

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 representation.

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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