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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Timothy J. Muris, Chairman**
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

In the Matter of	)	**DOCKET NO. C-4089**
UNITHER PHARMA, INC.,	)	
and	)	**DECISION AND ORDER**
UNITED THERAPEUTICS CORPORATION.	)	

The Federal Trade Commission having initiated an investigation 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, their attorneys, and counsel for Federal Trade 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 than 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 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 thirty (30) days for the receipt and

consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Unither Pharma, Inc. ("Unither Pharma") is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910. Unither Pharma is a wholly owned subsidiary of Unither Pharmaceuticals, Inc., which is wholly owned by respondent United Therapeutics Corporation.

2. Respondent United Therapeutics Corporation ("United Therapeutics") is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910.

3. 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

DEFINITIONS

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

1. "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.

2. Unless otherwise specified, "respondents" shall mean United Therapeutics Corporation, Unither Pharma, Inc., and their successors, assigns, officers, agents, representatives and/or employees.

3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

4. "Food" and "drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55, and "over-the-counter" shall mean available without a prescription.

5. "L-Arginine product" means any food, over-the-counter drug, medical food, or dietary supplement which contains as an ingredient the amino acid L-arginine.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of HeartBar, HeartBar Plus, HeartBar Sport (collectively "HeartBar"), or any other L-Arginine product used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that such product:

A. substantially decreases leg pain for people with cardiovascular disease;

B. reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk;

C. prevents age-related vascular problems, including "hardening of the arteries" and plaque formation, or reduces the risk of developing cardiovascular disease;

D. reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or

E. improves endurance, circulation, and energy for the general population;

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, medical food, or dietary supplement used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, shall not make any representation, in any manner, expressly or by implication, about the health benefits, performance, or efficacy of such product, unless, at the time the representation 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, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, medical food, or dietary supplement used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

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 drug application approved by the Food and Drug Administration.

V.

Nothing in this order shall 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.

VI.

IT IS FURTHER ORDERED that respondents shall, within thirty (30) days after the date of service of this order, send by first class certified mail, return receipt requested, to each distributor, seller, or purchaser for resale of any HeartBar product with whom respondents, or their agents, successors, or assigns, have done business since January 1, 2001, notice of this order in the form attached as Attachment A. The mailing shall not include any other documents.

In the event that respondents receive any information that, subsequent to its receipt of notice of this order, any distributor, seller, or purchaser for resale is using or disseminating any advertisement or promotional material containing claims about HeartBar prohibited by Parts I, II, or III of this order, respondents shall: (1) immediately send such distributor, seller, or purchaser for resale a letter requesting that it stop using or disseminating any such advertisement or promotional material and notifying it that any such use or dissemination will be reported to the Commission; and (2) within thirty (30) days notify the Associate Director for Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, in writing, of the identity of such distributor, seller, or purchaser for resale and its use or dissemination of any advertisement or promotional material containing claims about HeartBar prohibited by Parts I, II, or III of this order.

VII.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, 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 Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation including videotape recordings of all such broadcast advertisements;

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.

VIII.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall deliver a copy of this order to all current and future officers, directors, and managers, and to all current and future employees, and agents 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, for a period of five (5) years after the date of service of this order, to future personnel within thirty (30) days after the person assumes such position or responsibilities.

IX.

IT IS FURTHER ORDERED that respondents, and their 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 respondents learn less than thirty (30) days prior to the date such action is to take place, respondents 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 Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall, within sixty (60) days after the date of 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.

XI.

IT IS FURTHER ORDERED that this order will terminate on July 22, 2023, 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 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 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 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.

By the Commission.

Donald S. Clark
Secretary

ISSUED: July 22, 2003
SEAL

ATTACHMENT A

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED
[To be printed on letterhead of Unither Pharma, Inc. or United Therapeutics Corporation]

[date]

Dear [distributor, seller, or purchaser for resale]:

We write to announce Unither Pharma's new advertising policy for HeartBar related products. As you may be aware, on _____, 2003, the Federal Trade Commission ("FTC") announced a settlement and consent agreement with Unither Pharma, Inc. and United Therapeutics Corporation related to the marketing of HeartBar products. This agreement requires that the claims we make when marketing HeartBar products must be accurate and grounded in competent and reliable scientific evidence.

We are committed to obeying fully the requirements of this settlement agreement with the FTC, while, at the same time, vigorously supporting sales of HeartBar products. To better explain how this advertising policy change may affect you, we briefly summarize the agreement with the FTC and ask for your full cooperation in ensuring that HeartBar products are sold in a manner consistent with this policy.

The Settlement Agreement

In its complaint accompanying the consent order, the FTC alleged, among other things, that our advertisements made unsubstantiated claims that: (1) HeartBar substantially decreases leg pain for people with cardiovascular disease; (2) HeartBar reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency; (3) HeartBar prevents age-related vascular problems, including "hardening of the arteries" and plaque formation, and reduces the risk of developing cardiovascular disease; (4) HeartBar reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, and medications, such as nitroglycerin, in patients with cardiovascular disease; and (5) HeartBar Sport improves endurance and energy for the general population.

The FTC's complaint further alleged that our advertisements falsely claimed that clinical studies, research, and/or trials show that: (1) HeartBar decreases angina pain, including by as much as 70% within two weeks; (2) HeartBar decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease; (3) HeartBar reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; and (4) HeartBar Sport improves endurance and energy for the general population.

We deny the FTC's complaint allegations and do not admit to any wrongdoing or violation of law. However, in order to resolve this matter, Unither Pharma, Inc. and United Therapeutics

Corporation have entered into a settlement agreement with the FTC. Pursuant to the consent agreement, Unither Pharma, Inc. and United Therapeutics Corporation are required to request that our distributors and sellers stop using or distributing advertisements, packaging, or promotional materials containing claims challenged by the FTC. We are sending you this letter, because you are one of our distributors, sellers, or purchasers for resale.

Unless we have competent and reliable scientific evidence to support our claims, the consent agreement prohibits us from representing that any HeartBar product:

- substantially decreases leg pain for people with cardiovascular disease;
- reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk;
- prevents age-related vascular problems, including "hardening of the arteries" and plaque formation, or reduces the risk of developing cardiovascular disease;
- reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or
- improves endurance, circulation, and energy for the general population.

The consent agreement also prohibits us from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research regarding any HeartBar product.

Our Commitment

Unither Pharma, Inc. and United Therapeutics Corporation are committed to the continued study of the health benefits of the HeartBar product and L-arginine through scientifically valid, well-controlled clinical testing. It is the companies' hope that such testing will produce competent and reliable scientific evidence necessary to support additional claims that supplemental L-arginine provides certain health benefits. However, Unither Pharma, Inc. and United Therapeutics Corporation wish to emphasize that it is critically important that claims made pertaining to such health benefits only be made based upon such competent and reliable scientific evidence.

Your Assistance

We request your assistance in complying with the consent agreement. Please discontinue using, distributing, or relying on any of our advertising or promotional material, including packaging, for any HeartBar product that makes any of the claims mentioned above. Please also notify any of your customers who resell these products and who may have such materials to discontinue using such

promotional materials. If we receive information that you are continuing to use materials that do not comply with the consent agreement, we will notify the FTC of your failure to comply with this request.

We very much look forward to our mutual continued success and thank you very much for your assistance.

Sincerely,
[name]

President
Unither Pharma, Inc./United Therapeutics Corporation