

Part II of the order requires that future claims that any test or device provides a clinical gauge of an individual's overall healthiness or youthfulness be true and substantiated by competent and reliable scientific evidence.

Part III of the order requires competent and reliable scientific evidence as substantiation for future claims that LSF or any other food, drug, device, service, or dietary supplement provides any of the specific health benefits challenged above as unsubstantiated. In addition, Part III. L requires scientific substantiation for any future claim about the effect of covered products or services on any disease, on the structure or function of the human body, or about any other health benefit, or the safety, of any covered product or service.

Part IV of the order prohibits MaxCell from providing 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. "Means and instrumentalities" is defined as 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 ACI test or LSF or any other product or service covered under the order.

Part V of the order prohibits MaxCell from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part VI of the order requires dissemination of a notice ("Attachment A") about the order to MaxCell's distributors who have purchased the ACI Test or LSF since January 1, 2000. This notice indicates that MaxCell has agreed to cease making challenged representations, and warns distributors that they may be terminated if they do not conform their representations to the requirements placed on MaxCell.

Part VII of the order requires dissemination of Attachment A to future distributors, and that MaxCell monitor their distributors, and terminate sales to distributors who make representations prohibited by the order.

Part VIII of the order permits FDA-approved drug claims and claims for food or dietary supplements authorized under the Nutrition Labeling and Education Act of 1990.

Part IX of the order requires that MaxCell make a payment of \$150,000 to the Commission, which funds the FTC can forward to the U.S. Treasury as disgorgement or use for purposes of consumer redress.

Parts X, XI, XII, and XIV of the order require MaxCell to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part XIII requires Stephen Cherniske to notify the Commission of his employment status, and Part XV provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,
Secretary.

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FEDERAL TRADE COMMISSION

[File No. 002 3229]

Panda Herbal International, Inc., et al.; **Analysis to Aid Public Comment**

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before July 16, 2001.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Michael Bloom or Donald D'Amato, Federal Trade Commission, Northeast Region, One Bowling Green, Suite 318, New York, NY 10004. (212) 607-2801 or 607-2802.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for June 14, 2001), on the World Wide Web, at "<http://www.ftc.gov/os/2001/06/index.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed consent order from Panda Herbal International, Inc. ("Panda"), a corporation, and Everett L. Farr III, individually and as an officer of the corporation ("proposed respondents").

The proposed consent order has been placed on the public record for thirty (30) days for the receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and comments received and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves proposed respondents' making of health-related advertising claims on the Internet and elsewhere for their Herbal Outlook (a dietary supplement that contains St.

John's Wort) and HerbVeil 8 (a topical ointment) products. The proposed complaint alleges that proposed respondents violated Sections 5 and 12 of the Federal Trade Commission Act by making deceptive claims for these products.

The proposed complaint alleges that respondents' claims that ingestion of Herbal Outlook is effective in the treatment of HIV/AIDS, herpes simplex, tuberculosis, influenza, and hepatitis B infections are unsubstantiated. Further, the proposed complaint alleges that respondents deceptively fail to disclose significant adverse drug interactions in light of respondents' implied drug compatibility claim ("ingestion of St. John's Wort, an ingredient in Herbal Outlook, is effective in the treatment of HIV/AIDS"). The proposed complaint also alleges that respondents' claim that ingestion of St. John's Wort, an ingredient in Herbal Outlook, has no known contraindications or drug interactions is false because there is substantial information available documenting significant adverse drug interactions. In addition, the proposed complaint alleges that respondents' HerbVeil 8 claims that topical application of HerbVeil 8 is effective in the treatment of carcinomas, adenocarcinomas, and melanomas are unsubstantiated.

For purposes of the proposed order, a "covered product or service" means any service, program, dietary supplement, food, drug, or device.

The proposed order defines "Herbal Outlook product" as respondents' Herbal Outlook or any other covered product or service for which the term "Hypericum Perforatum" or "St. John's Wort" appears on the covered product or service label or in any advertising or promotion, and any covered product or service containing "Hypericum Perforatum" or "St. John's Wort."

Part I of the proposed consent order prohibits proposed respondents from representing that ingestion of any Herbal Outlook product or any covered product or service is effective in the treatment of HIV/AIDS, herpes simplex, tuberculosis, influenza, or hepatitis B infections, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The proposed order defines "HerbVeil 8 product" as respondents' HerbVeil 8 or any covered product or service for which the term "HerbVeil 8" appears on the product label or in any advertising or promotion, any covered product or service containing "HerbVeil 8," and any covered product or service

promoted for the topical treatment of any cancer. Part II of the proposed consent order prohibits proposed respondents from representing that application of any HerbVeil 8 product, or any covered product or service, is effective in the treatment of any cancer unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. Part III of the proposed consent order prohibits proposed respondents from representing that ingestion of any Herbal Outlook product has no known contraindications or drug interactions.

Part IV provides that in any advertisement, promotional material, or product label for any Herbal Outlook product, that contains any representation about the efficacy, performance, or safety of such product, and in any discussion, communicated via electronic mail or any telephone line, that contains any representation about the efficacy, performance, or safety of any Herbal Outlook product, proposed respondents shall make clearly and prominently, the following disclosure:

Warning: St. John's Wort can have potentially dangerous interactions with some prescription drugs. Consult your physician before taking St. John's Wort if you are currently taking anticoagulants, oral contraceptives, anti-depressants, anti-seizure medications, drugs to treat HIV or prevent transplant rejection, or any other prescription drug. This product is not recommended for use if you are or could be pregnant unless a qualified health care provider tells you to use it. The product may not be safe for your developing baby.

unless respondents possess competent and reliable scientific evidence that such product produces no adverse drug interactions or side effects. This disclosure was developed after discussions with the Food and Drug Administration. FDA has announced that it intends to initiate a rulemaking for dietary supplements for women who are or who may become pregnant. In the event that FDA issues a final rule requiring a warning for pregnant women on dietary supplements, respondents may substitute that warning for the disclosure on that topic required under the proposed order. Part IV specifies that the product label requirements of this Part shall not apply to products that are shipped to consumers or purchasers for resale less than thirty (30) days after the date of service of this order, and that with regard to products shipped after thirty (30) days of the date of service of this order, respondents may affix the disclosure clearly and prominently by

sticker or other device on the labels of products manufactured prior to thirty (30) days after the service of this order.

Part V provides that proposed respondents, in connection with the advertising or sale of any Herbal Outlook product, HerbVeil 8 product, or any covered product or service, shall not make any representation that such product or service is effective in the mitigation, treatment, prevention, or cure of any disease or illness, or about the health benefits, performance, safety, or efficacy of any such product or service, unless, at the time the representation is made, proposed respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The proposed order defines "purchaser for resale" as any purchaser of any proposed respondents' Herbal Outlook product or HerbVeil 8 product, who: (a) Is a distributor of, or operates a wholesale or retail business that sells, any such product(s); or (b) orders twenty (20) or more units of any such product(s) in any three (3) month period. Parts VI A and VI B of the proposed consent order require proposed respondents to deliver to the Commission lists containing information regarding purchasers for resale and consumers of Herbal Outlook, respectively. Parts VI C and VI D require proposed respondents to deliver to the Commission lists containing information regarding purchasers for resale and consumers of HerbVeil 8, respectively. Parts VI E and VI F require proposed respondents to send a notice to all purchasers of Herbal Outlook and HerbVeil 8 informing them of the Commission's complaint allegations and the terms of the settlement. Part VII of the proposed order requires proposed respondents to provide refunds upon request to consumer purchasers of HerbVeil 8. Part VIII requires proposed respondents to submit a report specifying the steps it has taken to comply with Part VI (notice provisions) and Part VII (refund provision).

Part IX requires proposed respondents to take reasonable steps to monitor and ensure that all employees and agents engaged in sales, order verification, and other customer service functions comply with Parts I through V of the order and requires proposed respondents to terminate any employee who knowingly engages in conduct that violates these parts of the order. Part X A requires proposed respondents to send each purchaser for resale for a period of five years following entry of the order, the notice provisions required by Part VI E (to the extent such

purchasers for resale have not already received such notice pursuant to Part VI E). Part X B requires proposed respondents to institute a purchaser for resale order compliance surveillance program and Part X C states that proposed respondents must terminate sales to those purchasers for resale they know or should know are violating Parts I through V of the proposed order. Part XI would allow proposed respondents to make any representation for any drug that is permitted by the FDA in the drug's labeling, and would allow proposed respondents to make any representation that is specifically permitted in the labeling for any product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

Part XII of the proposed order contains record keeping requirements for materials that substantiate, qualify or contradict claims covered by the proposed order. Part XIII of the proposed order requires distribution of a copy of the order to current and future officers, employees, and agents. Part XIV provides for Commission notification upon a change in the proposed corporate respondent and Part XV requires Commission notification when the proposed individual respondent changes his business or employment. Part XVI requires the proposed respondents to file with the Commission a report demonstrating compliance with the terms and provisions of the order. Part XVII provides for the termination of the order after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate the public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and the proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01106]

Addressing Asthma From a Public Health Perspective; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for "Addressing Asthma from a Public Health Perspective." This program addresses the "Healthy People 2010" focus areas Environmental Health, Respiratory Diseases and Occupational Safety and Health.

The purpose of the program is: Part A: Developing State Capacity to Address Asthma and Part B: Implementation of State Asthma Plans.

This funding is not to be used for any type of research.

B. Eligible Applicants

Assistance will be provided only to health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

In consultation with States, and with the written concurrence of the State, assistance may be provided to political subdivisions of States.

Part A: Eligible applicants are those entities listed above that do not have a finalized comprehensive asthma plan or a well developed asthma surveillance system. Grantees currently funded by CDC Announcement #99109

(Attachment 1) are not eligible to apply.

Part B: Eligible applicants are those entities listed above that have a completed comprehensive asthma plan and have an operational surveillance system for asthma. Grantees currently funded by CDC Announcement #99109 are eligible to apply. However, if awarded funds under Part B of this announcement, applicant will lose funds under Announcement #99109.

An eligible applicant may apply for both Part A and Part B; however, only one award per applicant will be made. To apply for both parts of this announcement, applicants must submit separate applications for Part A and Part B.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$3,600,000 is available in FY 2001 to fund awards under this announcement. Funding estimates may change.

Part A: Developing State Capacity to Address Asthma. Approximately \$2,000,000 is available to fund approximately 7-12 awards. It is expected that the average award will be \$200,000. Additionally, \$100,000 is available to increase Part A awards up to \$10,000 each, if an occupational component is included in the application and is favorably reviewed.

Part B: Implementation of State Asthma Plans. Approximately \$1,500,000 is available to fund approximately 2-4 awards. It is expected that the average award will be \$700,000.

It is expected that the awards will begin on or about September 30, 2001 and will be made for a 12-month budget period within a project period of up to 3 years for Part A and 5 years for Part B.

Continuation awards within the approved project periods will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Applicant should document assurance of ability of project staff to travel to Atlanta to participate in the CDC National Asthma Conference and/or grantee meetings and willingness to share innovations, information, data and materials.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

Part A. Developing State Capacity to Address Asthma

1. Recipient Activities:

- a. Develop or finalize a comprehensive State asthma plan.
- b. Develop and organize collaborative linkages with appropriate agencies and organizations.
- c. Implement a new (or enhance an existing) asthma surveillance system.
- d. Begin the statewide intervention program upon completion of the plan.