

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of)	
)	FILE NO. 002 3098
)	
MAXCELL BIOSCIENCE, INC.,)	
a corporation, and)	AGREEMENT CONTAINING
)	CONSENT ORDER
STEPHEN CHERNISKE,)	
individually and as an officer)	
of the corporation.)	
)	

The Federal Trade Commission has conducted an investigation of certain acts and practices of MaxCell BioScience, Inc., a corporation, and Stephen Cherniske, individually and as an officer of the corporation ("proposed respondents"). Proposed respondents, having been represented by counsel, 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 MaxCell BioScience, Inc., by its duly authorized officer, and Stephen Cherniske, individually and as an officer of the corporation, and counsel for the Federal Trade Commission that:

- 1.a. Proposed respondent MaxCell BioScience, Inc. is a Delaware corporation with its principal office or place of business at 100 Technology Drive, Broomfield, Colorado 80021.
- 1.b. Proposed respondent Stephen Cherniske is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of MaxCell BioScience, Inc.
2. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.
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 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.

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 complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. 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, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

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

ORDER

DEFINITIONS

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

1. Unless otherwise specified, "respondents" shall mean MaxCell BioScience, Inc., a corporation, its successors and assigns and its officers; Stephen Cherniske, individually and as an

officer of the corporation; and each of the above's agents, representatives, and employees.

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 objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

3. "Distributor" shall mean any purchaser or other transferee of any product or service covered by this order who acquires such product or service from respondents, with or without valuable consideration, and who sells, or who has sold, such product or service to other sellers or to consumers, including but not limited to individuals, retail stores, or catalogs.

4. "Food," "drug" and "device," shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

5. "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 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 the Anabolic/Catabolic Index test, or any other substantially similar device, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such device provides a clinical gauge of an individual's overall healthiness or overall youthfulness. For purposes of this Part, "substantially similar device" shall mean any product that measures the ratio of 17-ketosteroids to creatinine in one urine sample.

II.

IT IS FURTHER ORDERED that respondents, directly or through any 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 test or other device, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such device provides a clinical gauge of an individual's overall healthiness or overall youthfulness, unless the representation is true and, 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, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Longevity Signal Formula or any other food, drug, device, service, or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication:

- A. That such product or service reduces the risk of atherosclerosis,
- B. That such product or service cures arthritis,
- C. That such product or service lowers blood pressure,
- D. That such product or service lowers cholesterol levels in the bloodstream,
- E. That such product or service strengthens bones,
- F. That such product or service reduces or eliminates the need for corrective lenses,
- G. That such product or service promotes weight loss or muscle gain without dieting or exercise,
- H. That such product or service increases glucose tolerance,
- I. That such product or service increases Growth Hormone levels in the body, thereby causing positive clinical effects on health,
- J. That such product or service improves liver function,
- K. That such product or service prevents or reverses aging, or increases life expectancy, or
- L. About the effect of such product or service on any disease, or about the effect of such product or service on the structure or function of the human body, or about any other health benefit, or the safety, of 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.

IV.

IT IS FURTHER ORDERED that respondents shall not provide to any person or entity means and instrumentalities that contain any claim about the effect of any product or service on any disease, or about the effect of any product or service on the structure or function of the human body, or about any other health benefit, or the safety, of any product or service, unless such claim is true, and substantiated by competent and reliable scientific evidence. For purposes of this Part, "means and instrumentalities" shall mean any information, including but not necessarily limited to any advertising, labeling or promotional materials, for use by distributors in their marketing or sale of the Anabolic/Catabolic Index test or Longevity Signal Formula or any other product or service covered under this order, in or affecting commerce.

V.

IT IS FURTHER ORDERED that respondents, directly or through any 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 food, drug, device, service, or dietary supplement, 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 shall:

- A. Within seven (7) days after service of this order upon respondents, deliver to the Commission a list, in the form of a sworn affidavit, of all distributors who purchased the Anabolic/Catabolic Index test or Longevity Signal Formula from respondents or from one of respondents' other distributors on or after January 1, 2000. Such list shall include each distributor's name and address, and, if available, the telephone number and email address of each distributor.
- B. Within thirty (30) days after service of this order upon respondents, send by first class mail, with postage prepaid, an exact copy of the notice attached hereto as Attachment A, showing the date of mailing, to each distributor who purchased the Anabolic/Catabolic Index test or Longevity Signal Formula from respondents or from one of respondents' other distributors between January 1, 2000, and the date of service of this order. This mailing shall not include any other document.

VII.

IT IS FURTHER ORDERED that respondent MaxCell BioScience, Inc., directly or through any corporation, subsidiary, division, trade name, or other device, shall:

- A. For a period of three (3) years following entry of this order, send a copy of the notice attached hereto (Attachment A) by first class mail, with postage prepaid, to any distributor of the Anabolic/Catabolic Index test, Longevity Signal Formula, or any other food, drug, device, service, or dietary supplement; provided, however, that the requirement of this subpart shall not apply to any distributor who received a copy of the notice attached hereto (Attachment A) pursuant to the requirements of subpart VI.B of this order. Such notice shall be sent within one (1) week from the first shipment of respondent's products or programs to said distributor. The mailing shall not include any other documents.
- B. Institute a reasonable program of surveillance adequate to reveal whether any of respondent's distributors are disseminating advertisements or promotional materials that contain any representation about the Anabolic/Catabolic Index test, Longevity Signal Formula, or any other food, drug, device, service, or dietary supplement manufactured by or purchased from respondent, that is prohibited by Part I, II, III, or IV of this order.
- C. Terminate all sales of the Anabolic/Catabolic Index test, Longevity Signal Formula, or any other food, drug, device, service, or dietary supplement to any distributor who is engaged in disseminating advertisements or promotional materials that contain any representation about the Anabolic/Catabolic Index test, Longevity Signal Formula, or any other food, drug, device, service, or dietary supplement manufactured by or purchased from respondent, that is prohibited by Part I, II, III, or IV of this order once respondent knows or should know that the distributor is or has been engaged in such conduct.

VIII.

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 medical device application approved by the Food and Drug Administration. Nor shall it 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.

IX.

IT IS FURTHER ORDERED that respondents shall pay the **Âé¶'«Ã½ Trade Commission** the sum of **one hundred fifty thousand dollars** (\$150,000). 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 **Âé¶'«Ã½ Trade Commission**, the payment to be made no later than 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.
- 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 Longevity Signal Formula and/or the Anabolic/Catabolic Index test 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 these products 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.

X.

IT IS FURTHER ORDERED that respondent MaxCell BioScience, Inc., and its successors and assigns, and respondent Stephen Cherniske 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 **Âé¶'«Ã½ 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.

XI.

IT IS FURTHER ORDERED that respondent MaxCell BioScience, Inc., and its successors and assigns, and respondent Stephen Cherniske 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.

XII.

IT IS FURTHER ORDERED that respondent MaxCell BioScience, Inc., and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a 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 corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent 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 Consumer Protection, Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XIII.

IT IS FURTHER ORDERED that respondent Stephen Cherniske, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his 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

Âé¶¹´«Ã½, Bureau of Consumer Protection, Âé¶¹´«Ã½ Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XIV.

IT IS FURTHER ORDERED that respondent MaxCell BioScience, Inc., and its successors and assigns, and respondent Stephen Cherniske shall, within sixty (60) days after service of this order, and at such other times as the Âé¶¹´«Ã½ 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.

XV.

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 Âé¶¹´«Ã½ Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

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

Signed this _____ day of _____, 2001.

MAXCELL BIOSCIENCE, INC.

By:

STEPHEN CHERNISKE
President of the corporation

STEPHEN CHERNISKE, individually
and as President of the corporation

CLAUDE C. WILD III
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Attorney for Respondents

MATTHEW DAYNARD
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JOCK K. CHUNG
Counsel for the $\hat{A} \epsilon \eta \prime \ll \tilde{A}^{1/2}$ Trade Commission

APPROVED:

C. LEE PEELER
Associate Director
Division of Advertising Practices

JOAN Z. BERNSTEIN
Director
Bureau of Consumer Protection

ATTACHMENT A

LETTER SENT TO DISTRIBUTORS WITH WHOM RESPONDENT HAS DONE BUSINESS BETWEEN JANUARY 1, 2000, AND THE DATE OF SERVICE OF THIS ORDER

[To Be Printed on MaxCell BioScience letterhead]

[NAME AND ADDRESS OF RECIPIENT]

[DATE]

Dear [DISTRIBUTOR'S NAME]:

This letter is to inform you that MaxCell BioScience, Inc. recently settled a civil dispute with the Federal Trade Commission regarding its advertising for the *Anabolic/Catabolic Index test* and *Longevity Signal Formula*. Among other things, we have agreed to notify distributors of the settlement.

As a result of its agreement with the FTC, MaxCell BioScience, Inc. has consented to desist from, among other practices, making any claim about the effects on any disease or on the structure or function of the human body, or about any other health benefit, or the safety, of any dietary supplement, food, drug, device, or service, that is not supported by competent and reliable scientific evidence. Competent and reliable scientific evidence is defined as 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. Anecdotal evidence and consumer testimonials are not considered competent and reliable scientific evidence.

According to the FTC complaint, we did not have a reasonable basis to claim that the ACI test measures a person's overall healthiness or youthfulness or that LSF reduces the risk of atherosclerosis, cures arthritis, lowers blood pressure, lowers cholesterol levels in the bloodstream, strengthens bones, reduces or eliminates the need for corrective lenses, or promotes weight loss and muscle gain without dieting or exercise, increases glucose tolerance, increases Growth Hormone levels in the body, thereby causing positive clinical effects on health, or improves liver function.

As always, your responsibility as a distributor is to utilize only claims made directly from corporate communications or to have your advertising approved by the corporation before transmitting it. Failure to comply with these requirements can result in termination.

This letter has been provided for your files. If you have any questions or if you want a copy of the FTC order, please contact [insert name and telephone number of respondents' contact].

MaxCell BioScience, Inc.