

from the agreement or make final the agreement's proposed order.

The Commission's complaint alleges that the proposed respondents made the following unsubstantiated representations about Venoflash; it removes dangerous clogs in the circulatory system; it treats the symptoms of varicose veins; and it treats the symptoms of hemorrhoids.

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

Paragraph I of the proposed order prohibits proposed respondents from representing that Venoflash or any other product removes dangerous clogs in the circulatory system; treats the symptoms of varicose veins; and treats the symptoms of hemorrhoids, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph II of the proposed order prohibits respondents from making any representation about the health benefits, performance, safety, or efficacy of Venoflash, or any food, dietary supplement, or drug, promoted or used to treat conditions or illnesses related to the circulatory system, unless, at the time the representation is made, proposed respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph III of the proposed order provides that nothing in this order shall prohibit proposed respondents from making any representation for any product permitted by the Food and Drug Administration. Paragraph IV of the proposed order provides that nothing in this order shall prohibit proposed respondents from making any representation for any drug permitted by the Food and Drug Administration.

Paragraph V of the proposed order requires the proposed respondents to keep and maintain all advertisements and promotional materials containing any representation, and all materials that were relied upon in disseminating the representations, covered by the proposed order. Additionally, Paragraph VI requires distribution of a copy of the consent order to current and future officers and agents. Further, Paragraph VII provides for Commission notification upon a change in the corporate respondent, and Paragraph VIII requires Commission notification when the individual respondent changes his present business or employment. Paragraph IX requires

proposed respondents to file compliance reports with the Commission.

Lastly, Paragraph X provides for the termination of the order after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Benjamin Berman,

Acting Secretary.

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FEDERAL TRADE COMMISSION

[File No. 962-3194]

Rogério Monteiro and Eliana Crema, Individually and Doing Business as Leeka Products; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before September 5, 1997.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Michael J. Bloom, Federal Trade Commission, New York Regional Office, 150 William Street, Suite 1300, New York, NY 10038. (212) 264-1207.

Donald G. D'Amato, Federal Trade Commission, New York Regional Office, 150 William Street, Suite 1300, New York, NY 10038. (212) 264-1207

Denise Tighe, Federal Trade Commission, New York Regional Office, 150 William Street, Suite 1300, New York, NY 10038. (212) 264-1207.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and

desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the accompanying complaint. An electronic copy of the full text of the consent agreement package can be obtained from the Commission Actions section of the FTC Home Page (for June 26, 1997), on the World Wide Web, at "http://www.ftc.gov/os/actions/htm." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, Sixth Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326-3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

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 Rogério 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 the 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 "Treatments 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 respondent from representing that any product prevents hair loss, unless the product is the subject or 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 Caida 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 presentation.

Part V of the proposed order prohibits the respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretation 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 material 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.

Benjamin Berman,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Three Meetings of the National Bioethics Advisory Commission (NBAC): Its Genetics Subcommittee, Its Human Subjects Subcommittee, and a Full Commission Meeting

SUMMARY: Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of three meetings of the National Bioethics Advisory Commission. The Commission will continue addressing the protection of the rights and welfare of human subjects in research including disadvantaged populations as well as issues in genetics including genetics information relative to tissue storage. The meetings are open to the public and opportunities for statements by the public will be provided.

Dates/times	Locations
Genetics Subcommittee; July 14, 1997, 11:00 am-5:00 pm.	National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 10, Bethesda, Maryland 20892.

Dates/times	Locations
Human Subjects Subcommittee; July 15, 1997, 9:00 am-5:00 pm.	National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 10, Bethesda, Maryland 20892.
Full Commission And Subcommittees; September 18-19, 1997, 7:30 am-5:00 pm.	National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 10.

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) by Executive Order 12975 on October 3, 1995. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council and other entities on bioethical issues arising from the research on human biology and behavior, and in the applications of that research including clinical applications.

Public Participation

The meetings are open to the public with attendance limited by the availability of space. Members of the public who wish to present oral statements should contact the Deputy Executive Director of the NBAC by telephone, fax machine, or mail as shown below prior to the meeting as soon as possible. The Chairs of the full Commission and subcommittees will reserve time for presentations by persons requesting to speak. The order of speakers will be assigned on a first come, first serve basis. Individuals unable to make oral presentations are encouraged to mail or fax their comments to the NBAC staff office at least four business days prior to the meeting for distribution to the subcommittee members or Commission and inclusion in the public record. Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NBAC staff at the address or telephone number listed below as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Henrietta D. Hyatt-Knorr, National Bioethics Advisory Commission, MSC-7508, 6100 Executive Boulevard, Suite 3C01, Rockville, Maryland 20892-7508, telephone 301-402-4242, fax number 301-480-6900.

Henrietta D. Hyatt-Knorr,

Deputy Executive Director, Acting, National Bioethics Advisory Commission.

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