

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from The Council of Fashion Designers of America, Inc. (CFDA) and 7th on Sixth, Inc.

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 complaint alleges that CFDA, a trade association of fashion designers, and 7th on Sixth, a not-for-profit corporation, and their members, have engaged in acts and practices that have unreasonably restrained competition among fashion designers. The complaint alleges that CFDA and 7th on Sixth fixed prices for the hiring of runway models. The complaint alleges that this price fixing agreement among purchasers of modeling and modeling agency services violates Section 5 of the Federal Trade Commission Act.

CFDA and 7th on Sixth have signed a proposed consent agreement that requires them to cease and desist from any agreement which has the purpose or effect of fixing prices paid or terms of employment for modeling or modeling agency services and from encouraging others to engage in such activities. The proposed consent order requires that CFDA and 7th on Sixth distribute a copy of the complaint and a letter notifying their members and employees, modeling agencies and other designated parties listed in the order that neither the CFDA nor 7th on Sixth may negotiate on behalf of fashion designers collectively with models or modeling agencies, and they may neither continue nor enter into any agreement for the purpose of affecting modeling prices.

The proposed order includes a proviso which makes clear that fashion designers who choose to employ or use the services of the same model will not be deemed in violation of the order, where such employment or use is not otherwise in furtherance of any action prohibited by the order. The proviso will permit fashion designers to hire models independently without fear that the fact that they hire the same model itself will result in liability. The order also permits two or more designers to agree to hire and use models jointly without violating the order, so long as they do not agree to do so in furtherance

of the kind of prohibited agreement to which CFDA and 7th on Sixth were party.

In order to deter future law violations and facilitate FTC review of compliance with the order, the proposed order requires CFDA and 7th on Sixth to make and keep minutes of all meetings of their membership board, committees or subcommittees, for five years. These minutes must indicate if prices or terms of modeling services are discussed at any meeting. CFDA and 7th on Sixth must provide these minutes to the FTC upon request. The parties must also communicate to their members, officers, directors and employees their obligations under this order. Officers, directors and employees must in turn provide annual written certification that they have received such notice.

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.

Donald S. Clark,

Secretary.

[FR Doc. 95-16254 Filed 6-30-95; 8:45 am]

BILLING CODE 6750-01-M

[File No. 942-3058]

Live-Lee Productions, Inc.; Proposed Consent Agreement With Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, a Los Angeles based corporation, and Ruta Lee, who directs and controls the corporation, from making claims for any food, dietary supplement or drug unless they have competent and reliable scientific evidence to support the claims.

DATES: Comments must be received on or before September 1, 1995.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Lisa B. Kopchik or Joel Winston, FTC/S-4002, Washington, DC 20580. (202) 326-3139 or (202) 326-3153.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's rules

of practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. 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 § 4.9(b)(6)(ii) of the Commission's rules of practice (16 CFR 4.9(b)(6)(ii)).

In the Matter of: Live-Lee Productions, Inc., a corporation, and Ruta Lee, individually and as an officer and director of said corporation, File No. 942-3058.

Agreement Containing Consent Order to Cease and Desist

The Federal Trade Commission having initiated an investigation of certain acts and practices of Live-Lee Productions, Inc., a corporation, and Ruta Lee, individually and as an officer and director of said corporation, hereinafter sometimes referred to as proposed respondents, and it now appears that 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 Live-Lee Productions, Inc., a corporation, by its duly authorized officer, and Ruta Lee, individually and as an officer and director of said corporation, and counsel for the Federal Trade Commission that:

1. Proposed respondent Live-Lee Productions, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its offices and principal place and business at 2761 Laurel Canyon Boulevard, Los Angeles, California 90046.

Proposed respondent Ruta Lee is an officer and director of said corporation. She formulates, directs, and controls the policies, acts, and practices of said corporation. She resides at 2436 Shirley Avenue, Fort Worth, Texas 76109.

2. Proposed respondents admit all the jurisdictional facts set forth in the draft of the 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 of the complaint contemplated thereby, will be placed in 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 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 § 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 to the draft of complaint 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. The 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' addresses 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 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 reports 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

I

It is ordered that respondents Live-Lee Productions, Inc., a corporation, its successors and assigns, and its officers; and Ruta Lee, individually and as an officer and director of said corporation; and respondents' agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the manufacturing, advertising, packaging, labeling, promotion, offering for sale, sale or distribution of Life Way Vitamin C and Zinc Spray, Life Way Antioxidant Spray, Life Way Vitamin B-12 Spray, or any other food, food or dietary supplement, or drug, as "food" and "drug" are defined in section 15 of the Federal Trade Commission Act, 15 U.S.C. 55, 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 such product:

1. Is more fully absorbed by the human body than any other product;
2. Heals lesions in the mouth, cold sores on the mouth, or cracking of the corners of the lips;
3. Prevents common colds;
4. Effectively treats symptoms related to hangovers;
5. Increases energy;
6. Ensures the proper functioning of the immune system;
7. Reduces the risk of contracting infectious diseases;
8. Prevents facial lines; or

B. That use of the product can or will have any effect on the user's health, or on the structure or function of the human body,

unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For the purpose of this Order, "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 have 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;

Provided that it shall be a defense hereunder that the respondents neither knew nor had reason to know of the

inadequacy of substantiation for the representations.

II

It is further ordered that respondents Live-Lee Productions, Inc., a corporation, its successors and assigns, and its officers; and Ruta Lee, individually and as an officer and director of said corporation; and respondents' agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the manufacturing, advertising, packaging, labeling, promotion, offering for sale, sale or distribution of Life Way Smoke-Less Nutrient Spray or any other smoking cessation product, program, or service, 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 such product, program, or service enables smokers, regardless of how long they have smoked or how much they smoke, to stop smoking easily;

B. That such product, program, or service satisfies the physiological urge to smoke a cigarette, or eliminates the quivering, anxiety and weight gain attendant with quitting smoking; or

C. Regarding the performance, benefits, efficacy or safety of any such product, program, or service,

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

Provided that it shall be a defense hereunder that the respondents neither knew nor had reason to know of the inadequacy of substantiation for the representation.

III

It is further ordered that, for five (5) years after the last date of dissemination of any representation covered by this Order, respondents Live-Lee Productions, Inc., a corporation, its successors and assigns, and its officers; and Ruta Lee individually and as an officer and director of said corporation, 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.

IV

It is further ordered that respondents Live-Lee Productions, Inc. shall, within thirty (30) days after 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.

V

It is further ordered that respondent Live-Lee Productions, Inc. shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed change in its corporate structure, including but not limited to dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or affiliates, the planned filing of a bankruptcy petition, or any other corporate change that may affect compliance obligations arising out of this Order.

VI

It is further ordered that respondent Ruta Lee shall, for a period of five (5) years from the date of issuance of this Order, notify the Commission within thirty (30) days of the discontinuance of her present business or employment and of her affiliation with any new business or employment which involves the sale of consumer products. Each notice of affiliation with any new business or employment shall include the respondent's new business address and telephone number, current home address, and a statement describing the nature of the business or employment and her duties and responsibilities.

VII

It is further ordered that respondents Live-Lee Productions, Inc., a corporation, its successors and assigns, and its officers; and Ruta Lee, individually and as an officer and director of said corporation, shall, within sixty (60) days after service of this Order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Live-Lee Productions, Inc. ("Live-Lee") and Ruta Lee ("Lee").

The proposed consent order has been placed on the public record for sixty (60) days for receipt 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.

This matter involves alleged deceptive representations for three spray vitamin products and a spray smoking cessation product. The products at issue are Life Way Vitamin C and Zinc Spray, Life Way Antioxidant Spray, Life Way Vitamin B-12 Spray, and Life Way Smoke-Less Nutrient Spray. The complaint charges that Lee performed the functions of an advertising agency by creating and disseminating the representations, and that she received a royalty for each unit of product that was sold. The claims were made on television advertisements called "Spotlight on Ruta Lee." These advertisements were broadcast on the Home Shopping Club, commercial programming shown on the Home Shopping Network.

Live-Lee is Lee's closely-held corporation, which is engaged in the business of providing the services of Ruta Lee in connection with the marketing, advertising, sale and distribution of consumer products. Lee is an officer, director, and sole shareholder of Live-Lee.

According to the FTC complaint, Lee made claims that the vitamins in the spray products are more fully absorbed by the human body than vitamins taken in pill form; and that the vitamins would heal mouth lesions, cold sores, and cracking of the corners of the lips; prevent common colds; treat hangover symptoms; increase users' energy; ensure the proper functioning of the immune system; reduce the risk of contracting infectious diseases; and prevent facial lines. The complaint also alleges that Lee made claims that the smoking cessation spray would enable smokers, regardless of how long they have smoked or how much they smoke, to stop smoking easily; and would satisfy the physiological urge to smoke a cigarette and eliminate the quivering, anxiety and weight gain that go along with quitting smoking. The complaint

alleges that the respondents did not have substantiation for these representations at the time they were made. The complaint further alleges that the respondents knew or should have known that the representations were not substantiated.

The proposed consent order contains provisions designed to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits the respondents from representing that any food, food or dietary supplement, or drug can or will have any effect on the user's health, or on the structure or function of the human body, unless, at the time they make the representation, they possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Part II of the proposed order prohibits respondents from making any representation about the performance, benefits, efficacy, or safety of any smoking cessation product, program, or service, unless they have competent and reliable scientific evidence that substantiates the representation. With respect to both Parts I and II, the proposed order provides a defense to respondents if they neither knew nor had reason to know of the inadequacy of the substantiation for the representation.

Part III requires that the respondents keep records concerning claims covered by the order, including materials that they relied upon when making the claims.

Part IV requires respondent Live-Lee to provide a copy of the order to each of its 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 the order.

Part V requires respondent Live-Lee to notify the Commission of any change in its corporate structure that might affect its compliance with the order.

Part VI requires respondent Ruta Lee for 5 years to notify the Commission of any change in her business or employment or her affiliation with any new business or employment that involves the sale of consumer products.

Part VII requires respondents to file compliance reports with the Commission.

On March 3, 1995, the Commission issued a complaint against Home Shopping Network, Inc.; Home Shopping Club, Inc.; and HSN Lifeway Health Products, Inc. for their role in making and disseminating the same allegedly deceptive representations (Docket No. 9272). That case is now

pending before an Administrative Law Judge.

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.

Donald S. Clark,

Secretary.

[FR Doc. 95-16256 Filed 6-30-95; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

White House Conference on Aging

AGENCY: White House Conference on Aging, AoA, HHS.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given, pursuant to Title II of the Older Americans Act Amendments of 1987, Pub. L. 100-175 as amended by Pub. L. 102-375 and Pub. L. 103-171, that the 1995 White House Conference on Aging Business Advisory Committee will meet on Monday, July 17, 1995 from 10:00 AM-noon in the Hubert H. Humphrey Building at 200 Independence Avenue, SW in Washington, DC. Information on the specific room in which the meeting will be held can be obtained by calling the telephone number given below. The meeting of the Committee shall be open to the public.

The proposed agenda includes discussion of how the Committee and the business community can assist with implementation of the resolutions adopted by the Conference delegates. Records shall be kept of all Committee proceedings and shall be available for public inspection at 501 School Street, SW, 8th Floor, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: White House Conference on Aging, 501 School Street, SW, 8th Floor, Washington, DC 20024; telephone (202) 245-7116.

Fernando M. Torres-Gil,

Assistant Secretary for Aging.

[FR Doc. 95-16270 Filed 6-30-95; 8:45 am]

BILLING CODE 4130-02-M

Agency for Health Care Policy and Research

Health Care Policy and Research Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5

U.S.C., Appendix 2) announcement is made of the following special emphasis panel scheduled to meet during the month of August 1995:

Name: Health Care Policy and Research Special Emphasis Panel

Date and Time: August 10, 1995, 8:30 a.m.

Place: Hyatt Regency, One Bethesda Metro Center, Conference Room TBA, Bethesda, MD 20814.

Open August 10, 8:30 a.m. to 9 a.m. Closed for remainder of meeting.

Purpose

This panel is charged with conducting the initial review of grant applications proposing health services research training programs under the National Research Service Awards Program.

Agenda

The open session of the meeting on August 10, from 8:30 a.m. to 9 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the committee will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), it has been determined that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Linda W. Blankenbaker, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-1438.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: June 26, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95-16253 Filed 6-30-95; 8:45 am]

BILLING CODE 4160-90-M

Food and Drug Administration

[Docket No. 92N-0371]

New Drug Applications; Refusal to File; Change in Procedures to Include Industry Representatives in Meetings of the Review Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a change in the review process conducted

by the Center for Drug Evaluation and Research's (CDER's) Refusal to File (RTF) review committee. The new procedures will permit applicants that have received an RTF to attend the meeting at which the RTF review committee evaluates the RTF imposed on its application. This change, which will be implemented on a trial basis, may enhance understanding of and participation in the RTF review committee process. Additional changes to the procedures may be useful and comments are requested.

DATES: Comments may be submitted at any time.

ADDRESSES: Submit written comments on this change in procedures to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Janet M. Jones, Center for Drug Evaluation and Research (HFD-014), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5445.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 18, 1993 (58 FR 28983), FDA announced the establishment of a standing committee in CDER's to conduct periodic review of the CDER's RTF decisions. The committee was established on a 1-year trial basis. Initially, the committee invited companies to submit requests for review of RTF's that they considered to have been made inappropriately. The RTF review committee consists of senior CDER officials, a senior official from the Center for Biologics Evaluation and Research, and FDA's Chief Mediator and Ombudsman.

CDER created the RTF review committee because it believes that a clear, well-understood, and consistently applied RTF policy may improve substantially the efficiency of the new drug evaluation process. The practice of submitting an incomplete or inadequate application and then providing additional information during an extended review period is inherently inefficient and a waste of agency resources. In addition, it is unfair to those applicants who fulfill their scientific and legal obligations by submitting complete applications to have the review of their applications delayed while other incomplete applications submitted earlier undergo review and repair.

FDA regulations on filing applications, including grounds and procedures for RTF's, are found in § 314.101 (21 CFR 314.101). In the past, some CDER review divisions refused to