UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of

CALIFORNIA SUNCARE, INC., a corporation, and

DONALD J. CHRISTAL, individually and as an officer of said corporation.

File No. 942-3218

AGREEMENT CONTAINING CONSENT ORDER TO CEASE AND DESIST

The Federal Trade Commission, having initiated an investigation of certain acts and practices of California SunCare, Inc., a corporation, and Donald J. Christal, individually and as an officer of said corporation, and it now appearing that California SunCare, Inc., a corporation, and Donald J. Christal, individually and as an officer of said corporation, hereinafter sometimes referred to as proposed respondents, are willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated,

IT IS HEREBY AGREED by and between California SunCare, Inc., by its duly authorized officer, and Donald J. Christal, individually and as an officer of said corporation, and their attorney, and counsel for the Federal Trade Commission that:

1. Proposed respondent California SunCare, Inc., is a

- 3. Proposed respondents waive:
 - (a) Any further procedural steps;
 - (b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and
 - (c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.
- 4. 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 of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the 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 circumstances may require) and decision, in disposition of the proceeding.
- 5. 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 of complaint here attached, or that the facts as alleged in the draft of complaint, other than the jurisdictional facts, are true.
- 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 § 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 draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondents' address as stated in this agreement 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 in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondents have read the proposed complaint and order contemplated hereby. They understand that once the order has been issued, they will be required to file one or more compliance report showing that they have fully complied with the order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

ORDER

For purposes of this Order, the following definitions shall apply:

- 1. "California Tan Heliotherapy products" shall mean the HeliotherapyTM line of skin care products for use in connection with tanning as a result of exposure to sunlight or indoor UV radiation sold under the brand name California Tan®.
- 2. "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.
- 3. "Purchaser for resale" shall mean any person that has bought any California Tan Heliotherapy products to sell to another business or members of the public including, but not limited to, wholesalers, distributors, tanning salons, beauty parlors, health spas, and gyms.

I.

IT IS ORDERED that respondents, California SunCare, Inc., a corporation, its successors and assigns, and its officers, and Donald J. Christal, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any California Tan Heliotherapy product or any other product or service for use in connection with tanning, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing, in any manner, directly or by implication, that the negative effects of exposure to sunlight or indoor UV radiation, including skin cancer and premature skin aging, are caused only by overexposure and burning or are not caused by

sunlight or indoor UV radiation is not harmful to the skin;

- C. Misrepresenting, in any manner, directly or by implication, that the use of such product or service prevents or minimizes the negative effects of exposure to sunlight or indoor UV; or
- D. Representing, in any manner, directly or by implication, that exposure to sunlight or indoor UV radiation reduces the risk of skin cancer.

II.

IT IS FURTHER ORDERED that respondents, California SunCare, Inc., a corporation, its successors and assigns, and its officers, and Donald J. Christal, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any California Tan Heliotherapy product or any other product or service for use in connection with tanning, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that:

- A. Exposure to sunlight or indoor UV radiation prevents or reduces the risk of cancer, including but not limited to colon or breast cancer;
- B. Exposure to sunlight or indoor UV radiation lowers blood pressure;
- C. Exposure to sunlight or indoor UV radiation has benefits similar to those of exercise, including but not limited to decreased blood pressure or lower heart rate;
- D. Exposure to sunlight or indoor UV radiation reduces serum cholesterol;
- E. Exposure to indoor UV radiation is an effective treatment for Seasonal Affective Disorder;
- F. Exposure to sunlight or indoor UV radiation is an effective treatment for AIDS;

- G. Exposure to sunlight or indoor UV radiation enhances the immune system;
- H. For the general population, reduced winter sunlight leads to bone disorders such as osteoporosis and osteomalacia and increased exposure to sunlight or indoor UV radiation is necessary to reduce the risk of such disorders; or
- I. Exposure to sunlight or indoor UV radiation has any health benefit,

unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, California SunCare, Inc., a corporation, its successors and assigns, and its officers, and Donald J. Christal, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any California Tan Heliotherapy product or any other product or service for use in connection with tanning, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication:

A. That the use of such product or service prevents or

IT IS FURTHER ORDERED that respondents, California SunCare, Inc., a corporation, its successors and assigns, and its officers, and Donald J. Christal, individually and as an officer

dissemination to consumers of advertising and promotional material for the product(s) specified above.

For purposes of this subparagraph "advertising or promotional material" shall include such material that is disseminated to consumers either directly, or indirectly through any purchaser for resale, but shall not include television advertising, billboards, or advertising appearing in any periodical sold only by subscription for which fifty percent (50%) or more of the readership is comprised of tanning or beauty salon professionals. Provided, however, that in the event that respondents have not expended at least one million, five hundred dollars (\$1,500,000) on the dissemination of the advertising and promotional material defined above within two (2) years and six (6) months after the date of service of this Order, the exclusions contained in that definition shall terminate and all advertising and promotional material for any such product(s) shall be subject to the disclosure requirements of this subparagraph.

In calculating the amount of expenditures on the dissemination to consumers of the advertising and promotional materials specified above, the costs of distributing, publishing, or broadcasting the advertising and promotional material shall be included, but the costs of developing, designing, creating, or producing the advertising or promotional material (other than printing) shall not be included.

B. Making any representation in any advertising or promotional material for any such product(s), in any manner, directly or by implication, about the safety or any health benefits of exposure to sunlight or indoor UV radiation unless respondents disclose, clearly and prominently, the following:

CAUTION: Tanning in sunlight or under tanning lamps can cause skin cancer and premature skin aging.

For purposes of this subparagraph, "advertising or promotional material" shall include television advertising, billboards, or advertising appearing in any periodical sold only by subscription for which fifty percent (50%) or more of the readership is

comprised of tanning or beauty salon professionals, and, once the requirements of subparagraph A above have been satisfied, all other advertising and promotional material.

C. Making any representation on the labeling or package of any such product that does not contain a sunscreen ingredient providing a minimum of SPF 2, in any manner, directly or by implication, about the safety or any health benefits of exposure to sunlight or indoor UV radiation unless respondents disclose, clearly and prominently, the following:

CAUTION: Tanning in sunlight or under tanning lamps can cause skin cancer and premature skin aging.

This product does not contain a sunscreen and does not protect against sunburn.

For purposes of the display of the disclosure or the corrective statement required by this part ("required information"), "clearly and prominently" shall mean as follows:

- 1. In a television, broadcast, or video advertisement, the required information shall be presented simultaneously in both the audio and video portions of the advertisement. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it.
- 2. In a radio advertisement, the required information shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it.
- 3. In a print advertisement or other printed promotional material, the disclosure shall be displayed in a manner sufficient for an ordinary consumer to see and read it, considering factors including but not necessarily limited to type size and style, location, layout, and contrast with the background against which it appears. No other elements in the advertisement including but not necessarily limited to the layout, graphics, other copy, or depictions, shall detract from or obscure the

prominence of the disclosure. In multipage documents, the disclosure shall appear on the cover or first page.

- 4. On product labeling, the required information shall be set out in the same format in which it appears in subparagraph C above, in at least ten (10) point Times New Roman Bold, in a location on the principal display panel that is sufficiently noticeable for an ordinary consumer to read and comprehend it, and in a print that contrasts sharply with the background against which it appears.
- 5. On a product package, the required information shall be set out in the same format in which it appears in subparagraph C above, in at least twelve (12) point Times New Roman Bold, in a location on the principal display panel that is sufficiently noticeable for an ordinary consumer to read and comprehend it, and in a print that contrasts sharply with the background against which it appears.

Nothing contrary to, inconsistent with, or in mitigation of the required information shall be used in any advertising, promotional material, labeling, or packaging.

VI.

IT IS FURTHER ORDERED that respondents, California SunCare, Inc., its successors and assigns, and Donald J. Christal shall:

- A. Within thirty (30) days after the date of service of this Order, send by first class certified mail, return receipt requested, to each purchaser for resale of any California Tan Heliotherapy product with whom respondents have done business since January 1, 1993, an exact copy of the notice attached hereto as Attachment A. The mailing shall include no other document;
- B. In the event that respondents receive any information that subsequent to receipt of Attachment A any purchaser for resale is using or disseminating any advertisement or promotional material that contains any representation prohibited by this Order, respondents shall immediately notify the purchaser for resale that respondents will terminate the use of said purchaser for resale if it continues to use such advertisements and promotional materials; and

C. Terminate any purchaser for resale about whom respondents receive any information that such purchaser for resale has continued to use advertisements or promotional materials that contain any representation prohibited by this Order after receipt of the notice required by subpart B of this part.

VII.

IT IS FURTHER ORDERED that the provisions of this Order shall not apply to any label or labeling printed prior to the date of service of this Order and shipped by respondents to purchasers for resale prior to one hundred (100) days after service of this Order; provided, however, that any multipage fold-out labels that contain claims that violate Parts I through IV of this Order shall be removed from all products in respondents' inventory prior to shipping after the date of service of this Order.

VIII.

IT IS FURTHER ORDERED that respondents, California SunCare, Inc., its successors and assigns, and Donald J. Christal shall for five (5) years after the last correspondence to which they pertain, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. Copies of all notification letters sent to purchasers for resale pursuant to subparagraph A of part VI of this Order; and
- B. Copies of all communications with purchasers for resale pursuant to subparagraphs B and C of part VI of this Order.

IX.

Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any 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.

х.

IT IS FURTHER ORDERED that for five (5) years after the last date of dissemination of any representation covered by this Order, respondents, or their successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All materials that were relied upon in disseminating such representation; and
- B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers or government organizations.

XI.

IT IS FURTHER ORDERED that respondent California SunCare, Inc., its successors and assigns, shall:

- A. Within thirty (30) days after the date of service of this Order, provide a copy of this Order to each of respondent's current principals, officers, directors, and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this Order; and
- B. For a period of ten (10) years from the date of service of this Order, provide a copy of this Order to each of respondent's future principals, officers, directors,

- A. Any paragraph of this Order that terminates in less than twenty (20) years;
- B. The 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 paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondents 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 paragraph as though the complaint was never 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.

XV.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after service of this Order, and at such other times as the 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.

Signed	this		day of			, 199_	
		CALI	FORNIA	SUNCARI	E, INC.,	a corpora	tion.
		ву:	1100 (Slendon	Avenue,	President Suite 125 nia 90002	
			and as		ficer of	individual Californi	_

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Respondents

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APPROVED:

C. Lee Peeler
Associate Director
Division of Advertising Practices

Joan Z. Bernstein Director Bureau of Consumer Protection

ATTACHMENT A

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED
[To be printed on California SunCare, Inc., letterhead]

[date]

Dear [purchaser for resale]:

This letter is to inform you that California SunCare, Inc. ("California Tan"), recently settled a civil dispute with the Federal Trade Commission ("FTC") regarding certain alleged claims for our Heliotherapy $^{\text{TM}}$ line of skin care products. As part of that settlement, we are required to notify our distributors and others who sell our products to consumers to stop using or distributing any advertisements or promotional materials containing any such claims.

Allegations of the FTC complaint.

The FTC alleged that certain advertisements and promotional materials for California Tan Heliotherapy products made false and/or unsubstantiated claims, expressly or by implication, that tanning as a result of exposure to sunlight or indoor UV radiation:

reduces the risk of certain cancers;

- the negative effects of exposure to sunlight or indoor UV radiation, including skin cancer and premature skin aging, are caused only by burning and overexposure and not moderate exposure and tanning;
- tanning as a result of exposure to sunlight or indoor UV radiation is not harmful to the skin;
- use of the products prevents or minimizes the negative effects of exposure to sunlight and UV radiation, including skin cancer and premature skin aging;
- the MAXIMIZER products help users achieve up to 42% better tanning results; and
- the products that contain VITATAN improve users' ability to tan by up to 67%.

Finally, the complaint charges that advertising and promotional materials falsely represented, expressly or by implication, that scientific studies demonstrate that exposure to sunlight or indoor UV radiation provides the health benefits stated above and that the American Medical Association endorses exposure to sunlight or indoor UV as a medical treatment.

Our settlement with the FTC.

Our settlement with the FTC prohibits us from making the above listed claims for California Tan Heliotherapy products or any other product for use in connection with tanning, unless the claims are supported by competent and reliable evidence. The settlement also requires us to substantiate any claims about the health benefits of exposure to sunlight or indoor UV radiation and the performance and safety of our skin care products for use in connection with tanning. The settlement also precludes us from making misrepresentations about scientific studies or endorsements.

Under the terms of our settlement with the FTC, all of our advertising for tanning products, with the exception of billboards, television advertising, and advertisements in magazines for salon professionals, for a period of time, must contain a disclosure to the effect that tanning without burning, either with tanning lamps or in sunlight, can cause skin injury. Even after that period ends, if in the future we make any claim about the safety or health benefits of exposure to sunlight or indoor UV radiation in our advertising, labeling or packaging, we must disclose that tanning is associated with skin damage.

We deny the FTC's allegations, but in order to avoid protracted litigation we have entered into a settlement agreement

UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of

CALIFORNIA SUNCARE, INC., a corporation, and

DOCKET NO.

DONALD J. CHRISTAL, individually and as an officer of said corporation.

COMPLAINT

The Federal Trade Commission, having reason to believe that California SunCare, Inc., a corporation, and Donald J. Christal, individually and as an officer of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH ONE: Respondent California SunCare, Inc., is a California corporation, with its principal office or place of business at 1100 Glendon Avenue, Suite 1250, Los Angeles, California 90024.

Respondent Donald J. Christal is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs and controls the acts and practices of the corporate respondent, including the acts and practices alleged in this complaint. His principal office and place of business is the same as that of the corporate respondent.

PARAGRAPH TWO: Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed skin care products for use in connection with tanning in sunlight or indoor UV radiation emitted by tanning beds and artificial sunlamps, and other products. These skin care products are sold under the trade name HeliotherapyTM and the brand name California Tan® (hereinafter referred to as "California Tan Heliotherapy products"). California Tan Heliotherapy products are "drugs" or

"cosmetics" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PARAGRAPH THREE: 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.

PARAGRAPH FOUR: Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for California Tan Heliotherapy products, including but not necessarily limited to the attached Exhibits A-J. These advertisements and promotional materials contain the following statements and depictions:

A. "I love the sun, but how can I feel good about tanning?"

Heliotherapy $^{\text{TM}}$...

The Positive Effects of The Sun™

While overexposure to the sun and burning are bad for you, medical studies demonstrate that, in moderation, exposure to sunlight is crucial for the maintenance of good physical and psychological health. Besides making you feel good about how you look, numerous studies indicate that little to no exposure to the sun may be equally as bad, if not worse, to your overall health as too much sun.

Did You Know?

. . . .

- \bullet Exposure to sunlight increases the body's ability to metabolize cholesterol, leading to a 13% decrease in blood cholesterol levels. (New England Medical Journal, 1953)
- Studies indicate that exposure to UV light may have similar effects as exercise: a decrease in blood pressure, a lower resting heart rate and a 39% increase in the heart's output of blood. (University of Frankfurt, Germany, 1992)
- Seasonal Affective Disorder (SAD), with symptoms such as as [sic] sadness, insomnia and carbohydrate cravings, is common in northern areas where exposure to sunlight in winter months is significantly decreased. (National Institute of Mental Health, 1985)

Of course, no single study or studies may prove scientific fact. As further studies are done, science will tell us more about the effects of sun exposure. However, as these studies

REMEMBER! The key to maximizing the positive effects of the sun is to achieve the perfect balance. Take care to get just the right amount of sun to maintain your health, but don't ever allow yourself to burn. REPEATED OVEREXPOSURE TO THE SUN CAN LEAD TO PREMATURE AGING, WRINKLING AND SKIN CANCER. Moderate exposure, however, in combination with the use of California Tan's exclusive Heliotherapy™ formulas can help you to optimize a proven positive effect of the sun - your tan.

CAUTION: California Tan® products are intended to be used for tanning and moisturization only. They ARE NOT intended to produce any of the reported physiological and psychological benefits of the sun that are described above.

Studies provided by California Tan's Scientific Research Center (Exhibit A, brochure)

B. VITATAN™

The Tanning Technology of the Future

. . . .

• VITATAN™ delivers an additional molecule of oxygen to the surface of the skin which significantly enhances the oxidation of melanin for faster tanning results.

When compared to Unipertan, products containing 2% VITATAN^{\mathbb{M}} help improve your natural ability to develop a golden brown base tan by up to 67%.

Heliotherapy™ Maximizer - VT™

. . .

[new page]

$Heliotherapy^{TM}$. . .

The Positive Effects of The Sun™

California Tan's Scientific Research Center, a panel of renowned scientists and researchers, reviews thousands of studies on the effects of sunlight. Inspired by Heliotherapy $^{\text{\tiny TM}}$... The Positive Effects of the Sun $^{\text{\tiny TM}}$, California Tan® created the complete Heliotherapy three step system to help you maximize a proven positive effect of the sun - your tan

CONDITION

MEDICAL EFFECT

AIDS

AIDS is a fatal and uncurable epidemic.

Preliminary studies indicate that phototherapy may be beneficial in treating patients with AIDS-related complex.

Cancer Prevention

Breast and colon cancer can be fatal if not detected early.

Sunlight exposure may prevent certain types of cancer: colon and breast cancer rates are three times higher in northern states like New Hampshire and Vermont compared to sunny states like New Mexico and Arizona.

. . . .

Fitness

Fitness increases energy and reduces risk of

Exposure to sunlight may have similar effects to exercise: decreased blood pressure, lower resting

. . . .

• Scientists at the Baylor University Medical Center have successfully used heliotherapy to destroy the AIDS virus and other infectious diseases and are developing heliotherapy to decontaminate blood for transfusions.

. . . .

While fully recognizing that long term overexposure to the sun and burning can result in skin cancer, premature aging and wrinkling in some cases, the science of heliotherapy supports that the sun also offers many benefits. In the months to come, California Tan's Scientific Research Center will uncover the **FACTS** about **Heliotherapy**...The Positive Effects of The Sun^{TM} ...

Studies provided by California Tan's Scientific Research Center

. . . .

1 • 800 • SUN • CARE

CALIFORNIA TAN®

The science of heliotherapy has inspired the California Tan^{\otimes} **Heliotherapy** line of products. These products are intended to be used for tanning and moisturization only and **not** for any of the psychological or physiological benefits described in this advertisement.

SOLD IN SALONS

(Exhibit C, magazine ad)

D. Is Sunlight the Answer

for cancer prevention?

New studies from the University of California, San Diego indicate that exposure to sunlight may play an important role in the prevention of certain types of cancer. While long-term overexposure to the sun and burning can be harmful, this research shows that the sun may have many properties that help prevent breast, colon and ovarian cancer.

As a leader in the study of Heliotherapy, California Tan's Scientific Research Center has uncovered thousands of studies demonstrating the benefits of UV-exposure.

CALIFORNIA TAN® HeliotherapyTM... The Positive Effect of The SunTM (Exhibit D, magazine ad)

E. From high blood pressure to AIDS . . .

Is Sunlight the Cure of the `90's?

Although the experts warn against long-term overexposure to the sun and burning, new research points to the healing powers of the sun

Today, people are looking for more natural cures for everything from common ailments to serious diseases. As a major contributor to the science of Heliotherapy $^{\text{IM}}$, California Tan's Research Center has uncovered hundreds of studies demonstrating the positive effects of sun exposure.

• In a recent study by Dr. Zane Kime, patients with high blood pressure experienced a dramatic decrease in blood pressure lasting five to six days after just one treatment of UV- light.

. . . .

- According to studies conducted by Dr. Norman Rosenthal at the National Institute of Mental Health, light treatment is the most effective cure for Seasonal Affective Disorder (SAD), or the winter blues.
- UV-light treatment is on the forefront of the search for an AIDS cure. Scientists at Baylor University Medical Center have used light to destroy the AIDS virus and other infectious diseases.

Even though the jury is still out on the true effects of sun exposure, we are now discovering that the sun plays an important role in the maintenance of good health. Through the science of Heliotherapy $^{\text{TM}}$, we are learning that balance is most important. Overexposure and burning can lead to skin cancer in some cases. However, in the right amounts, we can benefit from the sun's healing powers.

• • •

CALIFORNIA TAN®

Heliotherapy™...The Positive Effects of The Sun™ (Exhibit E, magazine ad)

F. Heliotherapy™

The Positive Effects of The Sun™

CALIFORNIA TAN®

California Tan's Scientific Research Center, a panel of renowned doctors, researchers and dermatologists, reviews thousands of studies each year about the positive and negative effects of UV-light. Overexposure and burning are bad for you and may lead to premature aging and skin cancer. However, medical evidence shows that sunlight is connected to everything from osteoporosis prevention to vitamin D synthesis.

[picture of California Tan Heliotherapy products]

Inspired by the science of Heliotherapy, California Tan® has created scientifically proven formulations to help you maximize a proven positive effect of the sun-your tan. [caption]

CANCER PREVENTION: Research from Dr. Cedric Garland at the University of California, San Diego suggests that sunlight may prevent certain types of cancer: colon and breast cancer rates are three times higher in northern states compared to sunny southern states. OSTEOPOROSIS: A new study by Dr. J. Rosen demonstrates that reduced winter sunlight can lead to osteoporosis and the vitamin D deficient bone disease osteomalacia (adult rickets). SEASONAL AFFECTIVE DISORDER (SAD): A 1993 study by Dr. A. Wirz-Justice shows that 70% of SAD patients show improvement after light treatment, the only known cure for the "winter blues." SKIN CANCER: Skin cancer has been linked to non-UV causes: diet, genetics, and alcohol, according to a 1992 study by Dr. L. Marchand. VITAMIN D: A 1990 study by Dr. Matsuoka shows that vitamin D, which regulates calcium and phosphorus absorption and is needed to maintain a healthy skeleton, is produced during the tanning process.

California Tan products are intended to be used for tanning and moisturization only. They ARE NOT intended to produce any of the reported possible physiological and psychological benefits of the sun that are described above.

(Exhibit F, magazine ad)

G. CALIFORNIA TAN® TROPICAL **FURY™**

Heliotherapy™ MAXIMIZER™

Maximize The Positive Effects of the Sun™

. . . .

• A unique, scientifically proven blend of California Tan's **Heliotherapy™** MAXIMIZER Complex provides the most effective moisturization to help you achieve up to 42% better tanning results and counteract the drying effects of the sun for a spectacular, golden brown tan.

. . . .

CALIFORNIA TAN® **Heliotherapy™...**

The Positive Effects of The Sun™

California Tan's exclusive Heliotherapy™ formulas are a precise, scientifically proven combination of state-ofthe-art skin care and tanning ingredients that help you maximize a proven positive effect of the sun - your tan!

While it's true that over exposure to the sun and burning are bad for you, medical science has also discovered that, in moderation, exposure to the sun is crucial to the maintenance of good physical and psychological health.

In addition to the fact that a tan makes you feel good about how you look, a number of studies have noted that little to no sun exposure may be equally as bad, if not worse, to your overall health as too much sun.

DID YOU KNOW THAT?

- According to a study conducted by the University of Sydney and Melanoma Clinic in 1982, the people with the lowest risk of skin cancer were those whose main outdoor activity was sunbathing. (see note 1)
- The same study also found that the highest incidence of skin cancer occurred in those who spent most of their time indoors under fluorescent lighting which is deficient of the ultraviolet portion of the sun spectrum. (see note 2)

. . . .

• In a 1980 study, it was concluded that exposure to sunlight produces the same benefits as exercise: increases in strength, energy, endurance, tolerance to stress, and the ability of the blood to absorb and carry oxygen; and decreasing the resting heart rate, blood pressure, respiratory rate, blood sugar and lactic acid. (see note 6)

. . . .

- Researchers also found that the dietary vitamin D found in milk and vitamin supplements is not a sufficient replacement to the vitamin D that is produced by exposure to the sun for the maintenance of healthy bones and teeth and at high levels, dietary vitamin D has been found to be very toxic. (see note 8)
- Studies indicate that exposure to ultra-violet light is an effective tool for lowering elevated blood pressure. (see note 9)
- According to a recent study conducted at the Tulane University, the heart became stronger and pumped more blood when the subjects were exposed to ultra-violet light. (see note 10)

. . . .

- Sunlight has been scientifically proven in numerous studies to reduce serum cholesterol levels. (see note 12)
- In a study conducted by The American Society for the Study of Arteriosclerosis, 97% of the subjects had a 13% decrease in the level of cholesterol within two hours after the first exposure. (see note 13)

. . . .

• In 1987, the Wall Street Journal reported that chickens raised under full-spectrum lighting, the closest match to natural sunlight, lived twice as long, laid more eggs, were less aggressive, and laid eggs that were 25% lower in cholesterol than chickens raised under fluorescent lighting. (see note 15)

. . . .

Of course, no single study or studies may prove scientific fact. And as further studies are done, science will tell us more about the effects of sun exposure. But these studies emphasize that the sun may have positive as well as negative effects

REMEMBER!

The key to maximizing the positive effects of the sun is to achieve the perfect balance. Take care to get just the right amount of sun to maintain your health, but don't ever allow yourself to burn. REPEATED OVEREXPOSURE TO THE SUN CAN LEAD TO PRE-MATURE AGING, WRINKLING AND SKIN CANCER. Moderate exposure, however, in combination with the use of California Tan's exclusive Heliotherapy™ formulas can help you optimize the beneficial aspects of having a spectacular, golden brown tan while minimizing the negative effects of over exposure and skin dehydration.

CALIFORNIA TAN® Heliotherapy™

ACHIEVE A SPECTACULAR DEEP DARK, TAN AND FEEL GOOD ABOUT IT

CAUTION

California Tan products are intended TO BE USED FOR TANNING AND MOISTURIZATION ONLY. They ARE NOT intended to produce any of the physiological and psychological benefits of the sun that the studies describe.

Studies provided by California Tan's Scientific Research Center

(Exhibit G, Tropical Fury Heliotherapy

• Colon and breast cancer deaths are three times higher in northern states like New Hampshire and Vermont compared to sunny states like New Mexico and Arizona. (University of California, San Diego, 1986) 12

. . . .

Of course, no single study or studies may prove scientific fact. As further studies are done, science will tell us more about the effects of sun exposure. However, as these studies emphasize, the sun may have positive effects as well as negative effects.

Remember!!

The key to maximizing the positive effects of the sun is to achieve the perfect balance. Take care to get just the right amount of sun to maintain your health, but don't ever allow yourself to burn. REPEATED OVEREXPOSURE TO THE SUN CAN LEAD TO PRE-MATURE AGING, WRINKLING AND SKIN CANCER. However, moderate exposure in combination with the use of California Tan's exclusive Heliotherapy™ formulas can help you optimize the beneficial aspects of having a spectacular, golden brown tan while minimizing the negative effects of overexposure and dehydration.

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CAUTION:

California Tan® products are intended to be used for tanning and moisturization only. They ARE NOT intended to promote any of the reported physiological and psychological benefits of the sun that are described above.

Studies provided by California Tan's Scientific Research Center

(Exhibit H, Tropical Sizzle Heliotherapy™ Maximum Strength Intensifier label)(citations omitted)

I. HeliotherapyTM...

The Positive Effects of the Sun™

California Tan's Scientific Research Center, a panel of the world's most renowned scientists, reviews thousands of studies relating to light and health which inspired California Tan to create its exclusive **Heliotherapy**^M three step system that contains the precise combination of proven tanning and skin care ingredients to help you maximize a positive effect of the sun - your tan. *Burning and overexposure are bad for you.* But sunlight is essential for your psychological and physiological good health.

HELIOTHERAPY™ REFERENCE CHART

CONDITION

MEDICAL EFFECT

AIDS

AIDS is a fatal and incurable epidemic.

Preliminary studies indicate that phototherapy may be beneficial in treating patients with AIDS-related complex.

Cancer Prevention

Breast and colon cancer can be fatal if not detected early.

Sunlight exposure may prevent certain types of cancer: colon and breast cancer rates are three times higher in northern states like New Hampshire and Vermont compared to sunny states like New Mexico and Arizona.

Fitness

Fitness increases energy and reduces risk of heart disease.

Exposure to sunlight may have similar effects as exercise: decreased blood pressure, lower resting heart rate, a 39% increase in the output of blood.

. . . .

Osteoporosis

Osteoporosis is a growing epidemic of weak bones in the U.S.

Significant seasonal bone loss due to lack of sunlight produced vitamin D is prominent in areas with reduced winter sunlight and can lead to Osteoporosis.

. . . .

CONDITION

MEDICAL FACT/BENEFIT

Seasonal Affective Disorder (SAD)

More than 25 million Americans suffer from SAD each year.

. . . .

A 1993 study shows that 70% of patients with SAD show improvement after light treatment, the only known cure for the "winter blues."

Skin Cancer

Skin cancer has been linked to non-UV causes: diet, genetics and alcohol.

. . . .

[each "EFFECT" or "BENEFIT" accompanied by citation]

Studies provided by California Tan's Scientific Research Center

While these studies indicate a wealth of benefits may result from sun exposure, no single study or studies may prove scientific fact. As research continues, science will reveal more about the effects of the sun. These studies emphasize that the sun may have positive as well as negative effects.

J. **♣**% ♣ ♣

- B. Tanning as a result of exposure to sunlight or indoor UV radiation is not harmful to the skin.
- C. Use of California Tan Heliotherapy products prevents or minimizes the negative effects of exposure to sunlight or indoor UV radiation, including skin cancer and premature skin aging.
- D. Exposure to sunlight or indoor UV radiation reduces the risk of skin cancer.

PARAGRAPH SIX: In truth and in fact:

- A. The negative effects of exposure to sunlight or indoor UV radiation, including skin cancer and premature skin aging, are not caused only by overexposure or burning, but also can be caused by cumulative moderate exposure, over a period of years, including exposure sufficient to cause tanning.
- B. Tanning as a result of exposure to sunlight or indoor

- C. Exposure to sunlight or indoor UV radiation has benefits similar to those of exercise, including decreased blood pressure and lower heart rate.
- D. Exposure to sunlight or indoor UV radiation significantly reduces serum cholesterol.

materials attached as Exhibits A-J, respondents have represented, directly or by implication, that:

- A. Scientific studies demonstrate that exposure to sunlight or indoor UV radiation provides the health benefits set forth in PARAGRAPHS FIVE and SEVEN.
- B. The American Medical Association has endorsed exposure to sunlight or indoor UV radiation as an effective medical treatment.

PARAGRAPH ELEVEN: In truth and in fact,

- A. Scientific studies do not demonstrate that exposure to sunlight or indoor UV radiation provides the health benefits set forth in PARAGRAPHS FIVE and SEVEN.
- B. The American Medical Association has not endorsed exposure to sunlight or indoor UV radiation as an effective medical treatment.

Therefore, the representations set forth in PARAGRAPH TEN were, and are, false and misleading.

PARAGRAPH TWELVE: 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 day of 199 , has issued this complaint against respondents.

By the Commission.

Donald S. Clark Secretary

SEAL:

[Exhibits A-J attached to paper copies of complaint, but not available in electronic form.]

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from California Suncare, Inc., the manufacturer and marketer of "California Tan Heliotherapy" tanning products, and its president, Donald J. Christal [hereinafter sometimes referred to as respondents].

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) 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.

The Commission's complaint in this matter concerns representations made by respondents for their Heliotherapy line of skin care products, which are designed to be used in connection with tanning. The complaint alleges that certain advertisements and promotional materials disseminated by respondents have contained false or unsubstantiated claims about the safety and health benefits of exposure to ultraviolet radiation ("UVR") from the sun or indoor tanning salons, and about the benefits and efficacy of the Heliotherapy products.

More specifically, the complaint alleges that respondents falsely represented that:

- -- the negative effects of UVR, including skin cancer and premature skin aging, are caused only by overexposure and burning, and not by moderate exposure;
- -- tanning as a result of UVR exposure is not harmful to the skin;
- -- use of Heliotherapy products prevents or minimizes the negative effects of UVR; and
- -- exposure to UVR reduces the risk of skin cancer.

The complaint further challenges as unsubstantiated respondents' claims that exposure to UVR:

- -- prevents or reduces the risk of colon and breast cancer;
- -- lowers elevated blood pressure;

- -- has benefits similar to those of exercise, including decreased blood pressure and lower heart rate;
- -- significantly reduces serum cholesterol;
- -- is an effective treatment for AIDS;
- -- enhances the immune system; and
- -- is necessary for the general population to reduce the risk of bone disorders such as osteoporosis and osteomalacia, which can be caused by reduced winter sunlight.

The complaint also alleges that respondents' claim that exposure to indoor UVR is an effective treatment for Seasonal Affective Disorder is unsubstantiated.

In addition, the complaint challenges as unsubstantiated certain claims about the tanning efficacy of certain Heliotherapy products, including claims that Heliotherapy MAXIMIZERS help users achieve up to forty-two percent better tanning results and that Heliotherapy products with two percent VITATAN improve users' ability to tan by up to sixty-seven percent.

Finally, the complaint charges that respondents falsely represented that scientific studies demonstrate that exposure to UVR provides the health benefits set forth above and that the American Medical Association endorses exposure to UVR as an effective medical treatment.

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 order prohibits respondents from making the false claims alleged in the complaint about the lack of harm from moderate UVR exposure and tanning, and the benefits of UVR in reducing the risk of skin cancer. Part I also prohibits misrepresentations about the ability of any tanning products or services to prevent or minimize the adverse effects of UVR exposure.

Part II requires scientific substantiation for the claims about health benefits from UVR exposure challenged as unsubstantiated in the complaint, and for any claims about the health benefits of sunlight or indoor ultraviolet radiation. Part III of the order requires substantiation for claims that any tanning product or service prevents or minimizes the harms of UVR

or will improve tanning or about the performance, safety, benefits, or efficacy of any such product or service.

Part IV prohibits misrepresentations about studies or official endorsements for any product or service.

The order also requires certain clear and prominent disclosures in future advertising and labeling for certain tanning products about the risks of exposure to sunlight or indoor ultraviolet radiation. Part V.A requires a disclosure in future ads and promotional materials for all tanning products that do not contain a sunscreen ingredient providing a minimum sun protection factor (SPF) of two. The disclosure reads as follows:

CAUTION: Tanning in sunlight or under tanning lamps can cause skin cancer and premature skin aging -- even if you don't burn.

The disclosure is required in all advertising, with the exception of television advertising, billboards, and publications directed primarily to salon professionals. The exempted publications are limited to periodicals sold only by subscription with a readership of at least fifty percent salon professionals. The above disclosure must be made in all nonexempt advertising until the respondents have spent \$1,500,000 disseminating advertisements with the disclosure to consumers. If that amount is not spent within two years and six months after the order becomes effective, the exemptions no longer apply and the disclosure must appear in all advertising until the amount above is expended.

Parts V.B and C require disclosures about the adverse effects of tanning in advertising and product labeling for tanning products that contain representations about the health benefits or safety of exposure to UVR. The advertising disclosure becomes effective immediately in the case of the three types of advertising that are exempt from Part V.A as described above and becomes effective for all other types of advertising once the requirements of Part V.A have been satisfied. The labeling disclosure is required when the order becomes effective and applies to any tanning product not containing a sunscreen ingredient of at least SPF two. The label disclosure in addition to cautioning about the harms of tanning, states that the product does not contain a sunscreen and does not protect against burning.

Part VI requires respondents to send a letter (appended to the order) to people who purchased Heliotherapy products for

resale such as distributors and retailers. The letter describes the Commission's action and advises recipients to discontinue use of promotional materials that contain the challenged claims. The record keeping requirements for this part are laid out in Part VII. Part VII.C requires the respondents to warn and ultimately to stop doing business with recipients of the letter who continue to use materials that make the challenged claims.

Part VII contains a provision permitting respondents to use old labeling for 100 days after the effective date of the order. However, it requires the removal of all the fold-out labels once the order becomes effective.

The remaining parts of the order contain standard provisions with respect to record keeping, safe harbors for claims approved by the Food and Drug Administration, compliance, and sunsetting the order after twenty years.

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.

Statement of Commissioner Roscoe B. Starek, III, Concurring in Part and Dissenting in Part in California Suncare, Inc., File No. 942-3218

I have voted to accept for public comment the consent agreement with California Suncare, Inc. (CSI) because, for the most part, it provides appropriate relief for the extremely serious misrepresentations alleged in the complaint about the health and safety effects of ultraviolet radiation (UVR) exposure and the benefits and efficacy of the company's tanning products. However, I do not support including the "untriggered" disclosure in Part V.A. of the proposed order. In my view this remedy constitutes corrective advertising, and I am not convinced that the evidence here meets the standard for imposing corrective advertising set forth in *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 762 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

Both the characteristics and scope of the untriggered disclosure lead me to conclude that it is actually corrective advertising in disguise. The disclosure requirement has certain characteristics usually associated with corrective advertising: it runs until a specific time period expires and a specific sum of money is exhausted, and it must be made regardless of the representations CSI makes about its products. *See, e.g., American Home Products Corp. v. FTC*, 695 F.2d 681, 700 (3d Cir. 1982) ("[A] genuine corrective advertising requirement . . . demand[s] disclosure in future advertisements regardless of the content of those advertisements."). Most significant, however, the scope of the untriggered disclosure far exceeds its rationale. The disclosure must appear in CSI's general advertising as well as in all promotional materials distributed directly to consumers for any tanning product that does not

Part V.A. requires CSI to include the following statement in all advertising and promotional materials disseminated directly to consumers or through purchasers for resale (except television advertising, billboards and advertising in magazines sold only by subscription for which half or more of the readership is comprised of tanning or beauty salon professionals): "CAUTION: Tanning in sunlight or under tanning lamps can cause skin cancer and premature aging -- even if you don't burn." This disclosure is applicable to all of respondent's products that contain a sunscreen ingredient providing a sun protection factor (SPF) of less than 2 and must be made until CSI spends \$1.5 million on dissemination. If CSI does not expend this amount within $2\frac{1}{2}$ years after the service of the order, the untriggered disclosure then becomes applicable to all forms of advertising until the required amount is spent.

² It is difficult to draw bright lines between these possible forms of fencing-in relief, and I am not suggesting that the Commission forgo ordering affirmative disclosures in all circumstances in which the disclosures, while targeted primarily at the prevention of deception from future claims, may also incidentally affect a possible lingering public misimpression created by past advertising. This situation is not the case presented here.

³ In addition to prohibiting misrepresentations about the effects of UVR exposure and tanning and unsubstantiated claims about the performance, safety, benefits, or efficacy of products or services used in connection with tanning, the proposed order requires two additional affirmative disclosures (Parts V.B. and V.C.) that are triggered by claims about the safety or health benefits of exposure to sunlight or indoor UVR. The language of these triggered disclosures is similar to that of the untriggered disclosure. The triggered disclosures apply to labeling and packaging --forms of advertising exempted from the untriggered disclosure -- and, after the untriggered disclosure requirement runs out, to all other advertising

nature and extent of the advertising campaign. *Warner-Lambert*, 562 F.2d at 762-63.⁴ An affirmative disclosure remedy, on the other hand, requires only that the disclosure be "reasonably related" to the alleged violations. In my view, it is important to distinguish between corrective advertising and affirmative disclosures because the Commission should not evade the more demanding standard for corrective advertising where it is clearly applicable.

There appears to be little basis for Part V.A. of the proposed order when it is viewed

⁴ See, e.g., Eggland's Best, Inc., Docket No. C-3520 (Aug. 15, 1994) (Statement of Roscoe B. Starek, III).