



- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

5. 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 thirty (30) days and information about it will be 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 the proceeding.

6. 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.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1)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 frame 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' address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

8. Proposed respondents have read the draft complaint and consent order. Proposed respondents 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 purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "respondents" shall mean Hi-Health Supermart Corporation, a corporation, its successors and assigns and its officers, and Simon D. Chalpin, individually and as an officer of the corporation; and each of the above's employees with managerial authority.

2. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. "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.
4. "Covered product or service" shall mean any health-related service or program, dietary supplement, food, drug, or device.
5. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).
6. "Food," "drug," and "device," shall mean "food," "drug," and "device" as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.
7. "Substantially similar product" shall mean any product that is (1) substantially similar in ingredients to "Premier Formula for Ocular Nutrition-Optim 3" and (2) promoted for the treatment of eye diseases and conditions, including age-related macular degeneration, cataract, or floaters.
8. The term "including" in this Order shall mean "without limitation."
9. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, trade name, or other device, in connection with the advertising, promotion, offering for sale, or sale of "Premier Formula for Ocular Nutrition-Optim 3" or any substantially similar product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of endorsements, that such product:

- A. Restores vision lost from macular degeneration; or
- B. Eliminates floaters,

unless, at the time it 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, subsidiary, division, trade name, or other device, in connection with the advertising, promotion, offering for sale, or sale, of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, about the benefits, performance, efficacy, or safety of any such product or service, unless, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, trade name, or other device, in connection with the advertising, promotion, offering for sale, or sale, of any covered product or service, 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 or study.

IV.

IT IS FURTHER ORDERED that:

A. 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;

B. 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; and

C. Nothing in this order shall prohibit respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

V.

IT IS FURTHER ORDERED that respondents shall pay to the Federal Trade Commission the sum of **four hundred fifty thousand dollars** (\$450,000). This payment shall be made in the following manner:

A. The payment shall be made by wire transfer or certified or cashier's check made payable to the Federal Trade Commission, the payment to be made no later than

ten (10) days after the date that this order becomes final.

- B. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the amount due, together with interest, as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, shall immediately become due and payable to the Commission.
- C. The funds paid by respondents, together with any accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of Premier Formula for Ocular Nutrition in connection with the acts and practices alleged in the complaint, and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment as herein provided shall be deemed a payment of any fine, penalty or punitive assessment.
- D. Respondents relinquish all dominion, control, and title to the funds paid, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondents shall make no claim to or demand for return of funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of any respondent, respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

## VI.

IT IS FURTHER ORDERED that respondents Hi-Health, and its successors and assigns, and respondent Simon D. Chalpin 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.

VII.

IT IS FURTHER ORDERED that respondents Hi-Health, and its successors and assigns, and respondent Simon D. Chalpin shall deliver a copy of this order to all current and future principals, officers, directors, and other employees with managerial authority 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.

VIII.

IT IS FURTHER ORDERED that respondent Hi-Health, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations that may affect compliance obligations arising under this order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; 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 corporate name or address. Provided, however, that, with respect to any proposed change in the corporations 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, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondent Simon D. Chalpin, for a period of five (5) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his individual current business or employment, or of his individual affiliation with any new business or employment. 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, 601 New Jersey Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondents Hi-Health, and its successors and assigns, and respondent Simon D. Chalpin shall, within sixty (60) days after 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.

XI.

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 \_\_\_\_\_, 2004.

HI-HEALTH SUPERMART CORPORATION.

By: \_\_\_\_\_  
Simon D. Chalpin  
President of the corporation

\_\_\_\_\_  
Simon D. Chalpin, individually and as  
President of the corporation

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James H. Sneed  
McDERMOTT, WILL & EMERY LLP  
Attorney for Respondents

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MATTHEW DAYNARD  
Counsel for the Federal Trade Commission

APPROVED:

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MARY K. ENGLE  
Associate Director  
Division of Advertising Practices

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LYDIA B. PARNES  
Acting Director  
Bureau of Consumer Protection