UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Robert Pitofsky, Chairman Mary L. Azcuenaga Janet D. Steiger Roscoe B. Starek, III Christine A. Varney

In the Matter of

NATURAL INNOVATIONS, INC.,
a corporation, and

DECISION AND ORDER

WILLIAM S. GANDEE,
individually and as an officer and director of said corporation.

ODECISION AND ORDER

The Federal Trade Commission having initiated anvestigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other that jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent

agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments received, now in further conformity with the procedure prescribed in \$2.34 of its Rules, the Commission hereby issues its complaint, kees the following jurisdictional findings and enters the following order:

1. Respondent Natural Innovations, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio, with its office and principal place of business at 2717 South Arlington Road, Akron, Ohio 44312.

Respondent William SGandee is an officer, director, and sole shareholder of Natural Innovations, Inc. He formulates, directs, and controls the policies, acts and practices of said corporation, and his office and principal place of business is located at the above stated address.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that respondents, Natural Innovations, Inc., its successors and assigns, and its officers; and William SGandee, individually and as an officer and director of said corporation; and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, offering for sale, sale, or distribution for sale of any device, as "device" is defined in Section 15 of the Federal Trade Commission Act, 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 use of the device will significantly reduce, relieve, or eliminate musculoskeletal pain, including but not limited to pain in the back, feet, knees, wrists, knuckles, elbows, shoulders, ankles, joints, or calves; carpal tunnel syndrome; muscle spasms or strains; or sciatica;
- B. That use of the device will significantly reduce, relieve, or eliminate abdominal pain or pain or discomfort caused by allergies, sinus conditions verticulosis, cramps, or menstrual cramps;
- C. That use of the device will eliminate the pain caused by severe headaches, including but not limited to occipital, frontal, migraine, cluster, or stress headaches, or headaches caused by benign tumors;

- D. That the pain relief or pain elimination provided by the device is immediate;
- E. That use of the device provides long-term pain relief;
- F. That, for the treatment of pain, the device is as effective as, or more effectiventh, prescription or over-the-counter medications, including but not limited to aspirin, acetaminophen, Darvon, Darvocet, or codeine;
- G. That, for the treatment of pain, the device is as effective as, or more effective than, physical therapy, massage therapy, chiropractic treatment, acupuncture, acupressure, orreflexology; or
- H. About the efficacy or relative efficacy of the product in reducing, relieving, or eliminating pain from any source;

unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of this provision, "competent and reliable scientific evidence" shall mean adequate and well-controlled clinical testing conforming to acceptable designs and protocols and conducted by a person or persons qualified by training and experience to conduct such testing.

<u>Provided that,</u> for any representation that any device is effective for:

- (1) the temporary relief of minor aches and pais due to fatigue and overexertion, or
- (2) easing and relaxing of tired muscles, or
- (3) the temporary increase of local blood circulation in the area where applied,

"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.

II.

IT IS FURTHER ORDERED that respondents, Natural Innovations, Inc., its successors and assigns, and its officers; and William Sandee, individually and as an officer and director of

said corporation; and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, offering for sale, sale, or distribution for sale of any product 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, about the health or medical benefits of any such product unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of this provision, "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.

III.

IT IS FURTHER ORDERED that respondents, Natural Innovations, Inc., its successors and assigns, and its officers; and William Gandee, individually and as an officer and director of said corporation; and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, offering for sale, sale, or distribution of any product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that any endorsement (as "endorsement" is defined in 16 C.F.R. § 255.0(b)) of the product represents the typical or ordinary experience of members of the public who use the product, unless:

- A. at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates such 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 such product, 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 provision, "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.

Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

V.

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

- A. All materials that were relied upon in disseminating such represation; 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 for such representation, including but not limited to complaints from consumers and complaints or inquiries from governmental organizations.

VI.

IT IS FURTHER ORDERED that respondent Natural Innovations, Inc. shall notify the 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 change in the corporation that may affect compliance obligations arising out of this Order.

VII.

IT IS FURTHER ORDERED that respondent Natural Innovations, Inc. shall:

A. Within thirty (30) days after service of this Order, distribute a copy of this Order to each of its operating divisions and to each of its officers, agents, representatives, or

- employees engaged in the preparation or placement of advertisements or other materials covered by this Order.
- B. For a period of five (5) years from the date of entry of this Order, provide a copy of this Order to each of its future 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 who are associated with it or any subsidiary, successor, or assign, within ten (10) days after the person assumes his or her position.

VIII.

IT IS FURTHERED ORDERED that respondent William SGandee shall, for a period of seven (7) years from the date of entry of this Order, notify the Commission within thirty (30) days of the discontinuance of his present business or employment and of his affiliation with any new business or employment. Each notice of affiliation with any new business shall include the respondent's new business address and telephone number, current home address, and a statement describing the nature of the business and his duties and responsibilities.

IX.

IT IS FURTHER ORDERED that this Order will terminate on February 25, 2017, 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; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any paragraph 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 termindtoursuant to this Paragraph.

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

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after service of this Order, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

By the Commission.

SEAL Donald S. Clark Secretary

ISSUED: February 25, 1997