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JS-6

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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. LACLEDE, INC. and MICHAEL A. PELLICO, Defendants.	Case No. 14-4948 PA (FFMx) STIPULATED CONSENT DECREE

The additional counsel presenting this document to the Court are:

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Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a Complaint for Permanent Injunction against Laclede, Inc., a corporation, and Michael A. Pellico, an individual (collectively, "defendants"), and the defendants having appeared and consented to entry of this Decree without contest, solely for the purpose of settling this case, without admitting or denying the allegations set forth in the Complaint, and denying any liability in connection therewith, and before any testimony has been taken, and the United States of America, having consented to this Decree.

THEREFORE, on joint stipulation of the parties, it is hereby ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq. (the "FDCA").

3. The Complaint alleges that the defendants violate 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 within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. §§ 355(a) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The Complaint alleges that the defendants violate 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).

5. The Complaint alleges that the defendants violate 21 U.S.C. § 331(k) by causing drugs that they hold for sale after shipment in interstate commerce to be misbranded within the meaning of 21 U.S.C. §§ 352(c) and (e).

Actions Regarding Product Claims

6. The defendants represent that they have suspended distribution of all products bearing the term "prebiotic" or "actibiotic" in their labeling. Specifically, the defendants represent that they have suspended distribution of the following products that were marketed prior to the date of this Consent Decree: 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 the "Luvena Prebiotic Products"). The defendants shall not resume distribution of any product bearing the term "prebiotic" or "actibiotic" in its labeling unless and until they comply with the requirements of Paragraph 9.

7. The defendants represent that they have suspended distribution of all products that contain labeling that: (i) bears the term "lubricant," (ii) refers to lubrication or condom compatibility, and/or (iii) claims to restore or maintain pH pending FDA's review of their 510(k) submissions, 21 U.S.C. § 360(k), dated June 18 and 23, 2014. Specifically, the defendants represent that they have suspended

distribution of the following products currently under review by FDA: Luvena Vaginal Moisturizer & Lubricant ("LVML"); and Luvena Enhanced Personal Lubricant ("LEPL") (collectively referred to as the "Luvena Lubricant Products"). The defendants shall not resume distribution of any such products unless and until they comply with the requirements of Paragraph 8.

8. Upon entry of this Decree, the defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise (collectively, "Associated Persons") shall not directly or indirectly introduce or deliver for introduction, or caused to be introduced or delivered for introduction, into interstate commerce any Luvena Lubricant Product, unless and until FDA notifies the defendants in writing that such product is substantially equivalent to a legally marketed predicate device, 21 C.F.R. § 807.100(a)(1).

9. Upon entry of this Decree, the defendants and each and all of the Associated Persons are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product that requires FDA premarket approval, including but not limited to the Luvena Prebiotic Products, 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 the product; or

B. the following events occur:

i) the defendants remove all claims, including but not limited to the words "prebiotic" and "actibiotic," from their product labels, labeling, promotional materials, and any websites or other media owned, operated, or controlled

by the defendants that cause the product to require FDA premarket approval or clearance within the meaning of the FDCA; and

ii) FDA notifies the defendants in writing, after reviewing the report and submission required under Paragraph 10, that they appear to be in compliance with the requirements of this Decree, the FDCA, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

Mandatory Report

10. The defendants shall, within thirty (30) calendar days after entry of this Decree, submit a written report to FDA identifying the actions they have taken to operate in compliance with the FDCA and its implementing regulations and in particular, certifying that, as of the date of the report, the defendants have removed all claims from their product labels, labeling, promotional materials, and any websites or other media owned, operated, or controlled by the defendants that cause any of the defendants' products to be considered new drugs within the meaning of the FDCA. The report shall include references to product names, statutory provisions, and regulations addressed in the process of preparing the report. The report shall identify all Luvena products the defendants sell or distribute in interstate commerce at the time of the report and include the defendants' explanation of the jurisdictional status under the FDCA (e.g., device, cosmetic, etc.) of each product. The report shall include copies of all product labels, labeling, promotional materials, and any websites or other media owned, operated, or controlled by the defendants, including but not limited to: a description of each product bearing the name Luvena; copies of the labels, labeling, and advertisements of all products sold by the defendants bearing the name Luvena from January 1, 2015, to the date this Decree is entered; the intended use and directions for use for each product; each product's ingredients; and any other information the defendants deem relevant to determining the product's jurisdictional status under the FDCA. After reviewing the report or any other relevant information,

but no later than twenty (20) calendar days after receiving the report or as soon as practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled, FDA will notify the defendants in writing whether FDA agrees with the jurisdictional status of each of the defendants' products as established in the report.

A. If FDA notifies the defendants in writing that any of the products evaluated in the report appear to be a device within the meaning of the FDCA, 21 U.S.C. § 321(h), and the defendants have not already submitted a 510(k) premarket notification for that device, then the defendants shall, within ten (10) calendar days, submit such notification for that device in accordance with 21 U.S.C. § 360(k) and its implementing regulations. The defendants shall immediately cease manufacturing and distributing any device subject to a pending 510(k) premarket notification if: (1) FDA issues an order declaring the product to not be substantially equivalent to a legally marketed predicate device; (2) FDA notifies the defendants that their 510(k) submission is not substantially complete under FDA policies and regulations in effect at the time of the submission; (3) the defendants withdraw the 510(k) submission; or (4) FDA notifies the defendants that the agency considers the 510(k) submission withdrawn in accordance with 21 C.F.R. § 807.87(l).

B. If FDA notifies the defendants in writing that any of the products evaluated in the report requires further jurisdictional evaluation and must be referred to FDA's Office of Combination Products ("OCP"), along with FDA's basis for such jurisdictional evaluation, the defendants shall either: (1) submit revised labeling and/or other materials for that product for FDA's review; or (2) submit to OCP a request for designation ("RFD") for that product in accordance with 21 C.F.R. Part 3. Should the defendants' initial effort at submitting revised labeling, product formulation, or other materials fails to demonstrate, to FDA's satisfaction, that the defendants have brought their product into compliance with the FDCA, then the product will be evaluated by OCP. The defendants shall promptly submit all

information specified or requested by OCP. Upon receiving FDA's notification that further jurisdictional evaluation is required, the defendants shall immediately cease manufacturing and distributing that product, and shall not directly or indirectly introduce or deliver the product for introduction, or cause the product to be introduced or delivered for introduction, into interstate commerce unless and until:

(i) FDA notifies the defendants in writing, no later than thirty (30) business days after receiving the defendants' revised labeling and/or other materials or as soon as practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled, that the product does not require FDA premarket approval or clearance; or

(ii) FDA notifies the defendants in writing that it has determined that the product requires either 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), and the appropriate application is approved and in effect for that product; or

(iii) FDA notifies the defendants in writing that it has determined that the product requires a 510(k) premarket notification and the defendants submit such notification. The defendants shall immediately cease manufacturing and distributing any device subject to a pending 510(k) premarket notification if: (1) FDA issues an order declaring the product to not be substantially equivalent to a legally marketed predicate device; (2) FDA notifies the defendants that their 510(k) submission is not substantially complete under FDA policies and regulations in effect at the time of the submission; (3) the defendants withdraw the 510(k) submission; or (4) FDA notifies the defendants that the agency considers the 510(k) submission withdrawn in accordance with 21 C.F.R. § 807.87(l).

OCP's decision shall be final.

C. If FDA notifies the defendants in writing that any of the products evaluated in the report is a cosmetic within the meaning of the FDCA, 21 U.S.C.

§ 321(i), the defendants shall manufacture and distribute such cosmetic in compliance with all applicable laws and regulations for cosmetics.

Ongoing Injunctive Restraint

11. Upon entry of this Decree, and after satisfying the conditions set out in Paragraphs 6 – 10 and receiving FDA's written notification pursuant to Paragraph 9.B.ii, the defendants and all of their Associated Persons, as described in Paragraph 8, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following:

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 under 21 U.S.C. §§ 355(a) or (j), nor exempt from approval under 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);

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);

D. 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, articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), in that they are class III devices under 21 U.S.C. § 360c(f), and there are no approved applications for premarket approval ("PMAs") on file with the FDA as required by 21 U.S.C. § 360e(a), and the devices do not have approved applications for an investigational device exemption under 21 U.S.C. § 360j(g);

E. 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, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of 21 U.S.C. § 352(o), in that the defendants have failed to provide notice or other information respecting the device to FDA as required by 21 U.S.C. § 360(k);

F. Violating 21 U.S.C. § 331(k) by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), and/or misbranded within the meaning of 21 U.S.C. § 351(o), while such devices are held for sale after shipment in interstate commerce; and

G. Any act that results in the failure to implement and continuously maintain the requirements of this Decree.

12. After the defendants have complied with Paragraphs 6 – 10 and received FDA's written notification pursuant to Paragraph 9.B.ii., the defendants, for a period of five (5) years, shall notify FDA prior to marketing any new product bearing the name Luvena, or modifying any existing or introducing any new product labels, labeling, promotional materials, any websites or other media owned, operated, or controlled by the defendants for products bearing the name Luvena, except for changes to color schemes, revisions in package design or net quantity, and grammatical corrections.

A. Such notifications shall include defendants' explanation of the jurisdictional status under the FDCA (e.g., device, drug, cosmetic, etc.) of the product to be marketed or affected by the new or modified labels, labeling, promotional materials, websites or other media. The defendants shall provide notification under this paragraph in writing to the FDA District Director at the address specified in Paragraph 21 of this Decree, in addition to any other statutorily required submission or application. For any product that the defendants believe to be a cosmetic, the notification shall include, but is not limited to, the product's ingredients, directions for

use, label, labeling, promotional materials, any related websites or other media owned, operated, or controlled by the defendants, and any other information the defendants deem relevant to determining the product's jurisdictional status under the FDCA.

B. The defendants shall not market or distribute such products or such new or modified labels, labeling, promotional materials, websites or other media until FDA notifies the defendants in writing that the defendants appear to be in compliance with the requirements of this Decree, the FDCA, and its implementing regulations. If the defendants' notification under Paragraph 12 includes a statutorily required submission or application (e.g., NDA or 510(k) notification) or RFD, then FDA will respond in accordance with the timelines established by the FDCA, its implementing regulations, or any FDA policy in effect at the time of the submission, application, or RFD. If defendants' notification under Paragraph 12 does not include a statutorily required submission or application (e.g., NDA or 510(k) notification) or RFD, then FDA will, after reviewing such notification, notify the defendants in writing, within forty-five (45) business days of receiving the defendants' notification or as soon as practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled, whether FDA premarket clearance or approval is required. In no circumstance shall FDA's silence be construed as a substitute for written notification.

Other Provisions

13. Representatives of the FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect defendants' place(s) of business and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During inspections, FDA representatives shall be permitted to: have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other promotional material therein; take photographs and make video recordings; to take samples of the defendants' raw ingredients, in-process

materials, finished products, containers, packaging material, labeling, and other marketing material; and examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any drugs and their components. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the FDCA, 21 U.S.C. § 374.

14. If at any time after entry of this Decree, the FDA determines, based on the results of an inspection, the analysis of a sample, a report, or data prepared or submitted by the defendants, or any other information, that the defendants have failed to comply with any provision of this Decree, have violated the FDCA or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the FDCA, or its implementing regulations, the FDA may, as and when it deems necessary, notify the defendants in writing of the noncompliance and order the defendants to take appropriate corrective action, including, but not limited to, ordering the defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any or all drugs and/or devices;

B. Recall any drugs and/or devices at defendants' expense;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Re-implement any provision of this Decree;

E. Submit additional reports or information to FDA as requested;

F. Require the defendants to pay liquidated damages pursuant to Paragraph 22 below; or

G. Take any other corrective actions as the FDA, in its discretion, deems necessary to bring the defendants into compliance with this Decree, the FDCA, and its implementing regulations. These remedies shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under

the law.

15. Upon receipt of any order issued by the FDA pursuant to Paragraph 14, the defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 14 shall continue until the defendants receive written notification from the FDA that the defendants appear to be in compliance with this Decree, the FDCA, and its implementing regulations, and that the defendants may resume operations. The cost of FDA's inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 14 shall be borne by the defendants at the rates specified in Paragraph 16.

16. The defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $89.35 per hour or fraction thereof per representative for inspection and investigative work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

17. Within ten (10) calendar days after entry of this Decree, the defendants shall post a copy of this Decree in a common area at the defendants' facility, 2103 E. University Drive, Rancho Dominguez, California, and at any other location at which the defendants conduct business and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

18. Within ten (10) calendar days after entry of this Decree, the defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all Associated Person(s). Within thirty (30) calendar days after entry of this Decree, the defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

19. The defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Laclede, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. The defendants shall provide a copy of this Decree to any prospective successor or assign at least thirty (30) calendar days prior to any sale or assignment. The defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

20. In the event that any of the defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, the defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within ten (10) calendar days after each time any of the defendants becomes associated with any such additional Associated Person(s), the defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree. Within ten (10) calendar days after receiving a request from FDA for any information or documentation that FDA deems necessary to

evaluate defendants' compliance with this paragraph, the defendants shall provide such information or documentation to FDA.

21. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to: FDA District Director, Los Angeles District Office, Pacific Region, U.S. Food and Drug Administration, Department of Health and Human Services, 19701 Fairchild, Irvine, California, 92612-2508.

22. Should the defendants fail to comply with the FDCA, its implementing regulations, or any provision of this Decree, including any time frame imposed by this Decree, then such defendants shall pay to the United States of America: twenty thousand dollars ($20,000) in liquidated damages for each day such violation continues; an additional sum of five thousand dollars ($5,000) in liquidated damages per day, per violation for each violation of the FDCA, its implementing regulations, and/or this Decree; and an additional sum in liquidated damages equal to five times the retail value of any distributed products that are in violation of this Decree, the FDCA, or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

23. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, the defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

24. The defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

25. If the defendants have maintained to FDA's satisfaction a state of continuous compliance with applicable laws and regulations and this Decree for at least sixty (60) months after satisfying all of their obligations this Decree, the defendants may petition this court for relief from this Decree, and the United States will not oppose such petition.

26. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 29th day of January, 2015.

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PERCY ANDERSON
UNITED STATES DISTRICT JUDGE

WE HEREBY AGREE TO THE ENTRY OF THE ABOVE STIPULATED CONSENT DECREE

FOR DEFENDANTS:

Dated: JAN 26, 2015

MICHAEL A. PELLICO
Individually and on behalf of
Laclede, Inc.

Dated: Jan 27, 2015

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