

## **ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT**

### ***In the Matter of Basic Research LLC, et al., Docket No. 9318***

The Federal Trade Commission (“Commission”) has accepted an agreement containing a consent order, subject to final approval, with Basic Research L.L.C. (“Basic Research”) and five other limited liability companies (“Corporate Respondents”), as well as with Dennis Gay, Daniel Mowrey, and Mitchell Friedlander (“Individual Respondents”), all of whom were named as Respondents in the Complaint issued by the Commission on June 15, 2004.

The agreement and consent order settle charges that the Corporate Respondents and the Individual Respondents (together “Respondents”) violated Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52, by advertising and selling dietary supplements and drugs with unsubstantiated claims for fat loss and/or weight loss, falsely representing that some of these products were clinically proven to be effective, and falsely representing that Respondent Mowrey was a medical doctor. On February 27, 2006, the case was withdrawn from adjudication, so that the Commission could consider the proposed consent order.

The proposed consent order has been placed on the public record for thirty (30) days to receive comments from interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will review the agreement and any comments received, and decide whether to withdraw from the agreement or to make final the proposed order.

The purpose of this analysis is to facilitate comment on the proposed consent order. This analysis does not constitute an official interpretation of the agreement and proposed order and does not modify their terms in any way.

### **The Complaint Allegations**

According to the Commission’s Complaint, Individual Respondents Dennis Gay, Daniel Mowrey (also doing business as American Phytotherapy Research Laboratory), and Mitchell K. Friedlander all worked from the same Salt Lake City, Utah facility as Corporate Respondents Basic Research, L.L.C., A.G. Waterhouse, L.L.C., Klein-Becker usa, L.L.C., Nutrasport, L.L.C., Sovage Dermalogic Laboratories, L.L.C., and BAN, L.L.C., who have operated as a common enterprise to advertise and sell a broad line of topical gels and dietary supplements.

The Commission’s Complaint alleges that these Respondents engaged in deceptive practices in advertising and selling topical fat-loss gels (Dermalin-APg, Cutting Gel, and Tummy Flattening Gel), weight-loss and fat-loss dietary supplements for “significantly overweight” adults containing ephedrine, caffeine and aspirin (Anorex and Leptoprin), and a weight-loss

dietary supplement for children containing glucomannan (PediaLean). Specifically, the Commission's Complaint challenges the following claims as unsubstantiated:

- that Dermalin-APg, Cutting Gel, and Tummy Flattening Gel cause rapid and visibly obvious fat loss in areas of the body to which they are applied;
- that Leptoprin and Anorex cause weight loss of more than 20 pounds in significantly overweight users and that those products cause loss of substantial, excess fat in significantly overweight users; and
- that PediaLean causes substantial weight loss in overweight or obese children.

Additionally, the Complaint challenges the following claims as false:

- that published, clinical testing proves that Cutting Gel and Tummy Flattening Gel cause rapid and visibly obvious fat loss in areas of the body to which they are applied;
- that clinical testing proves that Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and that clinical testing proves that Leptoprin causes loss of substantial, excess fat in significantly overweight users;
- that clinical testing proves that PediaLean causes substantial weight loss in overweight or obese children; and
- that Respondent Mowrey is a medical doctor.

### **The Proposed Consent Order**

The proposed consent order contains provisions designed to prevent Respondents from continuing the illegal conduct alleged in the Complaint, and from engaging in future practices similar to those previously alleged. The proposed order's specific provisions are as follows:

The core prohibitions appear in Paragraphs I through IV. Paragraph I prohibits Respondents from making any unsubstantiated representations that Dermalin-APg, Cutting Gel, Tummy Flattening Gel, Anorex, Leptoprin, PediaLean, or any substantially similar product, cause weight loss or fat loss. At the time that any Respondents make weight loss or fat loss claims for any of those products, Respondents must possess and rely upon a reasonable basis for such claims, which shall consist of competent and reliable scientific evidence.

Paragraph II of the proposed order prohibits Respondents from making any unsubstantiated representations that any food, drug, or dietary supplement has an effect on any disease, on the structure or function of the human body, or other health benefits or weight loss benefits. At the time that any Respondents make any such claims, Respondents must possess and rely upon a reasonable basis for those claims, which shall consist of competent and reliable scientific evidence.

The proposed consent order also prohibits the Respondents from making misrepresentations concerning any test, study, or research (Paragraph III of the proposed order), or concerning the profession, expertise, training, education, experience or qualifications of Respondent Mowrey or any other endorser (Paragraph IV of the proposed order).

As defined in the proposed order, “competent and reliable scientific evidence” means 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. A “substantially similar product” means any product that is substantially similar in ingredients, composition, and properties to any of the six products challenged in the Complaint.

Paragraph V provides that Basic Research will pay the sum of three million dollars (\$3,000,000), on behalf of all Respondents, to the Commission. In the discretion of the Commission, these funds may be used to provide redress to purchasers of any of the products challenged in the Complaint and to pay the attendant administrative costs. If the Commission determines, in its sole discretion, that redress to product purchasers is wholly or partially impracticable or is otherwise unwarranted, any funds not used will be paid to the U.S. Treasury.

The proposed order allows Respondents to engage in various forms of legitimate conduct. The order does not prohibit Respondents from making any claim for any drug that is permitted in labeling for that drug under any tentative final or final standard established by the Food and Drug Administration (“FDA”), or under any new drug application approved by the FDA (Paragraph VI of the proposed order). The order also does not prohibit Respondents from making any claim for any product that is specifically permitted in labeling for that product under FDA regulations made under the Nutrition Labeling and Education Act of 1990 (Paragraph VII of the proposed order).

Additionally, Paragraphs VIII, IX, X, and XI provide for various compliance reports and notifications by the Respondents. Paragraph XII obligates the Respondents to cooperate in certain ways with any Commission inquiry into their compliance with the order. The proposed order will expire in 20 years.