UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of))
CMO DISTRIBUTION CENTERS)
OF AMERICA, INC.,)
a corporation, and)
KALON SAMULONIS,)
individually and as an officer))
of the corporation.)
)

FILE NO. 982 3180

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission has conducted an investigation of certain acts and practices of proposed respondents, CMO Distribution Centers of America, Inc. and Kalon Samulonis, individually and as an officer of the corporation. Proposed respondents are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between CMO Distribution Centers of America, Inc., by its duly authorized officer, and Kalon Samulonis, individually and as an officer of the corporation, and counsel for the Federal Trade Commission that:

1. Proposed respondent CMO Distribution Centers of America, Inc. ("CDC") is a Michigan and Florida corporation with its principal office or place of business at 6479 Parkland Drive, Sarasota, FL 34243.

2. Proposed respondent Kalon Samulonis is the President of the corporate respondent. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of CDC.

3. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.

- 4. 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.

5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect, and may be altered, modified, or set aside in the same manner and within the same time, provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondents' address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order. 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.

8. Proposed respondents have read the draft complaint and consent order. Proposed respondents understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

<u>ORDER</u>

DEFINITIONS

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

1. "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.

2. "CMO" shall mean any product or substance that contains or purports to contain cetylmyristoleate (also known as cetyl myristoleate) or "CMO," any analogue of cetylmyristoleate, or any formulation of cetyl alcohol and myristoleic acid, including but not limited to CMOTM.

3. Unless otherwise specified, "respondents" shall mean CDC, its successors and assigns; Kalon Samulonis, individually and as an officer of the corporation; and each of their agents, representatives and employees.

- 4. "Clearly and prominently" shall mean as follows:
 - A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. <u>Provided, however</u>, that in any advertisement presented solely through video or audio means, the disclosure may be made through the same means in which the ad is presented. 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. In addition to the foregoing, in interactive media the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.
 - B. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.
 - C. On a product label, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

5. "Purchaser" shall mean any transferee of any product covered by this order who purchased such product from respondents or any of respondents' distributors for personal use or for the use of a member of the purchaser's family.

6. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees, licensees or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of CMO or any substantially similar product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such product:

- A. Is effective in the mitigation, treatment, prevention and cure of arthritis;
- B. Provides significant relief from symptoms of arthritis, including pain, swelling, impaired mobility, or deformity;
- C. Is as effective as, or superior to, prescription medications for the treatment of arthritis or the relief of arthritis symptoms;
- D. Is effective in the treatment of multiple sclerosis, leukemia, lupus, emphysema, cancer, benign prostate hyperplasia, silicone breast disease, asthma, fibromyalgia, or scleroderma; or
- E. Is safe or has no harmful side effects;

unless, at the time the representation 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 partnership, corporation, subsidiary, division, or other device, including franchisees, licensees or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of CMO products or any other food, dietary supplement or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, or program, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the performance, safety, efficacy or health benefits of any such product or program, unless, at the time the representation 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 partnership, corporation, subsidiary, division, or other device, including franchisees, licensees or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of CMO products or any other food, dietary supplement or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, or program, in or affecting commerce, shall not use the name "cmocure," use the word "cure" in an address or telephone number, or use any other name, address, or telephone number that represents expressly or by implication, that the product will cure any disease or health-related condition, unless, at the time

the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the advertising, promotion, offering for sale, sale, or distribution of any product or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, that such product or program is endorsed or approved by any governmental, professional, or private organization or association, or complies with or meets standards or guidelines for such products or programs established by any such organization or association.

V.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the advertising, promotion, offering for sale, sale, or distribution of any product or program 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, study, or research.

VI.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees, licensees or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or program in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the experience represented by any user testimonial or endorsement of the product or program represents the typical or ordinary experience of members of the public who use the product or program, unless:

- A. At the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation; or
- B. Respondents disclose, clearly and prominently, and in close proximity to the endorsement or testimonial, either:
 - 1. What the generally expected results would be for users of the product or program; or
 - 2. The limited applicability of the endorser's experience to what consumers may generally expect to achieve, that is, that consumers should not expect to experience similar results.

For purposes of this Part, "endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).

VII.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in the labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VIII.

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

IX.

IT IS FURTHER ORDERED that:

- A. Respondents shall not disseminate to any distributor any material containing any representations prohibited by this order.
- B. Respondents shall not, directly or indirectly, authorize any distributor to make any representations prohibited by this order.
- C. Within thirty (30) days after service of this order, respondents shall send by first class mail, with postage prepaid, two exact copies of the notice attached hereto as Attachment A to each distributor with whom respondents have done business between January 1, 1996, and the date of service of this order, to the extent that such distributor is known to respondents through a diligent search of their records, including but not limited to computer files, sales records, and inventory lists. The mailing shall not include any other documents. For purposes of this mailing, respondents shall treat as a distributor any person:
 - 1. Who purchased a CMO product from respondents for resale;
 - 2. Who purchased a CMO product from respondents at a discounted or wholesale price unavailable to the general public at the time of the purchase; or
 - 3. Who purchased more than twelve (12) bottles or packages of CMO products from respondents within any twelve (12) month period.

Respondents shall require each distributor with whom they did business between January 1, 1996, and the date of service of this order, to execute and return a copy of Attachment A as a condition of remaining or once again becoming a distributor of CDC.

- D. For a period of three (3) years following service of this order, respondents shall provide two exact copies of the notice attached hereto as Attachment B to each new distributor with whom respondents do business after the service of this order. Such notice shall be sent with the first shipment of respondents' products or programs. Respondents shall require each new distributor to execute and return a copy of the letter as a condition of being a distributor of CDC.
- E. Respondents shall require distributors to submit to respondents all advertising and promotional materials and claims for any products or programs covered by this order for review prior to their dissemination and publication. Respondents shall not authorize distributors to disseminate these materials and claims unless they are in compliance with this order.

Respondents may also comply with the obligations set forth above in this Subpart by:

- 1. disseminating to distributors marketing materials that comply with this order; and
- 2. requiring those distributors to submit for review all advertising and promotional materials for a particular product or program covered by this order that contain representations that are not substantially similar to the representations for the same product or program contained in the advertising and promotional materials most recently forwarded to the distributors by respondents.
- F. Respondents shall use reasonable efforts to monitor distributors' advertising and promotional activities. In the event that respondents receive any information that, subsequent to receipt of Attachment A or Attachment B pursuant to Subparts C and D of this Part, any distributor is using or disseminating any advertisement or promotional material or making any oral statement that contains any representation prohibited by this order, respondents shall immediately terminate said distributor's right to market respondents' products or programs, and immediately provide, by certified mail, all relevant information, including name, address, and telephone number of the company at issue, the nature of the violation, and any relevant materials used or disseminated, to the Associate Director, Division of Enforcement, Federal Trade Commission, Washington, D.C. 20580.

Χ.

IT IS FURTHER ORDERED that respondents shall refund the full purchase price of their CMO products, including shipping and handling and applicable taxes, to each eligible purchaser who requests a refund, under the following terms and conditions:

- A. Within thirty (30) days after service of this order, respondents shall send by first class mail, with postage prepaid, an exact copy of the notice attached hereto as Attachment C, showing the date of mailing to each purchaser other than a distributor as defined in Part IX, who purchased respondents' CMO products between January 1, 1996, and the date respondents executed this order, to the extent that such purchaser is known to respondents through a diligent search of their records, including but not limited to computer files, sales records, and inventory lists. The mailing shall not include any other documents.
- B. If any purchaser other than a distributor as defined in Part IX, within one hundred and twenty (120) days of the service of this order, makes a request for a refund substantially in the form of the request contained in Attachment C, and respondents' diligent inquiry and examination of the corporate respondent's books and records reasonably substantiates the purchaser's claim of purchase or the purchaser provides proof of purchase, including but not limited to any of the following: return of goods or packaging, canceled check(s), credit card invoice(s) or receipt(s), the refund shall be paid within fifteen (15) business days of respondents' receipt of the refund request.

XI.

IT IS FURTHER ORDERED that respondent CDC and its successors and assigns, and respondent Kalon Samulonis shall, no later than one hundred eighty (180) days after the date of service of this order, send by certified mail a monitoring report, in the form of a sworn affidavit executed on behalf of respondents, to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580. This report shall specify the steps respondents have taken to comply with the terms of Part X of this order and shall state, without limitation:

- A. The name and address of each purchaser from whom respondents received a refund request;
- B. The date on which each request was received, the amount of the refund request, and the amount of the refund provided by respondents to each such purchaser;
- C. The status of any disputed refund request and the identification of each purchaser whose refund request is disputed, by name, address, and amount of the claim; and

D. The total amount of refunds paid by respondents.

XII.

IT IS FURTHER ORDERED that respondent CDC and its successors and assigns, and respondent Kalon Samulonis 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: Copies of all notification letters sent to distributors, communications between respondents and distributors referring or relating to the requirements of Part IX, and any other materials created pursuant to Parts IX or X of this order.

XIII.

IT IS FURTHER ORDERED that respondent CDC and its successors and assigns, and respondent Kalon Samulonis 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 contradicts, qualifies, or calls 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.

XIV.

IT IS FURTHER ORDERED that respondent CDC and its successors and assigns, and respondent Kalon Samulonis shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives 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.

XV.

IT IS FURTHER ORDERED that respondent CDC and its successors and assigns, and respondent Kalon Samulonis shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) 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. <u>Provided, however</u>, that, with respect to any proposed change in the corporation 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, Washington, D.C. 20580.

XVI.

IT IS FURTHER ORDERED that respondent CDC and its successors and assigns, and respondent Kalon Samulonis shall, within sixty (60) days after the date of 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.

XVII.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; <u>provided</u>, <u>however</u>, 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.

<u>Provided, further</u>, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this ______ day of ______, 1999.

CMO DISTRIBUTION CENTERS OF AMERICA, INC.

By: _____ KALON SAMULONIS, President

KALON SAMULONIS, individually and as an officer of the corporation

DILLING AND DILLING

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APPROVED:

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