

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright

In the Matter of

LORNAMEAD, INC.,
a corporation.

FILE NO. 122 3255

AGREEMENT CONTAINING
CONSENT ORDER

The Federal Trade Commission has conducted an investigation of certain acts and practices of Lornamead, Inc., a corporation (“proposed respondent”). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Lornamead, Inc., by its duly authorized officers, and counsel for the Federal Trade Commission that:

1. Proposed respondent Lornamead, Inc., is a Delaware corporation with its principal office or place of business at 175 Cooper Avenue, Tonawanda, New York 14150.
2. Proposed respondent neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in this order. Only for purposes of this action, proposed respondent admits the facts necessary to establish jurisdiction.
3. Proposed respondent waives:
 - a. Any further procedural steps;
 - b. The requirement that the Commission’s decision contain a statement of findings of fact and conclusions of law; and
 - c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.
4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it

will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent's address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

6. Proposed respondent has read the draft complaint and consent order. It understands that it may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" shall mean Lornamead, Inc., a corporation, its successors and assigns, and its officers, agents, representatives, and employees.
2. "Adequate and well-controlled human clinical study" means a human clinical study that is randomized, double-blind, placebo controlled, and conducted by persons qualified by training and experience to conduct such study.
3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
4. "Covered Product" means any drug, cosmetic, or pesticide, including but not limited to Lice Shield Products.
5. "Drug" and "cosmetic" mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55. "Pesticide" means any product intended to prevent, destroy, repel, or mitigate any pest.

6. “Essentially Equivalent Product” means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.
7. “Lice Shield Products” means any lice repellent product containing essential oils such as citronella, including, but not limited to Lice Shield Shampoo & Conditioner in 1, Lice Shield Leave In Spray, Lice Shield Gear Guard, and Lice Shield Long Lasting Spot Stick.
8. “Pediculosis” means infestation of the scalp by head lice.
9. The term “including” in this order means “without limitation.”
10. The terms “and” and “or” in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that the Covered Product is effective in: a) preventing pediculosis, b) eliminating or reducing the risk of pediculosis by a specific percentage or amount, or c) repelling all lice, or a specific percentage or amount of lice, from a person’s head, unless the representation is non-misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Part I, competent and reliable scientific evidence shall consist of at least one adequate and well-controlled human clinical study of the Covered Product, or of an Essentially Equivalent Product, that conforms to an acceptable design and protocol and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Respondent shall have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, other than representations covered by Part I of this order, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that the

Covered Product will reduce the risk of a head lice infestation or repel head lice, unless the representation is non-misleading, and, at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part II, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, other than representations covered under Part I of this order, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the health benefits of any Covered Product unless the representation is non-misleading, and, at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part III, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of any product name or endorsement, depiction, or illustration, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

IT IS FURTHER ORDERED that nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

VI.

IT IS FURTHER ORDERED that respondent shall pay to the Federal Trade Commission the sum of five hundred thousand dollars (\$500,000). This payment shall be made in the following manner:

- A. The payment shall be made by electronic funds transfer within ten (10) days after the date that this order becomes final and in accordance with instructions provided by a representative of the Federal Trade Commission.
- B. In the event of default on any obligation to make payment under this order, interest, computed pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for ten (10) calendar days beyond the date that payment is due, the entire amount shall immediately become due and payable.
- C. All funds paid to the Commission pursuant to this order shall be deposited into an account administered by the Commission or its agents to be used for equitable relief, including restitution, and any attendant expenses for the administration of such equitable relief. In the event that direct redress to consumers is wholly or partially impracticable or funds remain after the redress to consumers (which shall be the first priority for dispensing the funds set forth above) is completed, the Commission may apply any remaining funds for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to respondent's practices alleged in the complaint. Any funds not used for such equitable relief shall be deposited in the United States Treasury as disgorgement. Respondent shall be notified as to how the funds are distributed, but shall have no right to challenge the Commission's choice of remedies under this Part. Respondent shall have no right to contest the manner of distribution chosen by the Commission. No portion of any payment under this Part shall be deemed a payment of any fine, penalty, or punitive assessment.
- D. Respondent relinquishes all dominion, control, and title to the funds paid to the fullest extent permitted by law. Respondent shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise.
- E. Respondent agrees that the facts as alleged in the complaint filed in this action shall be taken as true without further proof in any bankruptcy case or subsequent civil litigation pursued by the Commission to enforce its rights to any payment or money judgment pursuant to this order, including but not limited to a nondischargeability complaint in any bankruptcy case. Respondent further agrees that the facts alleged in the complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and that this order shall have collateral estoppel effect for such purposes.

- F. In accordance with 31 U.S.C. § 7701, respondent is hereby required, unless it has done so already, to furnish to the Commission its taxpayer identifying number, which shall be used for the purposes of collecting and reporting on any delinquent amount arising out of respondent's relationship with the government.
- G. Proceedings instituted under this Part are in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law, including any other proceedings the Commission may initiate to enforce this order.

VII.

IT IS FURTHER ORDERED that respondent Lornamead, Inc., and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and, upon reasonable notice and request, make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VIII.

IT IS FURTHER ORDERED that respondent Lornamead, Inc., and its successors and assigns shall deliver a copy of this order to all current and, for the next three (3) years, all future principals, officers, directors, and other employees having primary responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent Lornamead, Inc., and its successors and assigns shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

IX.

IT IS FURTHER ORDERED that respondent Lornamead, Inc., and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty

(30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line: In the Matter of Lornamead, Inc., FTC File Number 122-3255. *Provided, however,* that, in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of such notices is contemporaneously sent to the Commission at Debrief@ftc.gov.

X.

IT IS FURTHER ORDERED that respondent Lornamead, Inc., and its successors and assigns shall, within sixty (60) days after the date of service of this order, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

XI.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

LORNAMEAD, INC.

Date: _____

By: _____

Date: _____

LEONARD L. GORDON, ESQ.
Venable, LLP
Attorney for respondent

Date: _____

LINDA K. BADGER
SYLVIA KUNDIG
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APPROVED:

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