

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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In the Matter of)	
)	
ROGERIO MONTEIRO,)	
individually and doing)	
business as Leeka Products,)	File No. 962-3194
and)	
)	
ELIANA CREMA,)	AGREEMENT CONTAINING
individually and doing)	CONSENT ORDER
business as Leeka Products.)	
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The Federal Trade Commission has conducted an investigation of certain acts and practices of Rogerio Monteiro and Eliana Crema, individually and doing business as Leeka Products ("proposed respondents"). Proposed respondents, having been represented by counsel, are 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 Rogerio Monteiro and Eliana Crema, individually and doing business as Leeka Products, and counsel for the Federal Trade Commission that:

1a. Proposed respondent Rogerio Monteiro is owner of Leeka Products. Individually or in concert with others, he formulates, directs or controls the policies, acts, or practices of Leeka Products. His principal office or place of business is 1614 South Central Avenue, Glendale, California 91204.

1b. Proposed respondent Eliana Crema is owner of Leeka Products. Individually or in concert with others, she formulates, directs or controls the policies, acts, or practices of Leeka Products. Her principal office or place of business is 1614 South Central Avenue, Glendale, California 91204.

2. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondents waive:
 - 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 sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, 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 this proceeding.
5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.
6. 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 respondents: (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 respondents by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondents waive any rights they 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.
7. Proposed respondents have read the draft complaint and consent order. They understand that they 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 the purposes of this Order:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. Unless otherwise specified, "respondents" shall mean Rogerio Monteiro and Eliana Crema, individually and doing business as Leeka Products, and each of the above's agents, representatives, and employees.
3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Super Formula Reductora, Crema Sudadora Perfect Shape, Tratamiento para Combatir la Caida del Cabello or any food, dietary supplement, cosmetic or drug, as "food," "cosmetic" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that:

- A. Such product controls and regulates metabolism;
- B. Such product reduces appetite;
- C. Such product burns or dissolves fat;
- D. Such product causes better results from exercise;
- E. Such product increases calories burned during exercise;
- F. Such product provides any weight loss, fat loss, weight regulation, weight control, or weight maintenance benefits; or
- G. Such product will prevent or retard hair loss

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any hair care product or drug, as "drug" is defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not represent that any product prevents hair loss, unless the product is the subject of an approved new drug application for such purpose under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., provided that, this requirement shall not limit the requirements of Order Part I herein.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Super Formula Reductora, Crema Sudadora Perfect Shape, Tratamiento para Combatir la Caida del Cabello or any other food, dietary supplement, cosmetic or drug, as "food," "cosmetic" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that respondents directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Tratamiento para Combatir la Caida del Cabello or any substantially similar product in or affecting commerce, shall not use the name "Tratamiento para Combatir la Caida del Cabello" or any other name that represents, expressly or by implication, that the product will prevent or retard hair loss, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

V.

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

VI.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in 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.

VII.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VIII.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon 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 their 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.

IX.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, partners, officers, directors, and managers, and to all current and future employees, agents, and representatives having 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. Respondents 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.

X.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed change in Leeka Products 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 company; 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 company name or address. Provided, however, that with respect to any proposed change in the company about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XI.

IT IS FURTHER ORDERED that respondent Rogerio Monteiro, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment or of his affiliation with any new business or employment which involves the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, cosmetic or drug, as "food," "cosmetic" and "drug" are defined in Section 15 of the Federal Trade Commission Act. The notice shall include respondent's new business address and telephone number, and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XII.

IT IS FURTHER ORDERED that respondent Eliana Crema, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of her current business or employment or of her affiliation with any new business or employment which involves the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, cosmetic or drug, as "food," "cosmetic" and "drug" are defined in Section 15 of the Federal Trade Commission Act. The notice shall include respondent's new business address and telephone number, and a description of the nature of the business or employment and her duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XIII.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XIV.

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.

Signed this _____ day of _____, 1997.

ROGERIO MONTEIRO, individually
and doing business as Leeka Products.

ELIANA CREMA, individually
and doing business as Leeka Products.

SUSAN ARTHUR
Counsel for the Federal Trade Commission

APPROVED:

THOMAS B. CARTER
Director
Dallas Regional Office

JOAN Z. BERNSTEIN
Director
Bureau of Consumer Protection

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FEDERAL TRADE COMMISSION**

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In the Matter of)	
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ROGERIO MONTEIRO,)	
individually and doing)	
business as Leeka Products,)	DOCKET NO.
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ELIANA CREMA,)	
individually and doing)	
business as Leeka Products.)	
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COMPLAINT

The Federal Trade Commission, having reason to believe that Rogerio Monteiro and Eliana Crema ("respondents"), owners of the business known as Leeka Products, have 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 Rogerio Monteiro is owner of Leeka Products, a sole proprietorship with its principal place of business at 1614 South Central Avenue, Glendale, California 91204. Individually or in concert with others, Rogerio Monteiro formulates, directs, or controls the policies, acts, or practices of Leeka Products, including the acts or practices alleged in this complaint. His principal place of business is the same as that of Leeka Products.

2. Respondent Eliana Crema is married to Rogerio Monteiro and is also an owner of Leeka Products. Individually or in concert with others, she formulates, directs, or controls the policies, acts or practices of Leeka Products, including the acts or practices alleged in this complaint. Her principal place of business is the same as that of Leeka Products.

3. Respondents have advertised, offered for sale, sold and distributed Super Formula Reductora, Crema Sudadora Perfect Shape, and Tratamiento para Combatir la Caida del Cabello. Super Formula Reductora is a "food" and/or a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. Crema Sudadora Perfect Shape is a "cosmetic" and/or a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. Tratamiento para Combatir la Caida del Cabello is a "cosmetic" and/or a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

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

5. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Super Formula Reductora, including but not necessarily limited to the attached Exhibits A-1 and B-1. Translations of these advertisements and promotional materials have been provided by the respondents and are attached as Exhibits A-2 and B-2. The translations of the advertisements and promotional materials contain the following statements:

A. Naturally Leeka
"Super Formula Reductora"
Was created to help you lose weight successfully by controlling the metabolism, reducing appetite and burning fat.

3 daily tablets contain:

Chromium Picolinate (200 mcg): Regulate metabolism and burn fat.

Cider Vinegar (240 mg): Dissolve fat.

Phenylalamine [sic] (100 mg): Reduce appetite.

Kelp (100 mg): Iodine Creator. Maintain optimum metabolism function.

Herbal Complex (600 mg): Reduce excess fluids.

Soya Lecithin (600 mg): Disperse fat globules in the body and maintain a low cholesterol level.

Vitamin B-6 (50 mg): Responsible for the metabolism of fat, carbohydrates and proteins.

* * * *

(Exhibit A-2)

B. **Super Formula Reductora**

"Super Formula Reductora" was created to help you lose weight successfully by: Controlling the metabolism, reducing appetite and burninmg [sic] fat. S.F.R. is formulated with 7 super ingredients in a natural base, including the patented Chromium Picolinate, which has demonstrated in clinical studies to be very effective in weight loss.

3 daily tablets contain:

Chromium Picolinate (200 mcg): Regulate metabolism, burn fat.

Cider Vinegar (240 mg): Dissolve fat.

Phenylalamine (100 mg); [sic] Reduce appetite.

Kelp (100 mg): Iodine Creator - Maintain optimum metabolism function.

Herbal Complex (600 mg): Reduce excess fluids.

Soya Lecithin (600 mg): Disperse fat globules in the body and maintain a low cholesterol level.

Vitamin B-6 (50 mg): Responsible for the metabolism of fat, carbohydrates and proteins.

* * * *

(Exhibit B-2)

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

- A. Super Formula Reductora will control and regulate metabolism.
- B. Super Formula Reductora will reduce appetite.
- C. Super Formula Reductora will burn or dissolve fat.
- D. Super Formula Reductora will cause weight loss.

7. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that they 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, respondents did not possess and rely upon a reasonable basis that substantiated the representations set 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, respondents have represented, expressly or by implication, that scientific studies of Chromium Picolinate demonstrate that Super Formula Reductora causes weight loss.

10. In truth and in fact, scientific studies of Chromium Picolinate do not demonstrate that Super Formula Reductora causes weight loss. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

11. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Crema Sudadora Perfect Shape, including but not necessarily limited to the attached Exhibits B-1 and C-1. A translation of Exhibit B-1 has been provided by the respondents and is attached as Exhibit B-2. A translation of the relevant portion of Exhibit C-1 is attached as Exhibit C-2. The translations of the advertisements and promotional materials contain the following statements:

A. **Crema Sudadora - Perfect Shape**

To have a beautiful body and be in good physical shape is the desire of all people. Perfect Shape can help you obtain better results from your workout because Perfect Shape activates circulation producing a "better sweat" in the areas that need it the most.

Sweating burns calories which is essential to lose inches.

* * * *

(Exhibit B-2)

B. Crema Sudadora
Perfect Shape

To have a beautiful body and be in good physical shape is the desire of all people. Perfect Shape can help you obtain better results from your workout because Perfect Shape activates circulation producing a "better sweat" in the areas that need it the most.

Burn more calories by sweating more.

* * * *

(Exhibit C-2)

12. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Crema Sudadora Perfect Shape, including but not necessarily limited to the attached Exhibit D. This English language advertisement contains the following statements:

SWEAT IT OUT & GET IN SHAPE!

Designed to improve the sweating process during your dynamic workout. Right where you need it the most.

Burn more calories by sweating more.

Get lean faster.

Get the most from your workout.

* * * *

(Exhibit D)

13. Through the means described in Paragraphs 11 and 12, respondents have represented, expressly or by implication, that:

- A. Crema Sudadora Perfect Shape will cause better results from exercise.
- B. Crema Sudadora Perfect Shape will increase the number of calories burned during exercise.
- C. Crema Sudadora Perfect Shape will cause the user to get lean faster.

14. Through the means described in Paragraphs 11 and 12, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 13, at the time the representations were made.

15. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 13, at the time the representations were made. Therefore, the representation set forth in Paragraph 14 was, and is false or misleading.

16. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Tratamiento para Combatir la Caida del Cabello ["Treatment to Fight Hair Loss"], including but not necessarily limited to the attached Exhibit B-1. A translation of this advertisement has been provided by the respondents and is attached as Exhibit B-2. A translation of the name of the product has also been provided by the respondents and is attached as Exhibit B-3. The translation of the advertisement contains the following statements:

Tratamiento para Combatir la Caida del Cabello [Treatment to Fight Hair Loss]

For Men and Women.

The most advanced treatment that combines 3 super products that help fight hair loss.

First Step (pre-shampoo): Contains Aloe and Biotin to leave hair clean, with body and texture.

Second Step: To deep clean scalp and pores.

Third Step: Increases blood flow to the scalp and nourishes the roots in a base of proteins, Biotin, Aloe and herbal extracts.

* * * *

(Exhibits B-2 and B-3)

17. Through use of the trade name Tratamiento para Combatir la Caida del Cabello ["Treatment to Fight Hair Loss"] and through the means described in Paragraph 16, respondents have represented, expressly or by implication, that Tratamiento para Combatir la Caida del Cabello will prevent or retard hair loss.

18. Through the means described in Paragraph 16, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 17, at the time the representation was made.

19. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 17, at the time the representation was made. Therefore, the representation set forth in Paragraph 18 was, and is, false or misleading.

20. The acts and practices of respondents as alleged in this complaint constitute unfair or 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 on this _____ day of _____, 1997, has issued this complaint against respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL:

[Exhibits A-D attached to paper copies of complaint, but not available in electronic form.]

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has provisionally accepted an agreement to a proposed consent order from respondents Rogerio Monteiro and Eliana Crema, doing business as Leeka Products, who market Super Formula Reductora, Perfect Shape Crema Sudadora, and Tratamiento para Combatir la Caida del Cabello.

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should make final the agreement's proposed order, or withdraw from the agreement and take other appropriate action.

This matter concerns the advertising of Leeka brand products. Advertisements for Super Formula Reductora make claims that the product will control and regulate metabolism, reduce appetite, burn or dissolve fat, and cause weight loss. The advertisements for Crema Sudadora Perfect Shape claim that the cream causes better results from exercise, increases the number of calories burned during exercise, and causes the user to get lean faster. Advertisements for Tratamiento para Combatir la Caida del Cabello, which means "Treatment to Fight Hair Loss," claim that the product will prevent or retard hair loss. The Commission's complaint charges that the respondents did not possess and rely upon a reasonable basis that substantiated the claims at the time they were made.

Additionally, the complaint alleges the advertisements falsely represent that scientific studies of Chromium Picolinate demonstrate that Super Formula Reductora will cause weight loss.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits the respondents from making unsubstantiated claims that Super Formula Reductora, Crema Sudadora Perfect Shape, Tratamiento para Combatir la Caida del Cabello or any food, dietary supplement, cosmetic or drug, controls and regulates metabolism; reduces appetite; burns or dissolves fat; causes better results from exercise; increases calories burned during exercise; provides any weight loss, fat loss, weight regulation, weight control, or weight maintenance benefits; or will prevent or retard hair loss.

Part II of the proposed order prohibits the respondents from representing that any product prevents hair loss, unless the product is the subject of an approved new drug application for such purpose under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., provided that, the requirement shall not limit the requirements of Order Part I.

Part III of the proposed order prohibits the respondents from making any representation about the benefits, performance, or efficacy of its products unless, at the time the representation is

made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation

Part IV of the proposed order prohibits the respondents from using the name "Tratamiento para Combatir la Caída del Cabello" or any other name that represents that a product will prevent or retard hair loss, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Part V of the proposed order prohibits the respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Parts VI and VII of the proposed order harmonize the requirements of the order with the Nutrition Labeling and Education Act of 1990 and with Food and Drug Administration procedures.

The proposed order requires respondents to maintain advertisements and promotional materials and materials relied upon to substantiate the claims covered by the order; to provide a copy of the consent agreement to certain personnel in the company; to notify the Commission of certain changes in the company; to notify the Commission of changes in the respondents' employment; and to file reports regarding compliance with the order.

Part IX of the proposed order states that the order terminates 20 years from the date of issuance, except under certain specified conditions.

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 agreement and proposed order or to modify in any way their terms.

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This matter concerns the advertising of Leeka brand products. Advertisements for Super Formula Reductora make claims that the product will control and regulate metabolism, reduce appetite, burn or dissolve fat, and cause weight loss. The advertisements for Crema Sudadora Perfect Shape claim that the cream causes better results from exercise, increases the number of calories burned during exercise, and causes the user to get lean faster. Advertisements for Tratamiento para Combatir la Caida del Cabello, which means "Treatment to Fight Hair Loss," claim that the product will prevent or retard hair loss. The Commission's complaint charges that the respondents did not possess and rely upon a reasonable basis that substantiated the claims at the time they were made.

Additionally, the complaint alleges the advertisements falsely represent that scientific studies of Chromium Picolinate demonstrate that Super Formula Reductora will cause weight loss.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits the respondents from making unsubstantiated claims that Super Formula Reductora, Crema Sudadora Perfect Shape, Tratamiento para Combatir la Caida del Cabello or any food, dietary supplement, cosmetic or drug, controls and regulates metabolism; reduces appetite; burns or dissolves fat; causes better results from exercise; increases calories burned during exercise; provides any weight loss, fat loss, weight regulation, weight control, or weight maintenance benefits; or will prevent or retard hair loss.

Part II of the proposed order prohibits the respondents from representing that any product prevents hair loss, unless the product is the subject of an approved new drug application for such purpose under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., provided that, the requirement shall not limit the requirements of Order Part I.

Part III of the proposed order prohibits the respondents from making any representation about the benefits, performance, or efficacy of its products unless, at the time the representation is

made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation

Part IV of the proposed order prohibits the respondents from using the name "Tratamiento para Combatir la Caída del Cabello" or any other name that represents that a product will prevent or retard hair loss, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Part V of the proposed order prohibits the respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Parts VI and VII of the proposed order harmonize the requirements of the order with the Nutrition Labeling and Education Act of 1990 and with Food and Drug Administration procedures.

The proposed order requires respondents to maintain advertisements and promotional materials and materials relied upon to substantiate the claims covered by the order; to provide a copy of the consent agreement to certain personnel in the company; to notify the Commission of certain changes in the company; to notify the Commission of changes in the respondents' employment; and to file reports regarding compliance with the order.

Part IX of the proposed order states that the order terminates 20 years from the date of issuance, except under certain specified conditions.

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 agreement and proposed order or to modify in any way their terms.