

**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.

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 corporate structure of the respondent.

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.

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.

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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