UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
NATURAL INNOVATIONS, INC., a corporation, and	)	File No. 942-3251
WILLIAM S. GANDEE, individually and as an officer and director of said corporation.	)	AGREEMENT CONTAINING CONSENT ORDER TO CEASE AND DESIST

The Federal Trade Commission having initiated an investigation of certain acts and practices of Natural Innovations, Inc., a corporation, and William S. Gandee, individually and as an officer and director of said corporation, hereinafter sometimes referred to as proposed respondents, and it now appearing 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 Natural Innovations, Inc., by its duly

(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 contemplated thereby, will be placed on 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

ORDER

I.

IT IS ORDERED that respondents, Natural Innovations, Inc., its successors and assigns, and its officers; and William S. 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 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, diverticulosis, 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 effective than, 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, or reflexology; 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.

Provided that, for any representation that any device is effective for:

(1) the temporary relief of minor aches and pains 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 S. 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 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 S. 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.

IV.

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 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 for such representation, including but not limited to complaints from consumers and complaints or inquiries from governmental organizations.

VI.

IT IS FURTHER ORDERED that 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; 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 terminated pursuant 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 th

Signed this _____ day of _____, 1996.

NATURAL INNOVATIONS, INC., a corporation

By: _____
WILLIAM S. GANDEE
Officer and Director

_____
WILLIAM S. GANDEE

_____
BARRY J. CUTLER
JULIA OAS
McCutchen, Doyle, Brown & Enersen
Counsel for Respondents Natural Innovations, Inc.
and William S. Gandee

_____
LESLEY ANNE FAIR
Counsel for the Federal Trade Commission

APPROVED:

_____
C. LEE PEELER
Associate Director for Advertising Practices

_____
JOAN Z. BERNSTEIN
Director
Bureau of Consumer Protection

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
NATURAL INNOVATIONS, INC., a corporation, and	)	DOCKET NO.
WILLIAM S. GANDEE, individually and as an officer and director of said corporation.	)	

COMPLAINT

The Federal Trade Commission, having reason to believe that Natural Innovations, Inc., a corporation, and William S. Gandee, individually and as an officer and director of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH ONE: Respondent Natural Innovations, Inc. is an Ohio corporation, with its principal office or place of business at 2717 South Arlington Road, Akron, Ohio 44312.

Respondent William S. Gandee is an officer, director, and sole shareholder of Natural Innovations, Inc. Individually or in concert with others, he formulates, directs, and controls the acts and practices of Natural Innovations, Inc., including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of the corporate respondent.

PARAGRAPH TWO: Respondents have manufactured, advertised, labeled, offered for sale, sold and distributed the Stimulator, a "device" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. The Stimulator is a purported pain relief device that emits a weak electric spark when activated.

PARAGRAPH THREE: The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PARAGRAPH FOUR: Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for the Stimulator, including but not necessarily limited to the attached Exhibit A, a transcription of the program-length television commercial, or "infomercial," entitled "Saying No To Pain;" the attached Exhibit B, an

F. JAMES LARIMORE (Consumer Endorser): [The Stimulator] works for me in the area of the sinus problem. (Exhibit A, p. 3)

G. DR. GANDEE: Sinuses. The Stimulator works very well with sinuses. (Exhibit A, p. 6)

H. RON HARTLINE (Consumer Endorser): It's just aches and pains. Carpal tunnel in the wrist, which I didn't think anything but surgery could take care of that. But [the Stimulator] works real well. I mean it loosens -- it's like instantly -- it loosens up the wrist. (Exhibit A, p. 4)

I. BILL RAMSELL (Consumer Endorser): I had excruciating pain in my knees. And [the Stimulator] was fantastic. I couldn't believe what it did for me. You know, it just felt wonderful. As a matter of fact, I golfed 18 holes yesterday and walked quite a bit and it never bothered me at all. (Exhibit A, p. 5)

J. EVEL KNIEVEL: When I wake up in the morning, my wrist tends to hurt me very badly. When I put [the Stimulator] on and I click it, and use it, say, half a dozen or a dozen times on different parts of my wrist, my wrist begins to feel good. . . . [Friends] know that if I use it after all I've been through and all the things that I've tried to kill pain -- that if I use it and they don't see me taking any kind of a drug for pain -- everybody that knows me knows that I do not take drugs -- and they just absolutely know that if I've got a product and I'm using it to help me, then it must be working for me and you can keep things that do not belong in your system out of your system. (Exhibit A, pp. 7-8)

K. DR. GANDEE: But I'll tell you, when I first saw the Stimulator, I personally needed something in my office to help me. And the reason is the knuckle on the forefinger of my hand hurt so bad for the last two years I thought I was going to have to quit chiropractic. I could not work on my patients the way I wanted to. I had to change techniques. I think, seriously, if I hadn't had the Stimulator, I wouldn't be in chiropractic right now. Or I would've had to cut back dramatically on the patients I was seeing. (Exhibit A, p. 3)

L. KEVIN CULVER (Consumer Endorser): I'm up at the club there and I'm bragging about this thing and that's how I ended up here. I said, "That thing worked." You know, I haven't had any pain since. (Exhibit A, p. 8))

M. RUTH MINARD (Consumer Endorser): I got up this morning and I wasn't feeling very well. My feet were hurting me so bad. And I came to sit down to eat my breakfast and Nan got the zapper and she come and zapped me good. Before I could eat my breakfast, my feet were better. It doesn't take me too long to eat either. (Exhibit A, p. 11)

N. BILL WALTON: I had approximately 30 operations on my feet. I was in physical therapy on a constant basis. I worked with people who practiced all sorts of medicine. Orthopedists at the top. Massage therapist, chiropractors, acupuncture, acupressure, reflexology, tremendous amounts of yoga. You name it, I did it. If you have a life where you sit around and are in pain, you're going to be thinking all day long about the things that cause those pains. One of the things I try to do with my life is help

U. UNIDENTIFIED WOMAN #6 (Consumer Endorser): Oh, I think it works much faster than any medication. (Exhibit A, p. 3)

V. LINDA ANTHONY (Consumer Endorser): He puts the Stimulator here and here, it's gone within seconds. The pain is so excruciating and the relief is so wonderful. I mean, it's like no aspirin, no pain medication, no nothing can take that -- give you that instant relief. I mean I'm talking instant. (Exhibit A, p. 6)

W. UNIDENTIFIED MAN #2 (Consumer Endorser): It's always there. It's handy. You don't have to go make a call or set an appointment. It just helps relieve the pain instantly. (Exhibit A, p. 10)

X. JOHN TRIPPE (Consumer Endorser): I've been on Darvocets and other pain killers all this time. Darvocets and Darvons and codeines, Tylenol with codeine. And since I've been introduced to this I haven't used any of it. (Exhibit A, p. 3)

Y. UNIDENTIFIED WOMAN #4 (Consumer Endorser): Some things are addictive. You don't want to -- you end up relying on something that it causes other health problems. And I look for a natural way to deal with any health problems that I have. (Exhibit A, p. 3)

Z. GLEN MATZ (Consumer Endorser): Some of us can't just take aspirin. Some of us just can't take certain medications or anti-inflammatory drugs because they upset our stomach. This, I can relieve that pain and I don't have to swallow anything. (Exhibit A, p. 3)

AA. INSTRUCTION BOOKLET: In most cases, The STIMULATOR provides almost instant relief from pain. In cases of chronic pain, it may require several treatments per day over a period of time to achieve results. It has been our experience that as your pain decreases, the frequency with which you use the STIMULATOR will decrease also, until it's only necessary to use it on an occasional basis. (Exhibit B, p. 2)

We all hurt at one time or another, and the STIMULATOR can provide relief for almost everyone. (Exhibit B, p. 3)

Painful conditions which the STIMULATOR may be helpful for: Painful joints; Stiff joints; Swollen joints; Muscle spasms; Sciatica; Frontal headaches; Occipital headaches; Migraine headaches; Cluster headaches; Stress headaches; Shoulder pain; Back pain; Menstrual cramps; Carpal tunnel syndrome; Numbness and tingling; Allergies; Neck pain; Muscle strain; Foot cramps; Abdominal pain. (Exhibit B, p. 3)

Although the STIMULATOR may not work 100% of the time on 100% of your problems, we are confident that you'll find it extremely effective for the vast majority of your aches and pains as well as enabling you to provide relief for family and friends. (Exhibit B, p. 4)

BB. DR. GANDEE: Who needs the Stimulator? Basically, anyone can use the Stimulator because it's safe and effective. My grandmother is 96 years old and she uses the Stimulator every day. She's got leg cramps and feet problems and she uses it just to help her get through the day. (Exhibit C, p. 1)

CC. DR. GANDEE: Yet I'm sure that as you use the Stimulator and as I show you today how to use the Stimulator more effectively, you're going to find that you're going to be able to get relief most of the time. (Exhibit C, p. 1-2)

DD. DR. GANDEE: At first I really didn't see improvement. It felt a little bit better for a short period of time but then it would go back to what it was before. It took about a week until one day just out of the blue I noticed I had no more pain. (Exhibit C, p. 2)

EE. DR. GANDEE: As I work with the Stimulator, it is very obvious to me that soon this product will be worldwide. I believe that every household in America very soon will own a Stimulator. It might even go to the point where each individual person in the household will own a Stimulator because they'll want to keep it with them all the time. I also sincerely believe that the Stimulator will help you lead a more active, productive, and pain-free life. And as you share the Stimulator with your family and friends, which I hope you do and soon, I know that your family and friends are going to be calling you "Doc" or they're going to be asking for you to use the Stimulator on them. (Exhibit C, p. 7-8)

PARAGRAPH FIVE: Through the use of the statements contained in the advertisements and promotional materials referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A

migraine, cluster, and stress headaches, and headaches caused by benign tumors.

D. The pain relief or pain elimination provided by the Stimulator is immediate.

E. Use of the Stimulator provides long-term pain relief.

F. For the treatment of pain, the Stimulator is as effective as, or more effective than, prescription and over-the-counter medications, including aspirin, acetaminophen, Darvon, Darvocet, and codeine.

G. For the treatment of pain, the Stimulator is as effective as, or more effective than, physical therapy, massage therapy, chiropractic treatment, acupuncture, acupressure, and reflexology.

H. Testimonials from consumers appearing in the advertisements and promotional materials for the Stimulator reflect the typical or ordinary experience of members of the public who have used the product.

PARAGRAPH SIX: Through the use of the statements contained in the advertisements referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through C, respondents have represented, directly or by implication, that at the time they made the representations set forth in PARAGRAPH FIVE, respondents possessed and relied upon a reasonable basis that substantiated such representations.

PARAGRAPH SEVEN: In truth and in fact, at the time they made the representations set forth in PARAGRAPH FIVE, respondents did not possess and rely upon a reasonable basis that substantiated such representations. Therefore, the representation set forth in PARAGRAPH SIX was, and is, false and misleading.

PARAGRAPH EIGHT: The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices and the making of false advertisements in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, on this _____ day of _____, 1996, has issued this complaint against respondents.

By the Commission.

DONALD S. CLARK
Secretary

[Exhibits A-C attached to paper copies of complaint, but not available in electronic form.]

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, agreements to a proposed consent order from Natural Innovations, Inc. ("Natural Innovations") and its officer and director, Ohio chiropractor William S. Gandee ("Dr. Gandee"), and a proposed consent from World Media T.V., Inc. ("World Media") (collectively "respondents").

The proposed consent orders have 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 agreements and the comments received and will decide whether it should withdraw from the agreements or make final the agreements' proposed orders.

The Commission's complaint against respondents Natural Innovations and Dr. Gandee alleges that they deceptively advertising the Stimulator, a purported pain relief device, primarily through an infomercial entitled "Saying No To Pain." The Stimulator is a syringe-shaped device that purports to relieve pain by emitting an electrical spark when applied to the skin. The complaint against World Media TV alleges that it served as an advertising agency, production company, and media buyer for Natural Innovations, Inc., and participated in the creation and dissemination of advertisements for the Stimulator.

The complaints further allege that respondents made unsubstantiated representations that the Stimulator will significantly relieve or eliminate a wide variety of pain, including musculoskeletal pain, carpal tunnel syndrome, abdominal pain, pain caused by allergies and sinus conditions, diverticulosis, menstrual cramps, and headaches, including but not limited to occipital, frontal, migraine, cluster, and stress headaches, and headaches caused by benign tumors.

The complaints also allege that respondents represented without substantiation that pain relief from the device is immediate; that the device provides long-term relief; and that the device is as effective as, or more effective than, prescription and over-the-counter medications, physical therapy, chiropractic treatment, acupuncture, acupressure, and reflexology.

The proposed consent orders contain provisions designed to remedy the violations charged and to prevent respondents from engaging in similar acts and practices in the future. Part I of both orders requires respondents to possess well-controlled clinical testing to support any claim that a device relieves or eliminates pain, relieves pain immediately, or is as effective as or better than over-the-counter pain medication or physical treatments. For representations that a device is effective for temporary relief of minor aches and pains due to fatigue or overexertion, easing and relaxing tired muscles, or temporary increase of local blood circulation, Part I requires that respondents possess competent and reliable scientific evidence.

Part II requires respondents to possess competent and reliable scientific evidence for any claims about the health or medical benefits of any product.

Part III of both orders forbids respondents from representing that an endorsement represents the typical experience of users of the product unless respondents possess competent and reliable scientific evidence substantiating that representation or they disclose clearly and prominently either the results that consumers can generally expect or that consumers should not expect to achieve results similar to the endorsers.

Part IV allows respondents to make representations for any drug that are permitted in labeling for that drug under any tentative or final FDA standard or under any FDA-approved new drug application.

Parts V through VIII and X of the Natural Innovations Order and Parts V through VII and IX of the World Media Order relate to respondents' obligations to make available to the Commission materials substantiating claims covered by the order; to notify the Commission of changes in Natural Innovation's or World Media's corporate structure; to notify the Commission of changes in Dr. Gandee's employment or business affiliations; to provide copies of the orders to certain Natural Innovations and World Media personnel; and to file compliance reports with the Commission. Part IX of the Natural Innovations Order and Part VIII of the World Media Order provide that the orders will terminate after twenty years under certain circumstances.