

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).¹ 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.

¹ 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.