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STUART F. DELERY U.S. DISTRICT COURT  
CENTRAL DIST. OF CALIF.  
LOS ANGELES

BY: \_\_\_\_\_

Attorneys for Plaintiff United States of America

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

**CV14-04948 - PA (FFM)**  
CASE NO..

UNITED STATES OF AMERICA,

Plaintiff,

v.

LACLEDE, INC. and  
MICHAEL A. PELLICO

Defendants.

**COMPLAINT FOR PERMANENT  
INJUNCTION**

[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);

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

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

## 8 **II. JURISDICTION AND VENUE**

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

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

## 12 **III. THE PARTIES**

13 4. Plaintiff is the United States of America.

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

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

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

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

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

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

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

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

#### 22 **IV. DEFENDANTS' VIOLATIONS OF THE ACT**

##### 23 Unapproved New Drugs

24 12. A product is a drug within the meaning of the Act if it is "intended for  
25 use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21  
26 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the  
27 body of man," 21 U.S.C. § 321(g)(1)(C). A product is also a drug if it is "intended for  
28

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

3 13. The intended use of a product may be determined from any relevant  
4 source, including the product’s labeling. See 21 C.F.R. § 201.128. The Act defines  
5 labeling as “all labels and other written, printed, or graphic matter (1) upon any article  
6 or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. §  
7 321(m). The Supreme Court has held that the term “accompanying” in the second  
8 clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at  
9 issue and that physical attachment to the article is not necessary. See Kordel v. United  
10 States, 335 U.S. 345, 349-50; 69 S.Ct. 106, 109-111; 93 L.Ed. 52, 57-58 (1948)

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

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

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

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

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

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

14 19. A "biological product" is a virus, therapeutic serum, toxin, antitoxin,  
15 vaccine, blood, blood component or derivative, allergenic product, protein (except any  
16 chemically synthesized polypeptide), or analogous product applicable to the  
17 prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. §  
18 262(i)(1).

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

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

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

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

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

25           c.        "D-Mannose is a little-known sugar that can help UTIs and  
26 Vaginal infections. In LuvenaPrebiotics; say good-bye to antibiotics" (Twitter entry  
27 dated March 18, 2013, accessed on March 27, 2014 and June 12, 2014);  
28

1           d.     “If you take antibiotics ‘friendly’ bacteria are destroyed along with  
2 ‘harmful’ bacteria. Use Luvenaprebiotics prophylactically” (Twitter entry dated May  
3 7, 2013, accessed on March 27, 2014 and June 12, 2014); and

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

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

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

18           b.     “Natural & Protective Certified Prebiotic . . . Contains Bio-Active  
19 Enzymes”;

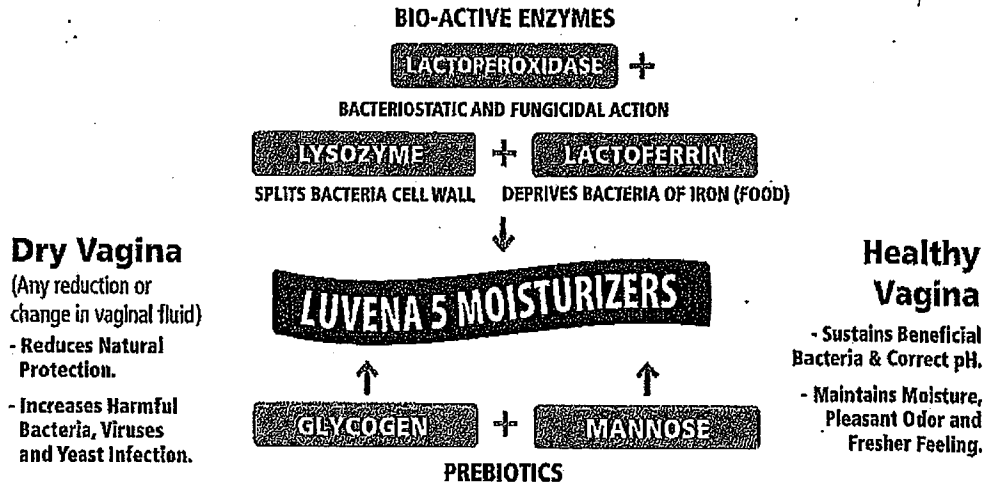
20           c.     “Lubricates and protects . . . LUVENA Prebiotic Vaginal  
21 Moisturizer & Lubricant”

22           d.     “Luvena Prebiotic Vaginal Moisturizer acts like a ‘bio-shield  
23 lubricant””; and



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

3 **HOW LUVENA® Prebiotic Moisturizer and Lubricant works:**



4  
 5  
 6  
 7  
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 10  
 11  
 12 f. “Q: . . . Does this product prevent vaginal odors? A: A bad odor  
 13 usually indicates infection or a disruption of the vaginal flora. . . . [A] woman’s vagina  
 14 needs to have a balanced pH flora. Use LUVENA® Prebiotic Moisturizer & Lubricant  
 15 as directed to maintain natural freshness . . . . Q: How long will it take for me to feel  
 16 results? A: . . . It can usually be cleared up as soon as the flora and pH are balanced.”

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

- 23 a. “Luvena Prebiotic Feminine Wipes with natural bio-active enzyme  
 24 protection”;  
 25 b. “gently cleans & inhibits odor causing bacteria”;  
 26 c. “Luvena Prebiotic Feminine Wipes . . . Relieves . . . & protects...  
 27 When having irritating discharge”; and  
 28



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

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

8           b. "Prebiotic to Support Healthy Intimacy";

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

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

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

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

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

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

24           27. The Luvena Prebiotic Products are "new drugs" within the meaning of 21  
25 U.S.C. § 321(p)(1) because they are not generally recognized among experts, qualified  
26 by scientific training and experience to evaluate the safety and effectiveness of drugs,  
27 as safe and effective for use under the conditions prescribed, recommended, or  
28

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

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

5 29. Because the Luvena Prebiotic Products are unapproved new drugs, the  
6 defendants' distribution of these products into interstate commerce violates  
7 21 U.S.C. § 331(d).

8 Misbranded Drugs

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

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

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

18 33. A drug is also misbranded if its label does not bear the "established name  
19 and quantity . . . of each active ingredient". 21 U.S.C. § 352(e)(1)(A)(ii). FDA's  
20 implementing regulation requires the outside container or wrapper of the retail  
21 package, or the immediate container label if no outside container or wrapper exists, of  
22 an OTC drug to include the heading "Active ingredients" followed by the established  
23 name and quantity of each active ingredient per dosage unit. 21 C.F.R. §  
24 201.66(c)(2).

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

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

4 35. LPFW is a misbranded drug within the meaning of 21 U.S.C. §  
5 352(e)(1)(A)(ii) because although certain ingredients are intended to be used as active  
6 drug ingredients, neither the outside container or wrapper of the retail package nor the  
7 immediate wrapper or container label for LPFW includes an “Active ingredients”  
8 heading followed by the established name and quantity of each of these active  
9 ingredients per dosage unit.

10 Interstate Commerce

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

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

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

19 History

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

22 40. By letters dated June 16, 2010, and September 8, 2010, FDA’s Center for  
23 Devices and Radiological Health (“CDRH”) informed the defendants that LPVML  
24 appeared to be regulated by CDER and that the defendants could not distribute it in  
25 interstate commerce without complying with the Act’s approval requirements. On  
26 September 13, 2010, CDER informed the defendants that LPVML was an unapproved  
27 new drug that requires premarket review and approval before it could be legally  
28

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

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

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

12 43. The defendants began distributing LPEPL in interstate commerce on or  
13 around March 16, 2012, without the statutorily required approval from FDA. Five  
14 months later, defendants then sought clearance from CDRH, by letter dated August  
15 30, 2012, to market LPEPL as a device. See 21 U.S.C. § 360(k). CDRH informed  
16 defendants, by letter dated October 17, 2012, that LPEPL appeared to be a  
17 combination product containing drug constituents for which CDER, not CDRH, has  
18 primary jurisdiction. CDRH also directed defendants to CDER for more information  
19 on applicable requirements for marketing LPEPL and to OCP should they wish to  
20 submit a Request for Designation and obtain a formal jurisdictional assignment for  
21 LPEPL.

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

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

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

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

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

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

25 49. FDA's August 20-September 4, 2013 inspection of the Facility  
26 documented that the defendants were distributing the Luvena Prebiotic Products,  
27 unapproved new drugs and misbranded drugs, in interstate commerce.  
28

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

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

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

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



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

3           55. Based on the defendant's course of conduct, it is evident that, unless  
4 restrained by this Court, the defendants will continue to violate the Act, 21 U.S.C.  
5 §§ 331(a), (d), and (k).

6 **V. PRAYER FOR INJUNCTIVE RELIEF**

7           WHEREFORE, the United States respectfully requests that the Court:

8           I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), the  
9 defendants, and each and all of their directors, officers, agents, representatives,  
10 employees, attorneys, successors, and assigns, and any and all persons in active  
11 concert or participation with any of them, from doing or causing to be done any of the  
12 following acts:

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

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

20           C. violating 21 U.S.C. § 331(k) by causing drugs that the defendants  
21 hold for sale after shipment of one or more of their components in interstate  
22 commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(c) and (e).

23           II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), the  
24 defendants, and each and all of their directors, officers, agents, representatives,  
25 employees, attorneys, successors, and assigns, and any and all persons in active  
26 concert or participation with any of them, from directly or indirectly introducing or  
27 delivering for introduction, or causing to be introduced or delivered for introduction,  
28 into interstate commerce any drugs including, but not limited to, the defendants'



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

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

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


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

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

17  
18 DATED: June 25, 2014

19 Respectfully submitted,

20  
21 STUART F. DELERY  
22 Assistant Attorney General  
23 United States Department of Justice  
24 Civil Division  
25 MICHAEL S. BLUME  
26 Director, Consumer Protection Branch

27   
28 DAVID A. FRANK  
Trial Attorney  
United States Department of Justice  
Consumer Protection Branch

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OF COUNSEL:

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United States Department of  
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Food and Drug Administration

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

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
Seal of the U.S. District Court, Central District of California

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

<b>I. (a) PLAINTIFFS</b> ( Check box if you are representing yourself <input type="checkbox"/> )  United States of America	<b>DEFENDANTS</b> ( Check box if you are representing yourself <input type="checkbox"/> )  Laclede, Inc.; Michael A. Pellico
<b>(b) County of Residence of First Listed Plaintiff</b> (EXCEPT IN U.S. PLAINTIFF CASES)	<b>County of Residence of First Listed Defendant</b> <u>Los Angeles County</u> (IN U.S. PLAINTIFF CASES ONLY)
<b>(c) Attorneys (Firm Name, Address and Telephone Number)</b> 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	<b>Attorneys (Firm Name, Address and Telephone Number)</b> If you are representing yourself, provide the same information.

<b>II. BASIS OF JURISDICTION</b> (Place an X in one box only.)  <input checked="" type="checkbox"/> 1. U.S. Government Plaintiff <input type="checkbox"/> 2. U.S. Government Defendant <input type="checkbox"/> 3. Federal Question (U.S. Government Not a Party) <input type="checkbox"/> 4. Diversity (Indicate Citizenship of Parties in Item III)	<b>III. CITIZENSHIP OF PRINCIPAL PARTIES-For Diversity Cases Only</b> (Place an X in one box for plaintiff and one for defendant) <table style="width:100%; border: none;"> <tr> <td style="border: none;">Citizen of This State</td> <td style="border: none;">PTF <input type="checkbox"/> 1</td> <td style="border: none;">DEF <input type="checkbox"/> 1</td> <td style="border: none;">Incorporated or Principal Place of Business in this State</td> <td style="border: none;">PTF <input type="checkbox"/> 4</td> <td style="border: none;">DEF <input type="checkbox"/> 4</td> </tr> <tr> <td style="border: none;">Citizen of Another State</td> <td style="border: none;">PTF <input type="checkbox"/> 2</td> <td style="border: none;">DEF <input type="checkbox"/> 2</td> <td style="border: none;">Incorporated and Principal Place of Business in Another State</td> <td style="border: none;">PTF <input type="checkbox"/> 5</td> <td style="border: none;">DEF <input type="checkbox"/> 5</td> </tr> <tr> <td style="border: none;">Citizen or Subject of a Foreign Country</td> <td style="border: none;">PTF <input type="checkbox"/> 3</td> <td style="border: none;">DEF <input type="checkbox"/> 3</td> <td style="border: none;">Foreign Nation</td> <td style="border: none;">PTF <input type="checkbox"/> 6</td> <td style="border: none;">DEF <input type="checkbox"/> 6</td> </tr> </table>	Citizen of This State	PTF <input type="checkbox"/> 1	DEF <input type="checkbox"/> 1	Incorporated or Principal Place of Business in this State	PTF <input type="checkbox"/> 4	DEF <input type="checkbox"/> 4	Citizen of Another State	PTF <input type="checkbox"/> 2	DEF <input type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	PTF <input type="checkbox"/> 5	DEF <input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	PTF <input type="checkbox"/> 3	DEF <input type="checkbox"/> 3	Foreign Nation	PTF <input type="checkbox"/> 6	DEF <input type="checkbox"/> 6
Citizen of This State	PTF <input type="checkbox"/> 1	DEF <input type="checkbox"/> 1	Incorporated or Principal Place of Business in this State	PTF <input type="checkbox"/> 4	DEF <input type="checkbox"/> 4														
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Citizen or Subject of a Foreign Country	PTF <input type="checkbox"/> 3	DEF <input type="checkbox"/> 3	Foreign Nation	PTF <input type="checkbox"/> 6	DEF <input type="checkbox"/> 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	CONTRACT	REAL PROPERTY/CONTRACT	IMMIGRATION	PRISONER PETITIONS	PROPERTY RIGHTS
<input type="checkbox"/> 375 False Claims Act	<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> 240 Torts to Land	<input type="checkbox"/> 462 Naturalization Application	<b>Habeas Corpus:</b>	<input type="checkbox"/> 820 Copyrights
<input type="checkbox"/> 400 State Reapportionment	<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 245 Tort Product Liability	<input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 463 Alien Detainee	<input type="checkbox"/> 830 Patent
<input type="checkbox"/> 410 Antitrust	<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 290 All Other Real Property	<b>TORTS</b>	<input type="checkbox"/> 510 Motions to Vacate Sentence	<input type="checkbox"/> 840 Trademark
<input type="checkbox"/> 430 Banks and Banking	<input type="checkbox"/> 140 Negotiable Instrument	<b>TORTS</b>	<b>PERSONAL PROPERTY</b>	<input type="checkbox"/> 530 General	<b>SOCIAL SECURITY</b>
<input type="checkbox"/> 450 Commerce/ICC Rates/Etc.	<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 370 Other Fraud	<input type="checkbox"/> 535 Death Penalty	<input type="checkbox"/> 861 HIA (1395ff)
<input type="checkbox"/> 460 Deportation	<input type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 315 Airplane Product Liability	<input type="checkbox"/> 371 Truth in Lending	<b>Other:</b>	<input type="checkbox"/> 862 Black Lung (923)
<input type="checkbox"/> 470 Racketeer Influenced & Corrupt Org.	<input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Vet.)	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 380 Other Personal Property Damage	<input type="checkbox"/> 540 Mandamus/Other	<input type="checkbox"/> 863 DIWC/DIWW (405 (g))
<input type="checkbox"/> 480 Consumer Credit	<input type="checkbox"/> 153 Recovery of Overpayment of Vet. Benefits	<input type="checkbox"/> 330 Fed. Employers' Liability	<input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 550 Civil Rights	<input type="checkbox"/> 864 SSID Title XVI
<input type="checkbox"/> 490 Cable/Sat TV	<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 340 Marine	<b>BANKRUPTCY</b>	<input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 865 RSI (405 (g))
<input type="checkbox"/> 850 Securities/Commodities/Exchange	<input type="checkbox"/> 190 Other Contract	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 422 Appeal 28 USC 158	<input type="checkbox"/> 560 Civil Detainee Conditions of Confinement	<b>FEDERAL TAX SUITS</b>
<input checked="" type="checkbox"/> 890 Other Statutory Actions	<input type="checkbox"/> 195 Contract Product Liability	<input type="checkbox"/> 350 Motor Vehicle	<input type="checkbox"/> 423 Withdrawal 28 USC 157	<b>FORFEITURE/PENALTY</b>	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)
<input type="checkbox"/> 891 Agricultural Acts	<input type="checkbox"/> 196 Franchise	<input type="checkbox"/> 355 Motor Vehicle Product Liability	<b>CIVIL RIGHTS</b>	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881	<input type="checkbox"/> 871 IRS-Third Party 26 USC 7609
<input type="checkbox"/> 893 Environmental Matters	<b>REAL PROPERTY:</b>	<input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 690 Other	
<input type="checkbox"/> 895 Freedom of Info. Act	<input type="checkbox"/> 210 Land Condemnation	<input type="checkbox"/> 362 Personal Injury-Med Malpractice	<input type="checkbox"/> 441 Voting	<b>LABOR</b>	
<input type="checkbox"/> 896 Arbitration	<input type="checkbox"/> 220 Foreclosure	<input type="checkbox"/> 365 Personal Injury-Product Liability	<input type="checkbox"/> 442 Employment	<input type="checkbox"/> 710 Fair Labor Standards Act	
<input type="checkbox"/> 899 Admin. Procedures Act/Review of Appeal of Agency Decision	<input type="checkbox"/> 230 Rent Lease & Ejectment	<input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability	<input type="checkbox"/> 443 Housing/Accommodations	<input type="checkbox"/> 720 Labor/Mgmt. Relations	
<input type="checkbox"/> 950 Constitutionality of State Statutes		<input type="checkbox"/> 368 Asbestos Personal Injury Product Liability	<input type="checkbox"/> 445 American with Disabilities-Employment	<input type="checkbox"/> 740 Railway Labor Act	
			<input type="checkbox"/> 446 American with Disabilities-Other	<input type="checkbox"/> 751 Family and Medical Leave Act	
			<input type="checkbox"/> 448 Education	<input type="checkbox"/> 790 Other Labor Litigation	
				<input type="checkbox"/> 791 Employee Ret. Inc. Security Act	

**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.

<p><b>QUESTION A: Was this case removed from state court?</b>  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>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.</p>	<p align="center"><b>STATE CASE WAS PENDING IN THE COUNTY OF:</b></p> <input type="checkbox"/> Los Angeles, Ventura, Santa Barbara, or San Luis Obispo <input type="checkbox"/> Orange <input type="checkbox"/> Riverside or San Bernardino	<p align="center"><b>INITIAL DIVISION IN CACD IS:</b></p> Western Southern Eastern	
<p><b>QUESTION B: Is the United States, or one of its agencies or employees, a PLAINTIFF in this action?</b>  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If "no," skip to Question C. If "yes," answer Question B.1, at right.</p>	<p><b>B.1. Do 50% or more of the defendants who reside in the district reside in Orange Co.?</b>  <i>check one of the boxes to the right</i> →</p> <p><b>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.)</b>  <i>check one of the boxes to the right</i> →</p>	<p><input type="checkbox"/> YES. Your case will initially be assigned to the Southern Division. Enter "Southern" in response to Question E, below, and continue from there.</p> <p><input checked="" type="checkbox"/> NO. Continue to Question B.2.</p> <p><input type="checkbox"/> YES. Your case will initially be assigned to the Eastern Division. Enter "Eastern" in response to Question E, below, and continue from there.</p> <p><input checked="" type="checkbox"/> NO. Your case will initially be assigned to the Western Division. Enter "Western" in response to Question E, below, and continue from there.</p>	
<p><b>QUESTION C: Is the United States, or one of its agencies or employees, a DEFENDANT in this action?</b>  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If "no," skip to Question D. If "yes," answer Question C.1, at right.</p>	<p><b>C.1. Do 50% or more of the plaintiffs who reside in the district reside in Orange Co.?</b>  <i>check one of the boxes to the right</i> →</p> <p><b>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.)</b>  <i>check one of the boxes to the right</i> →</p>	<p><input type="checkbox"/> YES. Your case will initially be assigned to the Southern Division. Enter "Southern" in response to Question E, below, and continue from there.</p> <p><input type="checkbox"/> NO. Continue to Question C.2.</p> <p><input type="checkbox"/> YES. Your case will initially be assigned to the Eastern Division. Enter "Eastern" in response to Question E, below, and continue from there.</p> <p><input type="checkbox"/> NO. Your case will initially be assigned to the Western Division. Enter "Western" in response to Question E, below, and continue from there.</p>	
<p><b>QUESTION D: Location of plaintiffs and defendants?</b></p> <p>Indicate the location(s) in which 50% or more of <i>plaintiffs who reside in this district</i> reside. (Check up to two boxes, or leave blank if none of these choices apply.)</p> <p>Indicate the location(s) in which 50% or more of <i>defendants who reside in this district</i> reside. (Check up to two boxes, or leave blank if none of these choices apply.)</p>	<p><b>A.</b> Orange County</p> <input type="checkbox"/>  <input type="checkbox"/>	<p><b>B.</b> Riverside or San Bernardino County</p> <input type="checkbox"/>  <input type="checkbox"/>	<p><b>C.</b> Los Angeles, Ventura, Santa Barbara, or San Luis Obispo County</p> <input type="checkbox"/>  <input type="checkbox"/>
<p><b>D.1. Is there at least one answer in Column A?</b>  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>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. →</p>	<p><b>D.2. Is there at least one answer in Column B?</b>  <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>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. ↓</p>		
<p><b>QUESTION E: Initial Division?</b></p> <p>Enter the initial division determined by Question A, B, C, or D above: →</p>	<p><b>INITIAL DIVISION IN CACD</b></p> Western		
<p><b>QUESTION F: Northern Counties?</b></p> <p>Do 50% or more of plaintiffs or defendants in this district reside in Ventura, Santa Barbara, or San Luis Obispo counties? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>			

**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))