

only to SPA's own proposed performance ordinarily would not encourage or facilitate an agreement among its participating physicians as to the terms under which the physicians would provide medical services. Therefore, a SPA-payor negotiation of terms applicable only to SPA's own proposed performance ordinarily would not be affected by the order. SPA's conduct in such a negotiation may not, however, encourage, facilitate, or conceal an agreement by or on behalf of participating physicians as to the terms upon which they would provide medical services. Thus, for example, the order would not ordinarily preclude SPA's negotiating with third-party payors as to whether, and on what terms, SPA itself would engage in delegated credentialing of physicians on behalf of the payor, undertake specified contract administration activities, maintain specified insurance coverages, or indemnify the payor.

Similarly, the order ordinarily would not affect SPA's communicating to its participating physicians accurate, factual, and objective analyses of proposed third-party payor contract terms, so long as such communication does not encourage, facilitate or conceal a prohibited agreement. SPA may not, however, do so in a manner that directly or by implication suggests that physicians should or should not accept the contract offers or particular terms thereof upon which they would provide medical services. Further, the order ordinarily would not preclude SPA's sharing with a third-party payor SPA's objective analysis of the proposed contract terms prior to communicating that analysis to its participating physicians, provided that SPA informs the payor that SPA will promptly messenger the contract proposal to its participating physicians upon the payor's request, that SPA promptly complies with each such request, and that any such communications by SPA to the payor do not directly or by implication encourage, facilitate, or conceal a prohibited agreement.

Paragraphs III.A and III.B require SPA to distribute the complaint and order to its members, payors with which it previously contracted, and specified others. Paragraph III.C requires SPA to terminate, without penalty, payor contracts that it had entered into during the collusive period, at any such payor's request. This provision is intended to eliminate the effects of Respondent's joint price setting. Paragraph III.C also contains a proviso to preserve payor contract provisions defining post-termination obligations relating to

continuity of care during a previously begun course of treatment.

The remaining provisions of the proposed order impose complaint and order distribution, reporting, and other compliance-related provisions. For example, Paragraph III.D requires SPA to distribute copies of the complaint and order to incoming SPA physicians, payors that contract with SPA for the provision of physician services, and incoming SPA officers, directors, and employees. Further, Paragraph III.F requires SPA to file periodic reports with the Commission detailing how SPA has complied with the order. Paragraph V. authorizes Commission staff to obtain access to Respondent's records and officers, directors, and employees for the purpose of determining or securing compliance with the order. The proposed order will expire in 20 years.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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## FEDERAL TRADE COMMISSION

[File No. 022 3036]

### Unither Pharma, Inc., et al.; Analysis To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before July 14, 2003.

**ADDRESSES:** Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: [consentagreement@ftc.gov](mailto:consentagreement@ftc.gov), as prescribed in the Supplementary Information section.

**FOR FURTHER INFORMATION CONTACT:** Mary Engle or Matthew Daynard, FTC, Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-3161 or 326-3291.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and Section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned 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 thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for June 12, 2003), on the World Wide Web, at "<http://www.ftc.gov/os/2003/06/index.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled "confidential." Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: [consentagreement@ftc.gov](mailto:consentagreement@ftc.gov). Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii).

### Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Unither Pharma, Inc. and its parent company, United Therapeutics Corporation (collectively "Unither").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) 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 allegedly misleading representations about Unither's HeartBar products, chewy food bars and powders enriched with L-Arginine, vitamins, and minerals. HeartBar's labeling describes the product as the only "medical food" for the dietary management of heart and vascular disease.

According to the FTC complaint, Unither failed to have substantiation for the claims that HeartBar: (1) Substantially decreases leg pain for people with cardiovascular disease; (2) reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency; (3) prevents age-related vascular problems, including "hardening of the arteries" and plaque formation, and reduces the risk of developing cardiovascular disease; (4) 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) improves endurance and energy for the general population. Among other reasons, several of the representations are not supported by any clinical studies on humans. Other representations are based on results reported in studies that suffer from various flaws, including the failure to account for the placebo effect and extremely small sample sizes, such that the experience of a single or a few subjects account for the benefits purportedly experienced by the active group as a whole.

The complaint further alleges that, contrary to Unither's claims, clinical studies, research, and/or trials do not show that HeartBar: (1) Decreases angina pain, including by as much as 70% within two weeks; (2) decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease; (3) reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; or (4) improves endurance and energy for the general population.

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

Part I of the order prohibits claims that HeartBar (HeartBar, HeartBar Plus, or HeartBar Sport), or any other L-Arginine product used in or marketed for the treatment, cure, or prevention of cardiovascular disease, or the improvement of cardiovascular or vascular function: (1) Substantially decreases leg pain for people with cardiovascular disease; (2) reverses

damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk; (3) prevents age-related vascular problems, including "hardening of the arteries" and plaque formation, or reduces the risk of developing cardiovascular disease; (4) 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 (5) improves endurance, circulation, and energy for the general population, unless the claims are substantiated by competent and reliable scientific evidence.

Part II of the order requires that Unither possess competent and reliable scientific evidence to support any future claims about the health benefits, performance, or efficacy 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. For the same products covered in Part II, Part III of the order prohibits Unither from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Parts IV and V of the order permit drug claims permitted in labeling under any tentative final or final standard promulgated by the FDA, or under any new drug application approved by the FDA, and any representation for any product permitted in labeling by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

Part VI of the order mandates that the respondents notify their distributors as to the claims the Commission has challenged and report to the Commission any distributors who continue to make claims that the Commission's order prohibits.

Parts VII, VIII, IX, and X of the order require Unither to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part XI provides that the order will terminate after twenty (20) years under certain circumstances.

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.

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

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## GENERAL SERVICES ADMINISTRATION

### Notice of the Availability of the Record of Decision for Badger Army Ammunition Plant Disposal

**AGENCY:** General Services Administration, New England Region.

**ACTION:** Notice of a Record of Decision.

**SUMMARY:** The General Services Administration (GSA) announces the availability of the Record of Decision (ROD) for the Environmental Impact Statement (EIS) for the disposal of Badger Army Ammunition Plant (Badger AAP), Sauk County, Wisconsin.

#### Background Information

Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969, the Council of Environmental Quality Regulations (40 CFR Parts 1500-1508), and GSA Orders ADM 1095.1F and ADM 1020.1, GSA has prepared an EIS for the disposal of approximately 7,354 acres of Badger AAP, located in Sauk County, Wisconsin. GSA's action is the administrative act of transferring ownership of this property through one, or a combination of, disposal mechanisms as dictated by Section 203 of the Federal Property and Administrative Services Act of 1949 (49 Act), as amended (40 U.S.C. 484).<sup>1</sup> Disposal mechanisms available to GSA include: Transferring property to other Federal agencies; conveying property to state or local governments and institutions; and conveying property to private entities.

#### Project Information

The Badger AAP was declared excess to the United States Army's (U.S. Army) mission in 1998. Government properties that are declared excess must be disposed of in accordance with Section 203 of the 49 Act, as amended.

<sup>1</sup> Subsequent to publication of the Draft EIS, Public Law 107-217 was enacted to revise and codify without substantive change certain laws related to public buildings, property, and works. GSA's real property policies were transferred from the Federal Property Management Regulations (FPMR) to the Federal Management Regulations (FMR) in Title 40 of the U.S.C. Reference to the conversion tables are provided in House Report 107-479, pp. 136-278, and are available at <http://thomas.loc.gov>. The ROD and Final EIS will reference the FPMR in conformity with the Draft EIS.