

**ANALYSIS OF PROPOSED CONSENT ORDER
TO AID PUBLIC COMMENT**

*In the Matter of Hi-Health Supermart Corporation and Simon D. Chalpin
File No. 032 3239*

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Hi-Health Supermart Corporation and Simon D. Chalpin (collectively, “Hi-Health”).

The proposed consent order has been placed on the public record for 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 or make final the agreement's proposed order.

This matter involves alleged misleading representations about a dietary supplement, Premier Formula for Ocular Nutrition-Optim3 (“Ocular Nutrition”), marketed by Hi-Health for the treatment of age-related macular degeneration (“AMD”), cataracts, and floaters.

The complaint alleges that Hi-Health failed to substantiate claims that its Ocular Nutrition: (1) restores vision lost from AMD; and (2) eliminates floaters. In addition, the complaint alleges that Hi-Health falsely claimed that: (1) several nutritional studies in responsible medical journals confirm that the ingredients available in Ocular Nutrition may help individuals with cataracts and/or floaters; and (2) a study financed by Hi-Health shows that 83% of ophthalmologists recommend or prescribe Ocular Nutrition to treat age-related macular degeneration and cataracts. The complaint alleges that there are no nutritional studies in responsible medical journals that confirm that the ingredients available in Ocular Nutrition may help individuals with cataracts and/or floaters. In fact, the complaint further alleges that a seven-year study by the National Eye Institute that included all of the primary ingredients available in Ocular Nutrition except lutein found that the ingredients used did not prevent the development or progression of cataract and did not assess the effects of any ingredients on floaters. According to the complaint, a statement issued by the National Eye Institute with regard to lutein cautions that while a number of studies suggest a link between lutein and decreased risk of eye disease, there is little, if any, definitive scientific evidence at this time to support claims that lutein can decrease the risk of developing cataract.

The proposed consent order contains provisions designed to prevent Hi-Health from engaging in similar acts and practices in the future. It also requires a monetary payment to the Commission.

Part I of the proposed order bans unsubstantiated claims that the Ocular Nutrition supplement, or any substantially similar product (1) restores vision lost from macular degeneration, or (2) eliminates floaters. “Substantially similar product” is defined as any product that is (1) substantially similar in ingredients to Ocular Nutrition and (2) promoted for the treatment of eye diseases and conditions, including age-related macular degeneration,

cataract, or floaters.

Part II is a fencing-in provision that would prohibit unsubstantiated benefits, performance, efficacy, or safety claims for any covered product or service. The proposed order defines “covered product or service” as any health-related service or program, dietary supplement, food, drug, or device.

Part III prohibits misrepresentations of the existence, contents, validity, results, conclusions, or interpretations of any test or study in connection with the marketing of any covered product or service.

Part IV permits drug, food, or device claims approved by the Food and Drug Administration under any tentative final or final standard or any new drug application, pursuant to the Nutrition Labeling and Education Act of 1990, or under any new medical device application, respectively.

Part V requires Hi-Health to pay \$450,000 to the Commission as consumer redress no later than ten days after the order becomes final.

Parts VI and VII require Hi-Health to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, and provide copies of the order to certain of its personnel.

Part VIII requires the corporate respondent to notify the Commission of changes in corporate structure.

Part IX of the proposed order requires the individual respondent to notify the Commission of his employment status.

Part X of the order requires Hi-Health to file compliance reports with the Commission, and Part XI provides that the order will terminate 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.