

Complaint

IN THE MATTER OF

HI-HEALTH SUPERMART CORPORATION, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4136; File No. 0323239
Complaint, May 12, 2005--Decision, May 12, 2005

This consent order, among other things, prohibits the respondents from making unsubstantiated claims that their dietary supplement -- which the respondents had marketed for the treatment of age-related macular degeneration of and cataracts and floaters in the eyes -- or any substantially similar product restores vision lost from macular degeneration or eliminates floaters. The order also prohibits the respondents from making unsubstantiated benefits, performance, efficacy, or safety claims for -- and from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study in connection with the marketing of -- any health-related service or program, dietary supplement, food, drug, or device. In addition, the order requires the respondents to pay \$450,000 to the Commission as consumer redress.

Participants

For the Commission: *Matthew Daynard, Heather A. Hipsley, Mary K. Engle, Carolyn A. Cox, and Gerard R. Butters.*

For the Respondents: *James H. Sneed and William Diaz, McDermott, Will & Emery.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Hi-Health Supermart Corporation, a corporation, and Simon D. Chalpin, individually and as an officer of the corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Hi-Health Supermart Corporation ("Hi-Health") is an Arizona corporation with its principal office or place of business at 7428 East Karen Drive, Scottsdale, Arizona 85260.

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2. Respondent Simon D. Chalpin is president and chief executive officer of Hi-Health. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Hi-Health, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of the corporation.
3. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
4. Respondents have advertised, offered for sale, and sold directly to the public and through the Paul Harvey "News and Comment" radio show "Premier Formula for Ocular Nutrition-Optim 3" ("Ocular Nutrition"), a dietary supplement containing Vitamins A, C, and E, zinc, lutein, zeaxanthin, and other ingredients for the purported treatment of eye diseases and conditions, including age-related macular degeneration, cataract, and floaters. Consumers pay \$39.95 plus shipping and handling for a 25-day supply of Ocular Nutrition. Ocular Nutrition is a "food" or "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
5. Respondents have disseminated or have caused to be disseminated advertisements through the Paul Harvey "News and Comment" radio show, including but not necessarily limited to the attached Exhibits A - F. These advertisements contain the following statements:

A. PAUL HARVEY NOON NEWS 6/17/03

PAUL HARVEY: From the mailbag: Dear Paul Harvey News, I was starting to get gray lines in my vision five years ago when I went to an eye care specialist and I was told that there were floaters made of protein deposits and nothing could be done. Well, they got worse 'til I had them in both eyes. I thought it was a lifetime thing.

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Then I heard you advertising a product called Ocular Nutrition and I thought, what did I have to lose, so I ordered it. And on the first day, my vision became brighter. And now, I've taken them for two days and the dark areas in my vision are nearly gone. I just wanted you to know how well it worked. Thank you very much. Signed, Dorothy Farnum (phonetic), Kearney, Nebraska.

The nutritional supplements now prescribed in three responsible medical journals are Flora Glo Lutein and Vitamins A and C and E and zinc, and you get them all in one capsule from Hi-Health Ocular Nutrition. You can order as I do with a phone call to 1-800-686-2299. Again, the 800 number is 686-2299. [Exhibit A]

B. PAUL HARVEY NOON NEWS 8/7/03

PAUL HARVEY: From the mailbag. Mr. Harvey, my mother is 84; has been to four different eye doctors and bought the strongest eyeglasses that she could get, but her eyesight was fading. We were not going to renew our newspaper or magazine subscriptions because she could not see. But then we got the vitamins you recommended and she started taking them Tuesday, and by Thursday, she was reading our county paper and by Friday, she was reading our Singing News Magazine, which she hadn't been able to read for more than six months. Thank you for telling us about Ocular Nutrition. Signed, Joanne Menshaw (phonetic) of Brighton, Georgia.

There are now several nutritional studies in three responsible medical journals reporting that Flora Glo Lutein and Vitamins A and C and E and zinc can help some individuals with macular degeneration and you can get all of these in one capsule from Hi-Health Ocular Nutrition.

You can order with a phone call as I do to 1-800-686-2299 or go online at www.hihealth.com. Ocular Nutrition from Hi-Health. Again, the 800 number is 686-2299. [Exhibit B]

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C. PAUL HARVEY NOON NEWS 8/20/03

PAUL HARVEY: Page four. Mr. Harvey -- I'm reading from the mailbag -- I'm a man of 83. I have had macular degeneration for four years. I was beginning to think that I'd have to spend the rest of my life in the dark. And then we heard you talking about Ocular Nutrition. My wife said, let's try it. Thank God, Paul Harvey, we did.

We ordered the Premier Formula Ocular Nutrition on March of this year. I stepped out on the porch the other night and I could see a beautiful sky filled with millions of stars and I can see my beautiful wife's face again. Thanks to you and your associates I'll not have to spend the rest of my life in the dark.

P.S. I had been to four eye doctors. They all said there was no cure until I found yours, end quote.

Well, Americans, there are now several nutritional studies confirming, three responsible medical journals confirming that Flora Glo Lutein and Vitamins A and C and E and zinc may help some individuals with macular degeneration and/or with cataracts. And you can get all this nutrition in one capsule from Hi-Health. It's called Ocular Nutrition. You order it with a phone call as I do to 1-800-686-2299 or online at www.hihealth.com.

By the way, a doctor in Chula Vista, California says, with Ocular Nutrition the floaters in his eyes that had been there for two years vanished in two weeks with Ocular Nutrition from Hi-Health. Again, that 800 number is 686-2299. 686-2299. [Exhibit C]

D. PAUL HARVEY SAT. NOON 8/23/03

PAUL HARVEY: Page three. Macular degeneration, MD, it used to a terrifying prognosis. Go home and go blind.

Complaint

We've come a long way. Today's newest nationwide study of ophthalmologists reveals that 93 percent of these professional ophthalmologists are now recommending nutrition therapy.

Now, this is the fourth published study in three years recommending that patients with macular degeneration and/or cataracts should try a combination of vitamins and minerals, A, C, and E and zinc and Flora Glo lutein. This newest study was financed by Hi-Health which makes and markets these vitamins and minerals in a single capsule. They call it Ocular Nutrition and 83 percent of the specialists, the ophthalmologists or anybody with age-related cataracts and/or macular degeneration, 83 percent of them specifically prescribe Ocular Nutrition.

You can get yours as I do with a phone call to 1-800-686-2299 or online at hihealth.com. You can get a copy of this newest research if you'd like to have it by asking for it. But let's start with a phone call to 1-800-686-2299. And for further information, you can go online at hihealth.com. That's hi spelled H-I-, hihealth.com. [Exhibit D]

E. PAUL HARVEY NOON NEWS 8/28/03

PAUL HARVEY: This is from the mailbag. Dear Paul Harvey News: Two years ago, I was diagnosed with macular degeneration and no chance of improvement. I couldn't read the newspaper. But my loving wife heard you touting the benefits of Hi-Health on radio. Immediately she called and ordered some Hi-Health Ocular Nutrition.

My vision has steadily improved. I can read the paper again. What a marvelous feeling. I want everybody to know that there is help for macular degeneration. My thanks to you and to Hi-Health and my wonderful wife for the fact that I can see again. Signed, Jeff Holland of Belle Verde, Texas.

There are several nutritional studies now in three responsible medical journals Reporting that certain nutrients may help

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individuals with macular degeneration and/or cataracts and/or those little floaters that get in your eyes sometimes, and all of those vitamins and minerals, all of them are available in one capsule, if you'll make a phone call to 1-800-686-2299. Ask for Ocular Nutrition. 1-800-686-2299.

If you want to go out and purchase all of those minerals and vitamins and such separately, they're Vitamins A and C and E and zinc and Flora Glo Lutein. But if you want them all in one capsule, just make a phone call as I do to 1-800-686-2299. 1-800-686-2299. [Exhibit E]

F. PAUL HARVEY NOON NEWS 9/9/03

PAUL HARVEY: In Denton, Texas, Harold Reed is a dental doctor, and when his mother was diagnosed with macular degeneration, when she was told there is no treatment for her blurred vision, Dr. Reed remembered that you and I had been talking about a special vitamin formula for Ocular Nutrition and he ordered some for his mother.

Within one month, she reported the dark spot -- the dark spot in her field of vision was gone. Gone. Her vision was back to normal. Dr. Reed says he's always been skeptical of testimonials, but he would never doubt his mother. Well, the nutritional supplements, since prescribed in three responsible medical journals, are Flora Glo Lutein and Vitamins A and C and E and zinc, and you can get them all in one capsule if you like from Hi-Health Ocular Nutrition.

You order with a phone call as I do to 1-800 then 686-2299 or online at www.hihealth.com, www.hihealth.com. Or you can always contact any client of this program through paulharvey.com.

By the way, a doctor in Chula Vista, California says, with Ocular Nutrition, the floaters in his eyes for two years vanished in two weeks. Ocular Nutrition from Hi-Health. Again, the 800 number is 686-2299. [Exhibit F]

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6. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that Ocular Nutrition:

A. Restores vision lost from macular degeneration.

B. Eliminates floaters.

7. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.

8. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.

Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.

9. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that:

A. Several nutritional studies in responsible medical journals confirm that the ingredients available in Ocular Nutrition may help individuals with cataracts and/or floaters.

B. A study financed by Hi-Health shows that 83% of ophthalmologists recommend or prescribe Ocular Nutrition to treat age-related macular degeneration and cataracts.

10. In truth and in fact:

A. 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, a seven-year study by the National Eye Institute that included all of the primary ingredients

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available in Ocular Nutrition except lutein found that the ingredients used did not prevent the development or progression of cataracts and did not assess the effects of any ingredients on floaters. In addition, 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 cataracts.

- B. A study financed by Hi-Health does not show that 83% of ophthalmologists recommend or prescribe Ocular Nutrition to treat age-related macular degeneration and cataracts. In fact, the study respondents were not asked whether they recommend or prescribe Ocular Nutrition to their patients with age-related macular degeneration and cataracts.

Therefore, the representations set forth in paragraph 9 were, and are, false or misleading.

11. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twelfth day of May, 2005, has issued this complaint against respondents.

P R O C E E D I N G S

PAUL HARVEY NOON NEWS 8/17/03

PAUL HARVEY: From the mailbag: Dear Paul Harvey News, I was starting to get gray lines in my vision five years ago when I went to an eye care specialist and I was told that there were floaters made of protein deposits and nothing could be done. Well, they got worse 'til I had them in both eyes. I thought it was a lifetime thing.

Then I heard you advertising a product called Ocular Nutrition and I thought, what did I have to lose, so I ordered it. And on the first day, my vision became brighter. And now, I've taken them for two days and the dark areas in my vision are nearly gone. I just wanted you to know how well it worked. Thank you very much. Signed, Dorothy Farnum (phonetic), Kearney, Nebraska.

The nutritional supplements now prescribed in three responsible medical journals are Flora Glo Lutein and Vitamins A and C and E and zinc, and you get them all in one capsule from Hi-Health Ocular Nutrition. You can order as I do with a phone call to 1-800-686-2299. Again, the 800 number is 686-2299.

(The taping was concluded.)

EXHIBIT A

P R O C E E D I N G S

PAUL HARVEY NOON NEWS 8/7/03

PAUL HARVEY: From the mailbag. Mr. Harvey, my mother is 84; has been to four different eye doctors and bought the strongest eyeglasses that she could get, but her eyesight was fading. We were not going to renew our newspaper or magazine subscriptions because she could not see. But then we got the vitamins you recommended and she started taking them Tuesday, and by Thursday, she was reading our county paper and by Friday, she was reading our Singing News Magazine, which she hadn't been able to read for more than six months. Thank you for telling us about Ocular Nutrition. Signed, Joanne Menshaw (phonetic) of Brighton, Georgia.

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We ordered the Premier Formula Ocular Nutrition on March of this year. I stepped out on the porch the other night and I could see a beautiful sky filled with millions of stars and I can see my beautiful wife's face again. Thanks to you and your associates I'll not have to spend the rest of my life in the dark.

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Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, and having duly considered the comment filed thereafter by an interested person pursuant to § 2.34 of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Hi-Health Supermart Corporation ("Hi-Health") is an Arizona corporation with its principal office or place of business at 7428 East Karen Drive, Scottsdale, Arizona 85260.

2. Respondent Simon D. Chalpin is president and chief executive officer of Hi-Health. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Hi-Health, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of the corporation.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

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).

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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

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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

Decision and Order

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 on May 12, 2025, 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

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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.

Analysis of Proposed Consent Order to Aid Public Comment

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

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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.

Complaint

IN THE MATTER OF

**PRITI SHARMA AND RAJEEV SHARMA,
INDIVIDUALLY AND AS OFFICERS OF Q.P.S., INC.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT.

*Docket C-4138; File No. 0223278
Complaint, June 1, 2005--Decision, June 1, 2005*

This consent order, among other things, prohibits the respondents -- in connection with the manufacturing or marketing of any product or service sold to consumers -- from making any unsubstantiated representation about the time in which any rebate will be mailed or otherwise provided to qualifying consumers; from failing to provide any such rebate within the time specified (or within 30 days, if no time is specified); and from misrepresenting any material terms of any such rebate program.

Participants

For the Commission: *Kerry O'Brien, Linda K. Badger, Matthew D. Gold, Jeffrey A. Klurfeld, Gerard R. Butters, and Paul A. Pautler.*

For the Respondents: *Carlton Varner, Sheppard Mullin Richter & Hampton.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Priti Sharma and Rajeev Sharma, individually and as officers of Q.P.S., Inc. ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Priti Sharma is an officer of Q.P.S., Inc. ("QPS"). Individually or in concert with others, she has formulated, directed, or controlled the policies, acts, or practices of QPS, including the acts or practices alleged in this complaint. Her