

Complaint

IN THE MATTER OF

LORNAMEAD, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4488; File No. 122 3255**Complaint, September 16, 2014 – Decision, September 16, 2014*

This consent order addresses Lornamead, Inc.’s advertising, marketing, and sale of a line of products including “Lice Shield Shampoo & Conditioner in 1,” “Lice Shield Leave In Spray,” and “Lice Shield Gear Guard” (collectively, “Lice Shield products”). The complaint alleges that respondent’s claims in various advertisements regarding the efficacy of Lice Shield products to deter lice are unsubstantiated and thus violate the FTC Act. The consent order requires respondent to pay five hundred thousand dollars (\$500,000) to be deposited in the United States Treasury as disgorgement. The order also prohibits respondent from representing that use of any drug, cosmetic, or pesticide 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.

Participants

For the *Commission*: Linda K. Badger and Sylvia Kundig.

For the *Respondent*: Leonard L. Gordon and Gary D. Hailey,
Venable, LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that Lornamead, Inc., a corporation (“respondent”), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Lornamead, Inc., is a Delaware corporation with its principal office or place of business at 175 Cooper Avenue, Tonawanda, New York 14150.

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2. Respondent has manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including the “Lice Shield” product line. This line of products has embraced a number of products for use on hair or head gear, including: “Lice Shield Leave In Spray,” “Lice Shield Gear Guard,” and “Lice Shield Shampoo & Conditioner in 1.” Lice Shield products are “cosmetics” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Lice Shield products are hair care products that contain citronella and other ingredients. Respondent promotes Lice Shield products as a way to avoid, or to reduce the risk of, getting head lice. All Lice Shield products are intended for use as deterrents, and they do not kill lice, kill lice eggs, or treat an infestation.

5. Respondent has disseminated or has caused to be disseminated advertisements for Lice Shield products including, but not necessarily limited to, the attached Exhibits A through H. These advertisements have contained the following statements and depictions:

a. Internet Banner Advertisement (Exhibit A)

Lice Shield: REPELS HEAD LICE: **The Best Way To Treat Lice? Avoid Getting Them!** [Depicts child dressed in knight’s helmet with shield, wielding a sword, while cartoon lice bounce off helmet.]

b. Website Advertisement (Exhibit B)

THE BEST WAY TO TREAT LICE IS TO AVOID GETTING THEM Introducing Lice Shield - a new line of hair care products demonstrated to repel lice while, at the same time, gently cleansing and conditioning hair. Specially formulated with a proprietary blend of natural oil extracts that repel lice, regular use of Lice Shield will dramatically reduce the

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likelihood your child will contract head lice when there is an outbreak.

Don't Get Lice, Get Lice Shield. [Depicts child dressed in knight's helmet with shield, wielding a sword, while cartoon lice bounce off helmet.]

- c. Website Advertisement: FAQ's (Exhibit C)

ITCHING FOR ANSWERS?

...

HOW EFFECTIVE IS LICE SHIELD AT HELPING TO REPEL HEAD LICE? Scientific studies have shown that the use of Lice Shield Shampoo & Conditioner in 1 and Lice Shield Leave In Spray decreases the chance of lice infestation by over 80%.

- d. Print Advertisement (Exhibit D)

Don't Get Lice, Get Lice Shield.

AVOIDING IS BETTER THAN TREATING.

Specially formulated with a proprietary blend of essential oils to repel lice, Lice Shield is remarkably effective, easy to use, and free of harmful pesticides.

Lice Shield products are scientifically proven to provide over 80% lice repellency, dramatically reducing a child's chance of catching lice during an outbreak.

The Results

Treatment Arm	Repellency Rate	P-Value
Control (tap water) vs. Untreated	--	0.29
Lice Shield Shampoo vs. Untreated	53%	0.04
Lice Shield Leave In Spray vs. Untreated	86%	<0.0001

For best results, use both products in combination.

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School lice outbreaks are a fact of life, but now you can help reduce the risk of infestation.

e. Print Advertisement (Exhibit E)

The Best Way To Treat Lice Is To Avoid Getting Them.

Be Prepared with Lice Shield**Scientifically shown to repel head lice**

Reducing a child's chance of catching lice during an outbreak.

Safe & pesticide free

Formulated with a proprietary blend of essential oils to repel lice.

Created with kids' scalps in mind

A Shampoo and Leave In Spray, gentle enough to use every day, with a refreshing, clean fragrance. And, Gear Guard, a spray product developed specially for your child's possessions.

Be Prepared with Lice Shield

School lice outbreaks are a fact of life, but now you can reduce the risk of infestation.

Don't Get Lice, Get Lice Shield.

f. Lice Shield Shampoo and Conditioner In 1 Product Label (Exhibit F)

[Front] Lice Shield**REPELS HEAD LICE****Shampoo & Conditioner in 1**

...

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[Back] **The best way to
treat lice is to avoid
getting them.**

. . .

For best results, use daily with Lice Shield Leave In Spray.

g. Lice Shield Leave In Spray Product Label (Exhibit G)

[Front] **Lice Shield
REPELS HEAD LICE**

LEAVE IN SPRAY

. . .

[Back] **The best way to
treat lice is to avoid
getting them.**

. . .

For best results, use daily after Lice Shield Shampoo & Conditioner in 1.

h. Lice Shield Gear Guard Product Label (Exhibit H)

[Front] ***Now shield your stuff!***

**Lice Shield
REPELS HEAD LICE**

GEAR GUARD

. . .

-Use on hats, helmets, clothing

. . .

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[Back] **The best way to
treat lice is to avoid
getting them.**

GEAR GUARD

*Specially formulated to help repel
lice from all types of objects.

6. Through the means described in Paragraph 5, respondent has represented, expressly or by implication, that:

- a. When used as directed, Lice Shield products prevent head lice infestations;
- b. When used as directed, Lice Shield products decrease the likelihood or chance of a head lice infestation by over 80%;
- c. When used as directed, Lice Shield products dramatically reduce the likelihood or chance of a head lice infestation during an outbreak;
- d. When used as directed, Lice Shield products reduce the likelihood or chance of a head lice infestation during an outbreak;
- e. Spraying Lice Shield Gear Guard on objects, such as hats or helmets, reduces the likelihood or chance of a head lice infestation; and
- f. Lice Shield Shampoo & Conditioner In 1 and Lice Shield Leave In Spray are most effective when they are used together.

7. Through the means described in Paragraph 5, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set

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forth in Paragraph 6, at the time the representations were made. Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.

9. Through the means described in Paragraph 5, respondent has represented, expressly or by implication that scientific tests prove that, when used as directed, Lice Shield products significantly reduce the likelihood or chance of a head lice infestation.

10. In truth and in fact, scientific tests do not prove that, when used as directed, Lice Shield products significantly reduce the likelihood or chance of a head lice infestation.

11. The representation set forth in Paragraph 9 was, and is, false or misleading.

12. The acts and practices of respondent as alleged in this complaint constitute deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, this sixteenth day of September, 2014, has issued this complaint against respondent.

By the Commission, Commissioner McSweeney not participating.

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Exhibit A

LICE SHIELD BANNER ADS



EXHIBIT A

LORNAMEAD-FTC 000087

Exhibit B

LICESHIELD.NET – JULY 2010 – APRIL 2012

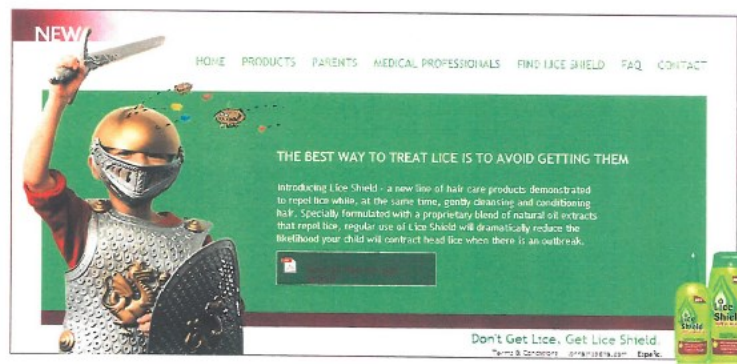


EXHIBIT B

LORNAMEAD-FTC 000003

Complaint

Exhibit C

NEW

HOMEPRODUCTSPARENTSMEDICAL PROFESSIONALSRIND LICE SHIELDFAQCONTACT



ITCHING FOR ANSWERS?

WHEN SHOULD I USE LICE SHIELD?
The best time to use Lice Shield is when you believe your children or family has been exposed to lice. This might be when your child comes home from school with a note warning of an infestation, or when a family member has caught lice that you have successfully treated with a pediculicide. Since Lice Shield helps to repel head lice, but does not treat an infestation, the time to use the product is before you catch lice. School lice outbreaks are a fact of life, but now you can help reduce the risk of infestation. During the next outbreak, recommend new Lice Shield hair care products.



Don't Get Lice. Get Lice Shield.
Terms & Conditions liceshield.com Lice Shield

WHO CAN USE LICE SHIELD?
Lice Shield products are specially formulated to be gentle to a child's hair and skin, however they are also appropriate for the whole family during a period of infestation.

HOW OFTEN AND HOW LONG CAN I USE LICE SHIELD?
Lice Shield is gentle enough to be used every day, in place of your regular shampoo or detangling spray. Lice Shield should be used during the duration of a lice outbreak, which is usually brought under control in about 2 weeks.

WHAT INGREDIENTS ARE IN LICE SHIELD?
Lice Shield contains natural essential oil extracts of:
Citronella, Eucalyptus, Rosemary and Lemongrass.

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Lice Shield contains natural essential oil extracts of:
Citronella, Eucalyptus, Rosemary and Lemongrass.

HOW EFFECTIVE IS LICE SHIELD AT HELPING TO REPEL HEAD LICE?
Scientific studies have shown that the use of Lice Shield Shampoo & Conditioner in 1 and Lice Shield Leave In Spray decreases the chance of lice infestation by over 80%.

DO YOU HAVE OTHER QUESTIONS OR COMMENTS?
Please contact us:
Call: 1-877-995-5495
Email: liceshield@lorismedna.com

EXHIBIT C

LORISMEAD-FTO 000011

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Exhibit D

Don't Get Lice, Get Lice Shield.

AVOIDING IS BETTER THAN TREATING.

Specially formulated with a proprietary blend of essential oils to repel lice, Lice Shield is remarkably effective, easy to use, and free of harmful pesticides.

Lice Shield products are scientifically proven to provide over 80% lice repellency, dramatically reducing a child's chance of catching lice during an outbreak.

The Results

Treatment Arm	Repellency Rate	P-Value
Control (tap water) vs. Untreated	---	0.29
Lice Shield Shampoo vs. Untreated	53%	0.04
Lice Shield Leave In Spray vs. Untreated	86%	<0.0001

For best results, use both products in combination.

School lice outbreaks are a fact of life, but now you can help reduce the risk of infestation.

During the next outbreak, recommend new Lice Shield hair care products.

TWO SAFE, EASY & EFFECTIVE WAYS TO HELP REPEL LICE.

Lice Shield is easy to substitute into a child's daily hair care routine during a period of infestation. Created with kids' finer hair and sensitive scalps in mind, it has a refreshing, clean fragrance.



SHAMPOO & CONDITIONER IN 1

- Gentle enough for daily use
- Contains extra conditioners for a tangle-free formula



LEAVE IN SPRAY

- With light detanglers to aid in combing
- Perfect to use in wet or dry hair, as well as hats, helmets, and winter gear

Lice Shield is widely available at neighborhood drug stores, supermarkets, and mass merchandisers at an affordable price. Visit liceshield.net to learn more about Lice Shield and for tips on lice prevention.

Don't Get Lice, Get Lice Shield.

For more information on head lice prevention, as well as online resources for the parent and school nurse, please visit us on the web, liceshield.net



LORNAMEAD-FITC 000027

EXHIBIT D

Complaint

Exhibit E

The Best Way To Treat Lice Is To Avoid Getting Them.

Be Prepared with Lice Shield

Scientifically shown to repel head lice
Reducing a child's chance of catching lice during an outbreak.

Safe & pesticide free
Formulated with a proprietary blend of essential oils to repel lice.

Created with kids' scalps in mind
A Shampoo and Leave In Spray, gentle enough to use every day, with a refreshing, clean fragrance. And, Gear Guard, a spray product developed specially for your child's possessions.

Be Prepared with Lice Shield
School lice outbreaks are a fact of life, but now you can reduce the risk of infestation.

Don't Get Lice, Get Lice Shield.

Available at neighborhood drug stores, supermarkets, and mass merchandisers. For more about Lice Shield, tips on lice prevention, and online resources for school nurses and parents visit liceshield.net.

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LORNAMEAD-FTC 000070

EXHIBIT E

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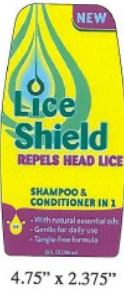
Exhibit F

LICE SHIELD SHAMPOO & CONDITIONER IN 1 FRONT LABEL

EXHIBIT F - 1



TRIMMED LABEL



LORNAMEAD, INC.		PROJECT AND PRODUCTION INFO	
DATE:	REVISION 1.000	PRINTED BY:	THE BOX
PROJECT:	LICE SHIELD SHAMPOO FRONT LABEL	PRINTED BY:	THE BOX
PRINT:	100	PRINTED BY:	THE BOX
GRAPHIC:	100	PRINTED BY:	THE BOX
FILE NAME:	LICE SHIELD SHAMPOO FRONT LABEL	PRINTED BY:	THE BOX
PRINTED:	100	PRINTED BY:	THE BOX
PRINTED:	100	PRINTED BY:	THE BOX

Complaint

LICE SHIELD SHAMPOO & CONDITIONER IN 1 BACK LABEL

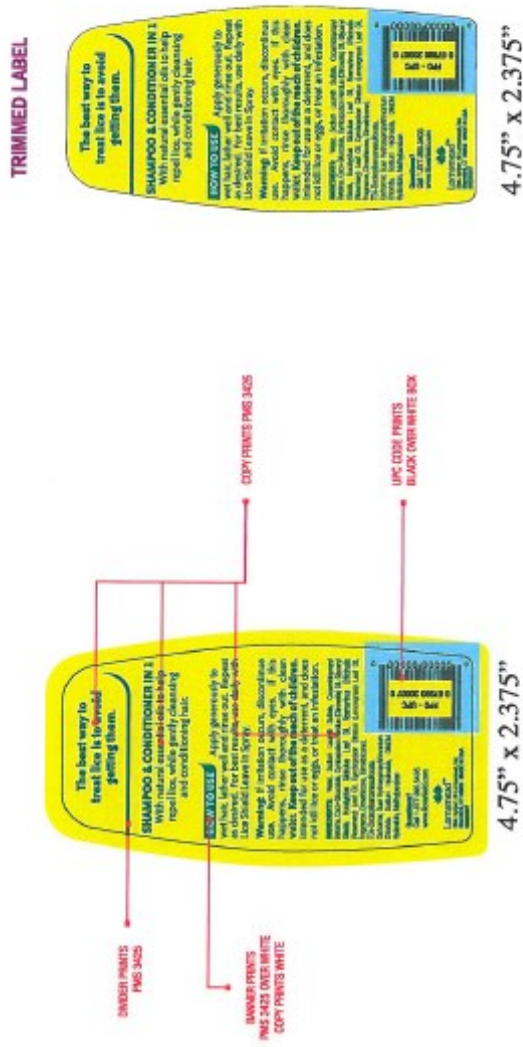
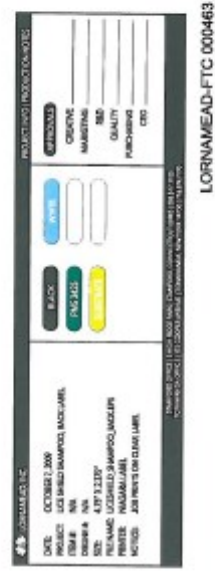


EXHIBIT F - 2



LORNAHEAD-FTC 000463

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Exhibit G

LICE SHIELD SPRAY FRONT LABEL



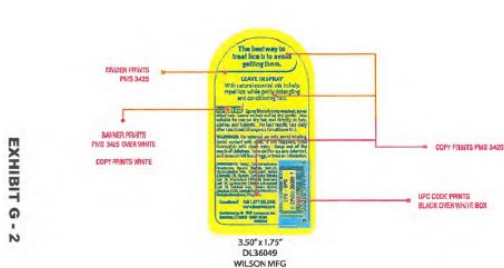
TRIMMED LABEL



LORNAMEAD, INC.		PROJECT AND PROCESS NUMBERS	
DATE	OCTOBER 1, 2011	PROJECT	DL36049
PROJECT	LICE SHIELD SPRAY FRONT LABEL	PROCESS	DL36049
DESIGNER	ALA	CREATING	
DESIGNER	ALA	MARKETING	
DATE	SEP 11, 2011	REP	
FILE NAME	LORNAMEAD_SPRAY_FRONT_LABEL	PROPERTY	
PRINTED	WILSON MFG	PERFORMER	
NOTES	FOR PRINTS ON OTHER LABELS	COO	

LORNAMEAD-FTC 000486

LICE SHIELD SPRAY BACK LABEL



TRIMMED LABEL



LORNAMEAD, INC.		PROJECT AND PROCESS NUMBERS	
DATE	OCTOBER 1, 2011	PROJECT	DL36049
PROJECT	LICE SHIELD SPRAY BACK LABEL	PROCESS	DL36049
DESIGNER	ALA	CREATING	
DESIGNER	ALA	MARKETING	
DATE	SEP 11, 2011	REP	
FILE NAME	LORNAMEAD_SPRAY_BACK_LABEL	PROPERTY	
PRINTED	WILSON MFG	PERFORMER	
NOTES	FOR PRINTS ON OTHER LABELS	COO	

LORNAMEAD-FTC 000486

Decision and Order

Exhibit H



DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a complaint which the Western Region-San Francisco proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violations of the Federal Trade Commission Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“consent agreement”), which includes: a statement by respondent that it neither admits nor denies any of the allegations in the draft complaint except as specifically stated in the consent agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; and waivers and other provisions as required by the Commission’s Rules; and

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The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Lornamead, Inc., is a Delaware corporation with its principal office or place of business at 175 Cooper Avenue, Tonawanda, New York 14150.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

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

- A. Unless otherwise specified, “respondent” shall mean Lornamead, Inc., a corporation, its successors and assigns, and its officers, agents, representatives, and employees.
- B. “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.

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- C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “Covered Product” means any drug, cosmetic, or pesticide, including but not limited to Lice Shield Products.
- E. “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.
- F. “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.
- G. “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.
- H. “Pediculosis” means infestation of the scalp by head lice.
- I. The term “including” in this order means “without limitation.”
- J. 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.

Decision and Order

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

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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

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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

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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

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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

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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.

Analysis to Aid Public Comment

XI.

This order will terminate on September 16, 2034, 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.

By the Commission, Commissioner McSweeney not participating.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing consent order from Lornamead, Inc. ("respondent"). The proposed consent order has been placed on the public record for

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thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves respondent's advertising, marketing, and sale of a line of products including "Lice Shield Shampoo & Conditioner in 1," "Lice Shield Leave In Spray," and "Lice Shield Gear Guard" (collectively, "Lice Shield products"). Respondent marketed Lice Shield products in retail stores and on the Internet. According to the FTC's proposed complaint, respondent promoted Lice Shield products, which contain essential oils such as citronella, as a way to avoid, or to reduce the risk of, getting a head lice infestation ("pediculosis"). Lice Shield products are intended strictly as a means to deter lice, and not as a means to treat an existing head lice infestation. These products do not kill head lice or their eggs.

The proposed complaint alleges that respondent made several claims in various advertisements regarding the efficacy of Lice Shield products to deter lice, including that applying the products to hair or head gear: prevents head lice infestations; decreases the likelihood of an infestation by over 80%; dramatically reduces the likelihood of an infestation during an outbreak; or reduces the likelihood of an infestation during an outbreak. Respondent also allegedly represented that Lice Shield products are more effective when consumers use both the shampoo and the leave-in spray. The proposed complaint alleges that these claims are unsubstantiated and thus violate the FTC Act. Further, the proposed complaint alleges that respondent represented, in various advertisements, that scientific tests prove that, when used as directed, Lice Shield products will significantly reduce the likelihood or chance of a head lice infestation. The complaint alleges that this claim is false and thus violates the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Part I of the order prohibits respondent from representing that use of any drug, cosmetic, or pesticide is effective in: a) preventing pediculosis, b) eliminating or reducing

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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 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.

Part II of the proposed order prohibits any representation, other than those covered under Part I, that use of any drug, cosmetic, or pesticide, will reduce the risk of a head lice infestation or repel lice, unless the representation is non-misleading, and, at the time of making such representation, 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, 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.

Part III of the proposed order prohibits any representation, other than those covered under Part I, about the health benefits of any drug, cosmetic, or pesticide, 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, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified

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persons, and that are generally accepted in the profession to yield accurate and reliable results.

Part IV of the proposed order addresses the allegedly false claim that scientific tests prove that use of Lice Shield products significantly reduces the risk or likelihood of a head lice infestation. Part IV prohibits respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, when advertising any drug, cosmetic, or pesticide.

Part V of the proposed order states that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for that drug under any tentative or final standard promulgated by the Food and Drug Administration (“FDA”), or under any new drug application approved by the FDA.

Part VI of the proposed order requires respondent to pay five hundred thousand dollars (\$500,000) to the Commission. This payment shall be deposited in the United States Treasury as disgorgement.

Parts VII, VIII, IX, and X of the proposed order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part XI provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

Complaint

IN THE MATTER OF

AKORN, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

Docket No. C-4479; File No. 141 0162
Complaint, August 1, 2014 – Decision, September 16, 2014

This consent order addresses the \$324 million acquisition by Akorn, Inc. of certain assets of VersaPharm Inc. The complaint alleges that the acquisition violates Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening future competition in the sale of generic rifampin. The consent order requires Akorn to divest its rights related to generic rifampin to Watson Laboratories, Inc., a wholly-owned subsidiary of Actavis plc.

Participants

For the *Commission*: *Jasmine Y. Rosner*.

For the *Respondents*: *Marin Boney* and *Mark Kovner*,
Kirkland & Ellis LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Akorn, Inc. (“Akorn”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire VPI Holdings Corp., the parent company of VersaPharm Incorporated (“VersaPharm”), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows: