitter entry dated May 7, 2013, accessed on March 27, 2014 and June 12, 2014); and

e. "If your vagina pH isn't slightly acidic, correct it with LuvenaPrebiotics and rebalance the flora for fewer infections" (Twitter entry dated February 11, 2013, accessed on March 27, 2014 and June 12, 2014).

23. In addition to the claims on Laclede's websites about their Luvena Prebiotic product line in general, the defendants make numerous claims on the LPVML product label that LPVML is: (1) intended to mitigate, treat, or prevent diseases such as vaginosis and yeast infection; and/or (2) intended to affect the structure or function of the human body by modulating vaginal microflora. Such claims include, but are not limited to, the following:

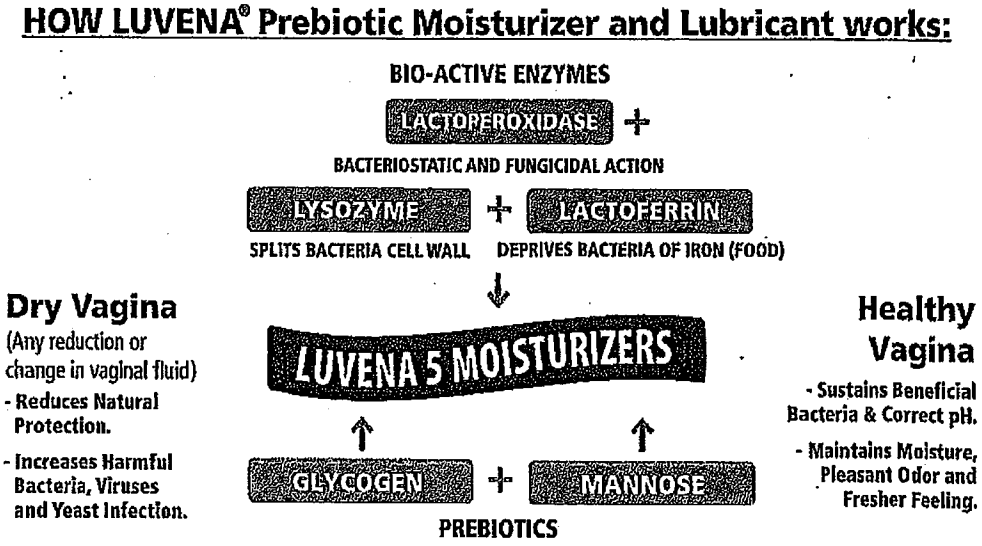
a. "LUVENA Prebiotic Vaginal Moisturizer is vital to women prone to vaginal dryness. Any change in vaginal fluid can alter the correct pH and disrupt the vagina's natural protective action against microbial growth. These changes are gradual and often go unnoticed until they lead to vaginosis, yeast infection, odor, and painful intercourse";

b. "Natural & Protective Certified Prebiotic . . . Contains Bio-Active Enzymes";

c. "Lubricates and protects . . . LUVENA Prebiotic Vaginal Moisturizer & Lubricant"

d. "Luvena Prebiotic Vaginal Moisturizer acts like a 'bio-shield lubricant'"; and

e. Below is a copy of a portion of the insert found within the LPVML product carton.




f. "Q: . . . Does this product prevent vaginal odors? A: A bad odor usually indicates infection or a disruption of the vaginal flora. . . . [A] woman's vagina needs to have a balanced pH flora. Use LUVENA® Prebiotic Moisturizer & Lubricant as directed to maintain natural freshness . . . . Q: How long will it take for me to feel results? A: . . . It can usually be cleared up as soon as the flora and pH are balanced."

24. In addition to the claims on Laclede's websites about the Luvena Prebiotic product line in general, the defendants also make numerous claims on the LPFW product label that LPFW is: (1) intended to mitigate disease such as irritating discharge; and/or (2) intended to affect the structure or function of the human body by modulating the microflora of the external vaginal area. These claims include, but are not limited to, the following:

a. "Luvena Prebiotic Feminine Wipes with natural bio-active enzyme protection";

b. "gently cleans & inhibits odor causing bacteria";

c. "Luvena Prebiotic Feminine Wipes . . . Relieves . . . & protects… When having irritating discharge"; and

25. In addition to the claims on Laclede's websites about their Luvena Prebiotic product line in general, the defendants also make numerous claims on the LPEPL product label that LPEPL is intended to affect the structure or function of the human body by modulating vaginal microflora. Such claims include, but are not limited to, the following:

a. "Luvena Prebiotic Enhanced Personal Lubricant . . . Natural & Restorative Certified Pre-biotic";

b. "Prebiotic to Support Healthy Intimacy";

c. "A new prebiotic lubricant designed to protect naturally while lubricating"; and

d. "Prebiotic formula containing natural bio-active enzymes".

26. In addition to the claims on Laclede's websites about their Luvena Prebiotic product line in general, the defendants also make numerous claims on the LPTW product label that LPTW is: (1) intended to mitigate, treat, or prevent disease such as yeast infection; and/or (2) intended to affect the structure or function of the human body by modulating the microflora of the external vaginal area. Such claims include, but are not limited to, the following:

a. "Luvena Prebiotic Feminine Wash contains bio-active enzymes that fight odor-causing bacteria naturally";

b. "Uses: Complete prebiotic formula for daily feminine cleansing care . . . Fights bacteria and yeast growth"; and

c. "Luvena Prebiotic Daily Therapeutic Wash . . . Bio-Active Enzyme Protection . . . "

27. The Luvena Prebiotic Products are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1) because they are not generally recognized among experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or

suggested in their labeling. Moreover, FDA's review indicates that there is no applicable OTC monograph for these products.

28. FDA does not have an NDA, ANDA, or IND on file for the defendants' Luvena Prebiotic Products.

29. Because the Luvena Prebiotic Products are unapproved new drugs, the defendants' distribution of these products into interstate commerce violates 21 U.S.C. § 331(d).

Misbranded Drugs

30. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

31. A drug is misbranded if its label or labeling do not comply with FDA's format and content requirements for OTC drug product labeling by, for example, failing to include a "Drug Facts" panel. 21 U.S.C. § 352(c); 21 C.F.R. § 201.66(c) & (d).

32. LPVML, LPEPL, and LPTW are misbranded drugs within the meaning of 21 U.S.C. § 352(c) because they lack a "Drug Facts" panel on their outside container, wrapper, or immediate container. 21 C.F.R. § 201.66(c) & (d).

33. A drug is also misbranded if its label does not bear the "established name and quantity . . . of each active ingredient". 21 U.S.C. § 352(e)(1)(A)(ii). FDA's implementing regulation requires the outside container or wrapper of the retail package, or the immediate container label if no outside container or wrapper exists, of an OTC drug to include the heading "Active ingredients" followed by the established name and quantity of each active ingredient per dosage unit. 21 C.F.R. § 201.66(c)(2).

34. LPVML, LPEPL, and LPTW are misbranded drugs within the meaning of 21 U.S.C. § 352(e)(1)(A)(ii) because although certain ingredients are intended to be used as active drug ingredients, neither the outside container or wrapper of the retail package nor the immediate wrapper or container label for these products

includes an "Active ingredients" heading, distinguishing between active and inactive ingredients, followed by the established name and quantity of each of these active ingredients per dosage unit.

35. LPFW is a misbranded drug within the meaning of 21 U.S.C. § 352(e)(1)(A)(ii) because although certain ingredients are intended to be used as active drug ingredients, neither the outside container or wrapper of the retail package nor the immediate wrapper or container label for LPFW includes an "Active ingredients" heading followed by the established name and quantity of each of these active ingredients per dosage unit.

Interstate Commerce

36. During an inspection conducted during August 20-September 4, 2013, FDA documented the shipment of the Luvena Prebiotic Products from Laclede's Facility to recipients outside California.

37. As of June 12, 2014, the Luvena Prebiotic Products could be ordered from Laclede's website, http://laclede.com, for shipment nationwide.

38. The defendants receive raw materials from outside of California (including, but not limited to, New York and Virginia) which they use to manufacture the Luvena Prebiotic Products.

History

39. The defendants are well aware that their conduct violates the Act and that continued violations could lead to regulatory action.

40. By letters dated June 16, 2010, and September 8, 2010, FDA's Center for Devices and Radiological Health ("CDRH") informed the defendants that LPVML appeared to be regulated by CDER and that the defendants could not distribute it in interstate commerce without complying with the Act's approval requirements. On September 13, 2010, CDER informed the defendants that LPVML was an unapproved new drug that requires premarket review and approval before it could be legally

distributed in interstate commerce. Despite such warnings, the defendants began distributing LPVML in interstate commerce without the statutorily required approval.

41. During FDA's June 2011 and June 2012 inspections of Laclede's Facility, FDA documented that the defendants had sold LPVML with claims that caused the products to be unapproved new drugs.

42. During a regulatory meeting in September 2011, OCP informed the defendants that LPVML was a combination product for which CDER has primary jurisdiction for premarket review and regulation. On or around March 9, 2012, OCP received from the defendants a Request for Designation, pursuant to 21 C.F.R. § 3.7, recommending that FDA classify LPVML as a device and assign the product to CDRH, rather than CDER, for premarket review and regulation.

43. The defendants began distributing LPEPL in interstate commerce on or around March 16, 2012, without the statutorily required approval from FDA. Five months later, defendants then sought clearance from CDRH, by letter dated August 30, 2012, to market LPEPL as a device. See 21 U.S.C. § 360(k). CDRH informed defendants, by letter dated October 17, 2012, that LPEPL appeared to be a combination product containing drug constituents for which CDER, not CDRH, has primary jurisdiction. CDRH also directed defendants to CDER for more information on applicable requirements for marketing LPEPL and to OCP should they wish to submit a Request for Designation and obtain a formal jurisdictional assignment for LPEPL.

44. In a May 15, 2012 letter to the defendants, OCP responded to defendants' Request for Designation concerning LPVML, which OCP had received on or around March 9, 2012. OCP's letter set forth its determination that LPVML was a combination product containing drugs, for which CDER has primary jurisdiction for premarket review and regulation. OCP further stated that it was aware that LPVML was being marketed without FDA authorization and that, in order for the product to be legally marketed, defendants were required to have an NDA. In a June 12, 2013 letter

to the defendants, FDA, through its Office of Special Medical Programs, reaffirmed its determination, as set forth in the May 15, 2012 letter, regarding LPVML.

45. As a follow up to the June 2012 inspection of Laclede's Facility, FDA sent the defendants a Warning Letter, dated February 14, 2013, notifying them that, among other things, they were distributing LPVML, an unapproved new drug and misbranded drug, in violation of the Act.

46. In a subsequent letter dated June 14, 2013, FDA informed the defendants that their March 7, 2013 response to FDA's February 14, 2013 Warning Letter, by which defendants stated that they would remove certain claims from their labels and/or labeling, was inadequate because the defendants continued to make claims that caused their products to be unapproved new drugs. FDA again warned the defendants that their continuing violations could result in legal action without notice, including an injunction.

47. On or around May 23, 2013, OCP received from the defendants a Request for Designation, pursuant to 21 C.F.R. § 3.7, recommending that FDA classify LPEPL as a device and assign the product to CDRH, rather than CDER, for premarket review and regulation.

48. In response, OCP sent the defendants a letter, dated July 25, 2013, setting forth its determination that LPEPL was a combination product containing drugs for which CDER has primary jurisdiction for premarket review and regulation. FDA notified the defendants that they were legally required to have an approved NDA in effect prior to distributing LPEPL in interstate commerce. In an August 22, 2013 letter to the defendants, OCP reaffirmed its determination regarding LPEPL, as set forth in the July 25, 2013 letter.

49. FDA's August 20-September 4, 2013 inspection of the Facility documented that the defendants were distributing the Luvena Prebiotic Products, unapproved new drugs and misbranded drugs, in interstate commerce.

50. In response to the August 20-September 4, 2013 inspection, the defendants informed FDA, by a letter dated September 10, 2013, that they planned to meet with the FDA Ombudsman to resolve their dispute with the FDA, and were "willing to file for New Drug Application for Luvena Lubricant products, if necessary after meeting." The meeting occurred on October 24, 2013. During this meeting, OCP stated that its prior determinations for LPVML and LPEPL remained unchanged. OCP also stated that if the defendants wished to continue pursuing assignment of their LPVML or LPEPL, with different claims, to CDRH, they could submit a new RFD for such products.

51. By email dated February 26, 2014, OCP again notified the defendants that they were distributing in interstate commerce unapproved new drugs and misbranded drugs, specifically the drug components of the LPVML and LPEPL combination products, in violation of the Act. OCP also informed defendants that their most recent Request for Designations for LPVML and LPEPL, which defendants submitted to OCP on December 16, 2013, were incomplete and deemed not filed.

52. On or around March 13, 2014, the defendants continued to distribute products labeled "Luvena Prebiotic Vaginal Moisturizer & Lubricant," "Luvena Prebiotic Feminine Wipes," "Luvena Prebiotic Enhanced Personal Lubricant," and "Luvena Prebiotic Daily Therapeutic Wash" in interstate commerce.

53. On or around March 14, 2014, the defendants sought premarket clearance from CDRH to distribute in interstate commerce a product named "Luvena Actibiotic Enhanced Personal Lubricant" as a device. See 21 U.S.C. § 360(k). According to Laclede's March 19, 2014, Facebook entry (https://www.facebook.com/Luvenaactibiotic, formerly https://www.facebook.com/LuvenaPrebiotic): "We're back online with a minor name change. We've changed from Luvena Prebiotic to Luvena Actibiotic due to logo difficulties. Same products, same ingredients, same helpful information for all. Sorry for the inconvenience."

54. To date, the defendants have not filed an NDA, ANDA, or IND for the Luvena Prebiotic Products.

55. Based on the defendant's course of conduct, it is evident that, unless restrained by this Court, the defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (d), and (k).

## V. PRAYER FOR INJUNCTIVE RELIEF

WHEREFORE, the United States respectfully requests that the Court:

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

A. violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce unapproved new drugs;

B. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(c) and (e); and

C. violating 21 U.S.C. § 331(k) by causing drugs that the 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(c) and (e).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), the 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 introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any drugs including, but not limited to, the defendants'

Luvena Prebiotic Products, all formulations of these products, and the same or similar products designated by any other name, unless and until:

A. an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. §§ 355(a), (j), or (i) is in effect for such drugs; or

B. the defendants have removed all claims from their product labels, labeling, marketing materials, websites owned or controlled by or related to the defendants, and in any other media that cause any of defendants' products to be a drug within the meaning of the Act.

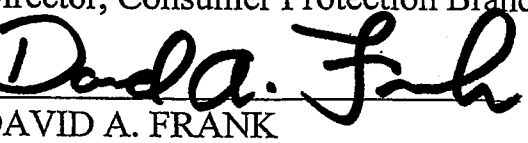
III. Order that FDA be authorized to inspect the defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any of defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

IV. Order that the Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED: June 25, 2014

Respectfully submitted,

STUART F. DELERY
Assistant Attorney General
United States Department of Justice
Civil Division
MICHAEL S. BLUME
Director, Consumer Protection Branch



DAVID A. FRANK
Trial Attorney
United States Department of Justice
Consumer Protection Branch

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel
United States Department of
Health and Human Services

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Administration

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

YEN HOANG
Assistant Chief Counsel
for Enforcement
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ORIGINAL

AO 440 (Rev. 06/12) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Central District of California

United States of America

*Plaintiff(s)*

v.

Laclede, Inc.; Michael A. Pellico

*Defendant(s)*

Civil Action No. CV14-04948-PA(FFMx)

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Laclede, Inc.
2103 East University Drive
Rancho Dominguez, CA 90220

Michael A. Pellico
President
Laclede, Inc
2103 E. University Drive
Rancho Dominguez, CA 90220

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: David A. Frank
United States Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044-0386

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Date: 6/25/2014

*CLERK OF COURT*

*Signature of Clerk or Deputy Clerk*

1202

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA**
**CIVIL COVER SHEET**

**I. (a) PLAINTIFFS** ( Check box if you are representing yourself ☐ )

United States of America

**DEFENDANTS** ( Check box if you are representing yourself ☐ )

Laclede, Inc.; Michael A. Pellico

(b) County of Residence of First Listed Plaintiff _____
*(EXCEPT IN U.S. PLAINTIFF CASES)*

County of Residence of First Listed Defendant Los Angeles County
*(IN U.S. PLAINTIFF CASES ONLY)*

(c) Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.
Stuart F. Delery, Michael S. Blume, and David A. Frank
U.S. Department of Justice, Civil Division
P.O. Box 386, Washington, DC 20044-0386
(202) 307-0061, David.Frank@usdoj.gov

Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

**II. BASIS OF JURISDICTION** (Place an X in one box only.)

☒ 1. U.S. Government Plaintiff
☐ 3. Federal Question (U.S. Government Not a Party)
☐ 2. U.S. Government Defendant
☐ 4. Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES**-For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant)

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated or Principal Place of Business in this State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated and Principal Place of Business in Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

**IV. ORIGIN** (Place an X in one box only.)

☒ 1. Original Proceeding ☐ 2. Removed from State Court ☐ 3. Remanded from Appellate Court ☐ 4. Reinstated or Reopened ☐ 5. Transferred from Another District (Specify) ☐ 6. Multi-District Litigation

**V. REQUESTED IN COMPLAINT: JURY DEMAND:** ☐ Yes ☒ No (Check "Yes" only if demanded in complaint.)

**CLASS ACTION under F.R.Cv.P. 23:** ☐ Yes ☒ No ☐ **MONEY DEMANDED IN COMPLAINT:** $ _____

**VI. CAUSE OF ACTION** (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
This is an action brought under 21 U.S.C. § 332(a) to permanently enjoin the defendants, under the Federal Food, Drug, and Cosmetic Act, for violations of 21 U.S.C. §§ 331(a), (d), and (k), involving the introduction of unapproved new drugs and misbranded drugs into interstate commerce.

**VII. NATURE OF SUIT** (Place an X in one box only).

**OTHER STATUTES**
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/Etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Org.
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Info. Act
- ☐ 896 Arbitration
- ☐ 899 Admin. Procedures Act/Review of Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Vet.)
- ☐ 153 Recovery of Overpayment of Vet. Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment

**REAL PROPERTY CONT.**
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS PERSONAL INJURY**
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpratice
- ☐ 365 Personal Injury-Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

**IMMIGRATION**
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

**TORTS PERSONAL PROPERTY**
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**CIVIL RIGHTS**
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 American with Disabilities-Employment
- ☐ 446 American with Disabilities-Other
- ☐ 448 Education

**PRISONER PETITIONS**

**Habeas Corpus:**
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

**Other:**
- ☐ 540 Mandamus/Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee Conditions of Confinement

**FORFEITURE/PENALTY**
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Ret. Inc. Security Act

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405 (g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405 (g))

**FEDERAL TAX SUITS**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

**FOR OFFICE USE ONLY:** Case Number: CV14-04948

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA**
**CIVIL COVER SHEET**

**VIII. VENUE:** Your answers to the questions below will determine the division of the Court to which this case will be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

| **QUESTION A: Was this case removed from state court?** ☐ Yes ☒ No | STATE CASE WAS PENDING IN THE COUNTY OF: | INITIAL DIVISION IN CACD IS: |
|---|---|---|
| If "no," skip to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question E, below, and continue from there. | ☐ Los Angeles, Ventura, Santa Barbara, or San Luis Obispo | Western |
| | ☐ Orange | Southern |
| | ☐ Riverside or San Bernardino | Eastern |

| **QUESTION B: Is the United States, or one of its agencies or employees, a PLAINTIFF in this action?** ☒ Yes ☐ No | **B.1.** Do 50% or more of the defendants who reside in the district reside in Orange Co.? *check one of the boxes to the right* → | ☐ YES. Your case will initially be assigned to the Southern Division. Enter "Southern" in response to Question E, below, and continue from there. |
|---|---|---|
| | | ☒ NO. Continue to Question B.2. |
| If "no," skip to Question C. If "yes," answer Question B.1, at right. | **B.2.** Do 50% or more of the defendants who reside in the district reside in Riverside and/or San Bernardino Counties? (Consider the two counties together.) *check one of the boxes to the right* → | ☐ YES. Your case will initially be assigned to the Eastern Division. Enter "Eastern" in response to Question E, below, and continue from there. |
| | | ☒ NO. Your case will initially be assigned to the Western Division. Enter "Western" in response to Question E, below, and continue from there. |

| **QUESTION C: Is the United States, or one of its agencies or employees, a DEFENDANT in this action?** ☐ Yes ☐ No | **C.1.** Do 50% or more of the plaintiffs who reside in the district reside in Orange Co.? *check one of the boxes to the right* → | ☐ YES. Your case will initially be assigned to the Southern Division. Enter "Southern" in response to Question E, below, and continue from there. |
|---|---|---|
| | | ☐ NO. Continue to Question C.2. |
| If "no," skip to Question D. If "yes," answer Question C.1, at right. | **C.2.** Do 50% or more of the plaintiffs who reside in the district reside in Riverside and/or San Bernardino Counties? (Consider the two counties together.) *check one of the boxes to the right* → | ☐ YES. Your case will initially be assigned to the Eastern Division. Enter "Eastern" in response to Question E, below, and continue from there. |
| | | ☐ NO. Your case will initially be assigned to the Western Division. Enter "Western" in response to Question E, below, and continue from there. |

| **QUESTION D: Location of plaintiffs and defendants?** | **A.** Orange County | **B.** Riverside or San Bernardino County | **C.** Los Angeles, Ventura, Santa Barbara, or San Luis Obispo County |
|---|---|---|---|
| Indicate the location(s) in which 50% or more of *plaintiffs who reside in this district* reside. (Check up to two boxes, or leave blank if none of these choices apply.) | ☐ | ☐ | ☐ |
| Indicate the location(s) in which 50% or more of *defendants who reside in this district* reside. (Check up to two boxes, or leave blank if none of these choices apply.) | ☐ | ☐ | ☐ |

| **D.1. Is there at least one answer in Column A?** ☐ Yes ☐ No | **D.2. Is there at least one answer in Column B?** ☐ Yes ☐ No |
|---|---|
| If "yes," your case will initially be assigned to the SOUTHERN DIVISION. Enter "Southern" in response to Question E, below, and continue from there. If "no," go to question D2 to the right. → | If "yes," your case will initially be assigned to the EASTERN DIVISION. Enter "Eastern" in response to Question E, below. If "no," your case will be assigned to the WESTERN DIVISION. Enter "Western" in response to Question E, below. ↓ |

| **QUESTION E: Initial Division?** | INITIAL DIVISION IN CACD |
|---|---|
| Enter the initial division determined by Question A, B, C, or D above: → | Western |

**QUESTION F: Northern Counties?**

Do 50% or more of plaintiffs or defendants in this district reside in Ventura, Santa Barbara, or San Luis Obispo counties? ☐ Yes ☒ No

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA**
**CIVIL COVER SHEET**

**IX(a). IDENTICAL CASES:** Has this action been previously filed **in this court?** ☒ NO ☐ YES

If yes, list case number(s): _____

**IX(b). RELATED CASES:** Is this case related (as defined below) to any cases previously filed **in this court?** ☒ NO ☐ YES

If yes, list case number(s): _____

Civil cases are related when they:

☐ A. Arise from the same or closely related transactions, happening, or event;

☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or

☐ C. For other reasons would entail substantial duplication of labor if heard by different judges.

Check all boxes that apply. That cases may involve the same patent, trademark, or copyright is not, in itself, sufficient to deem cases related.

**X. SIGNATURE OF ATTORNEY (OR SELF-REPRESENTED LITIGANT):** Dada. fl DATE: 6/25/2014

**Notice to Counsel/Parties:** The submission of this Civil Cover Sheet is required by Local Rule 3-1. This Form CV-71 and the information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. For more detailed instructions, see separate instruction sheet (CV-071A).

Key to Statistical codes relating to Social Security Cases:

| Nature of Suit Code | Abbreviation | Substantive Statement of Cause of Action |
|---|---|---|
| 861 | HIA | All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b)) |
| 862 | BL | All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923) |
| 863 | DIWC | All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g)) |
| 863 | DIWW | All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g)) |
| 864 | SSID | All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended. |
| 865 | RSI | All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g)) |