



April 25, 2025

Kyle Diamantas  
Deputy Commissioner for Human Foods  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Deputy Commissioner Diamantas:

Thank you for meeting with us on April 17, 2025. At the meeting, we identified two types of cases where a company may have determined that a use of substance is generally recognized as safe (GRAS), despite information indicating that the safety determination may not be warranted. As a follow-up from our discussion on GRAS and per your request, we are sharing information that we believe may be useful to you. This information is on two groups of cases that warrant review by FDA to determine if the company made GRAS determinations contrary to the criteria outlined at 21 CFR 170.30 *Eligibility for classification as generally recognized as safe (GRAS)*.

The first group consists of those cases submitted to FDA that the Agency subsequently ceased to evaluate at the request of the manufacturer. In our April 26, 2024 analysis of the FDA [Inventory of GRAS notifications](#), we found that of the 1163 GRAS notifications in the inventory FDA ceased to evaluate 192 at the request of the manufacturer. EDF and others have reported<sup>1</sup> on FDA's safety concerns for at least a dozen cases, including because of a "lack of detailed composition of the substance" (Venetron) and "[l]ack of explanation for animal studies showing effects in the thyroid, testis, spleen, pituitary, liver, and gastrointestinal tract; potentially dangerous interactions with sodium nitrite, a common preservative, or with acetaminophen and other over the counter painkillers." (epigallocatechin-3-gallate). More information on the concerns FDA raised on these and other cases is provided in Appendix 1. Given the concerns raised by FDA reviewers, we believe that the category of "ceased to evaluate at the request of the manufacturer" cases should be investigated to determine for each case whether there is a lack of a basis to conclude that the intended use of the substance is GRAS and because of the potential harms these substances may present to consumers.

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<sup>1</sup>Environmental Defense Fund. [Broken GRAS](#) blog series. Natural Resources Defense Council. Generally Recognized as Safe: Chemicals Added to Food in the United States [report](#) (May 14, 2014).

The second group of cases are those uses of a substance a company markets as GRAS that were not the subject of a GRAS notification to FDA. These GRAS determinations do not appear to comply with the eligibility requirements of 21 CFR 170.30 *Eligibility for classification as generally recognized as safe (GRAS)*. These GRAS conclusions are often made public through magazine articles and press releases, while the safety assessments remain undisclosed.

“Fundamental to all conclusions of GRAS status is the criterion that general recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use.” (81 Fed. Reg. 54960, August 17, 2016).

General recognition of safety through scientific procedures must be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or method.”

(81 Fed. Reg. 54960, 54961, August 17, 2016).

Thus, a chemical additive cannot be ‘generally recognized as safe’ if its identity, chemical composition, and safety determination are not publicly disclosed. Press releases and magazine articles do not equate with general recognition of safety based on “common knowledge throughout the scientific community knowledgeable about the safety of substances.”

In November 2022, EDF shared with FDA a list of 10 companies that publicized GRAS products between September 20 and November 15, 2022 in our comments on Substances Generally Recognized as Safe: Best Practices for Convening a Generally Recognized as Safe (GRAS) Panel (Docket [FDA-2017-D-0085-0043](#)). These comments are attached.

Table 1 of Appendix 2 includes information for an additional 31 examples of substances and companies advertising GRAS products not reviewed by FDA. Like the previous list, it was assembled from information collected using a browser’s alert on ‘generally recognized as safe’ phrasing.

We recommend that you also investigate each of these cases to determine whether there is a lack of a basis for a conclusion that the substance is GRAS under the conditions of its intended use, given the potential to harm consumers

Please let us know if you have any questions or would like to discuss the information we have provided.

Sincerely,



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Senior Director, Chemical Policy



Maricel V. Maffini, Ph.D.  
Consultant

## **Appendix 1 – Analysis of FDA Inventory of GRAS notifications; Cases that FDA ceased to evaluate at the request of the manufacturer.**

Based on our analysis, as of April 26, 2024, the FDA [Inventory of GRAS notifications](#) (GRN) included a total of 1163 GRNs. There were:

- 64 pending resolution
- 890 that FDA had no questions (81%)
- 192 that FDA ceased to evaluate at the request of the manufacturer (17.5%)
- 17 that FDA found no basis for GRAS determination (1.5%)

### **Regarding GRAS notification withdrawn from review:**

FDA has information on the 192 GRNs including the detailed exchanges with companies and FDA's concerns about the safety determination. This information is only available to the public via FOIA request.

In the last several years, we reviewed a substantial number of GRNs that received a ceased to evaluate letter to understand why companies were withdrawing. For some of them, we also checked whether the products were marketed as GRAS. Following are a few examples of the concerns expressed by FDA reviewers:

**Venetron**: Marketed as [self-affirmed GRAS](#). According to the Venetron product website, the “synergistic effect of VENETRON® and GABA” together “may be more potent for stress [relief].”

- Doesn't meet the GRAS standard “due to FDA's classification of the substance as a new drug” based on the company's promotion of Venetron to treat health conditions.
- Lacks discussion of intended use on specific food categories and information on per serving use levels.
- Lacks explanation of how an intake level of 50 mg/person/day would be achieved.
- Lacks detailed composition of the substance and discussion of the components present in the extract.
- Lacks safety discussion of the major potential health risks associated with the components of the extract, including: Hyperoside and reproductive effects; Isoquercitrin and effects on calcium regulation and body weight; Quercetin and genotoxicity and carcinogenic effects in rats.

**GABA (gamma aminobutyric acid)**: Marketed as PharmaGABA “a functional food ingredient in multiple kinds of food products worldwide.

- The cumulative estimated dietary exposure values were above the toxicology values considered safe, meaning people could consume unsafe levels of GABA under the expected uses.
- Failure to discuss absorption, distribution, metabolism, and excretion (ADME) studies, resulting in a lack of information on how the body would process and eliminate GABA.
- Lack of developmental and reproductive toxicity studies, as well as ADME studies to support safety in pregnant or lactating women or in young children.

- Insufficient data to rule out potential effects on the pituitary gland and effects on individuals with high blood pressure, interference with blood pressure medication.
- Lack of consideration of effects of ingestion of GABA on the gastrointestinal tract, including effects on the gut immune system.

**Epigallocatechin-3-gallate (EGCG):** In the United States, it is marketed as Teavigo but most commonly as green tea extract. In the European Union, it is included in the restricted substances list.<sup>2</sup>

- The company did not address evidence in the published literature that these compounds may cause leukemia in fetuses based on in vitro studies using newborn and adult human cells.
- Lack of explanation for animal studies showing effects in the thyroid, testis, spleen, pituitary, liver, and gastrointestinal tract; potentially dangerous interactions with sodium nitrite, a common preservative, or with acetaminophen and other over the counter painkillers.

**COZ corn oil:** Marketing for human food is unclear. It is manufactured from distillers corn oil, a byproduct of ethanol production that is extracted from the mash that remains after corn is fermented into ethanol. The mash can contain antibiotics and other additives.

- Missing or inappropriate documentation regarding the chemical composition and manufacturing method of COZ corn oil, dietary exposure estimates and safety narrative.
- Lack explanation of adverse health effects from long-term consumption of corn oil including an association with diabetes, maternal effects such as loss of pups, and other adverse effects in the kidneys, pancreas, and heart.
- Lack of information on absorption, distribution, metabolism, and excretion.
- Lack of adequate information on possible pesticide contamination or the levels of mycotoxins in COZ corn oil and antibiotics used in the fermentation process.

As mentioned above, FDA has all the information it needs to identify the companies and the products that, based on the agency's review, would not have been authorized as GRA

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<sup>2</sup> On November 30, 2022, the European Commission issued Regulation (EU) 2022/2340 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council, which included green tea extracts containing (-)- epigallocatechin-3-gallate (EGCG) in restricted substance list. In 2015, a potential risk to consumers was associated with the intake of catechins (in particular EGCG in green tea extracts used in the manufacture of food).

## Appendix 2. GRAS determinations made without notice to FDA

**Table: Examples of products marketed as GRAS**

Product	Commercial name	Company	GRAS statement	Source
Plant-based lactoferrin	LF+	<a href="#">TurtleTree</a>	Turtle Tree's LF+ — the world's first plant-based lactoferrin — obtains access to the US market by achieving self-affirmed Generally Recognized As Safe (GRAS) status. Having secured self-GRAS validation from a panel of experts, LF+ is now available for sale in the US.	<a href="https://www.nutritioninsight.com/news/turtle-trees-world-first-plant-based-lactoferrin-targets-us-market-after-safety-validation.html">https://www.nutritioninsight.com/news/turtle-trees-world-first-plant-based-lactoferrin-targets-us-market-after-safety-validation.html</a>
Hemp extract	+PlusCBD™	<a href="#">CV Sciences</a>	+PlusCBD™ was the first hemp extract supplement brand to invest in the scientific evidence necessary to receive self-affirmed Generally Recognized as Safe (GRAS) status.	<a href="https://ir.cvsciences.com/press-releases/detail/220/cv-sciences-inc-to-announce-year-end-and-fourth-quarter">https://ir.cvsciences.com/press-releases/detail/220/cv-sciences-inc-to-announce-year-end-and-fourth-quarter</a>
Beta-lactoglobulin	Vivici Whey protein	<a href="#">Vivici</a>	Vivici achieved self-affirmed GRAS status in the United States for its fermentation-derived whey protein — beta-lactoglobulin— now commercially available for its customers.	<a href="https://www.nutritioninsight.com/news/beyond-the-headlines-vivici-achieves-gras-status-fda-supplement-directory-revisited.html">https://www.nutritioninsight.com/news/beyond-the-headlines-vivici-achieves-gras-status-fda-supplement-directory-revisited.html</a>
Bovine colostrum	PanTheryx Bovine Colostrum Recognized as GRAS	<a href="#">PanTheryx</a>	Independent expert panel recognizes gut and immune supporting ingredient from leading biotechnology company as Generally Recognized as Safe (GRAS). This designation marks an important milestone towards integrating colostrum	<a href="https://pantheryx.com/pantheryx-bovine-colostrum-recognized-as-gras/">https://pantheryx.com/pantheryx-bovine-colostrum-recognized-as-gras/</a>

			into consumer food & beverage products nationwide.	
Casein	New Culture cheese	<a href="#">New Culture</a>	New Culture, the animal-free dairy company, has self-affirmed that its animal-free casein is Generally Recognized as Safe ("GRAS") following a recent review by an independent panel of qualified scientific and toxicology experts. The company's self-GRAS determination means its casein can be sold, used, and consumed in the U.S. like any other food ingredient.	<a href="https://www.prnewswire.com/news/new-culture/">https://www.prnewswire.com/news/new-culture/</a>
Alternative protein (meat and seafood analog, egg replacement, etc.)	Nosh protein	<a href="#">Nosh.bio</a>	From a regulatory perspective, meanwhile, Aspergillus Oryzae is not considered a novel food and is GRAS (Generally Recognized as Safe) in the US, enabling rapid market entry into the firm's two initial target markets.	<a href="https://www.nosh.bio/solutions">https://www.nosh.bio/solutions</a>
Pomegranate fiber	Pomegranate fiber	<a href="#">POM Wonderful</a>	The Pomegranate Fiber, which is upcycled from POM Wonderful pomegranate husks after juicing, is a GRAS, fiber-dense powder that can be used in a variety of food applications, including crackers, sauces, dressings, baked goods and plant-based food.	<a href="https://www.globenewswire.com/news-release/2024/03/13/2845900/0/en/POM-Wonderful-Adds-Pomegranate-Fiber-to-its-Specialty-Ingredients-Lineup.html">https://www.globenewswire.com/news-release/2024/03/13/2845900/0/en/POM-Wonderful-Adds-Pomegranate-Fiber-to-its-Specialty-Ingredients-Lineup.html</a>
Baker's yeast beta 1,3/1,6 glucan	Wellmune	<a href="#">Kerry Group</a>	Wellmune received a generally recognized as safe status from the US Food and Drug Administration and Novel Food approval from the EU and China.	<a href="https://www.nutritioninsight.com/news/kerry-releases-latest-research-backing-postbiotics-immune-health-potential.html">https://www.nutritioninsight.com/news/kerry-releases-latest-research-backing-postbiotics-immune-health-potential.html</a>

Spermidine	Spermidine Life	The Longevity Labs GmbH	<p>FDA has issued Generally Recognized As Safe (GRAS) status.</p> <p><b>Note:</b> <a href="#">GRN No. 889</a>. At the notifier's request, FDA ceased to evaluate this notice.</p>	<p><a href="https://healthnews.com/nutrition/vitamins-and-supplements/spermidinelife-review/">https://healthnews.com/nutrition/vitamins-and-supplements/spermidinelife-review/</a></p> <p><b>Note:</b> no GRAS claim was found in the <a href="#">manufacturer's webpage</a>, however others note the “GRAS status”</p>
Animal free egg protein	Bioalbumen®	<a href="#">Onego Bio</a>	Preparing FDA filing. Onego Bio is on track to receive self-affirmed "Generally Recognized as Safe" status for Bioalbumen® this year, with a no-objections letter expected from the FDA in 2025.	<a href="https://www.onego.bio/press/our-news/series-a-funding">https://www.onego.bio/press/our-news/series-a-funding</a>
Dried algal biomass product	<a href="#">Algal protein</a>	<a href="#">Zivo Bioscience</a>	Received an updated dossier from an independent scientific review panel reconfirming the Company's “Generally Recognized As Safe” (GRAS) designation for its proprietary algal biomass to be marketed and used as an ingredient in a defined range of foods and beverages for human consumption.	<a href="https://www.zivobioscience.com/news-media/press-releases/detail/73/zivos-gras-designation-reaffirmed-for-proprietary-algal">https://www.zivobioscience.com/news-media/press-releases/detail/73/zivos-gras-designation-reaffirmed-for-proprietary-algal</a>
Natural (R)-1,3-Butanediol	<a href="#">Avela™</a>	<a href="#">Geno</a>	Avela was launched in the U.S. in November of 2022 and has an independent conclusion of GRAS (generally recognized as safe) for use as a source of energy in beverages, bars, and gels.	<a href="https://www.nutritionaloutlook.com/view/ketogenic-ingredient-1-3-butanediol-may-increase-ketone-levels-according-to-recent-study">https://www.nutritionaloutlook.com/view/ketogenic-ingredient-1-3-butanediol-may-increase-ketone-levels-according-to-recent-study</a>

Collagen peptide	<a href="#"><u>PeptENDURE</u></a>	<a href="#"><u>Gelita</u></a>	PeptENDURE is Generally Recognized as Safe (GRAS)	<a href="https://nutraceuticalbusinessreview.com/gelita-introduces-the-first-collagen-protein-solution-for"><u>https://nutraceuticalbusinessreview.com/gelita-introduces-the-first-collagen-protein-solution-for</u></a>
Selenium yeast	<a href="#"><u>SelenoExcell</u></a>	<a href="#"><u>Cypress Systems</u></a>	Cypress Systems recently announced that it has achieved self-affirmed Generally Recognized as Safe (GRAS) for its organically bound, natural food form of selenium yeast, SelenoExcell. The company obtained infant GRAS because selenium has been mandated in infant formula for the past four years. “—Yet, no selenium ingredient has achieved it—we are the first organically-bound selenium yeast to obtain infant GRAS status.	<a href="https://www.nutraingredients-usa.com/Article/2023/10/16/SelenoExcell-achieves-self-affirmed-GRAS"><u>https://www.nutraingredients-usa.com/Article/2023/10/16/SelenoExcell-achieves-self-affirmed-GRAS</u></a>
Protein from aquatic plant lemna	<a href="#"><u>Rubi Protein™</u></a> <a href="#"><u>Rubi Wisk</u></a>	<a href="#"><u>Plantible Foods</u></a>	In the United States, it is self-GRAS (Generally Recognized as Safe) and can be listed on ingredient labels as ‘lemna leaf protein.’	<a href="https://agfundernews.com/plantible-foods-launches-egg-replacer-from-lemna-that-outperforms-eggs"><u>https://agfundernews.com/plantible-foods-launches-egg-replacer-from-lemna-that-outperforms-eggs</u></a>
Fining agent derived from the upcycled stems of white button mushrooms	<a href="#"><u>MycoKleer™</u></a>	<a href="#"><u>Chinova Bioworks</u></a>	Derived from upcycled white button mushrooms, MycoKleer is a vegan, clean-label, self-affirmed Generally Recognized as Safe (GRAS) processing aid.	<a href="https://www.food-safety.com/articles/8647-vegan-clean-label-fining-agent-for-clarifying-beverages"><u>https://www.food-safety.com/articles/8647-vegan-clean-label-fining-agent-for-clarifying-beverages</u></a>
Flavonoids, standardized to >38% polyphenolic flavanoids	<a href="#"><u>Bergamonte</u></a>	<a href="#"><u>HP Ingredients</u></a>	Bergamonte bergamot has been self-affirmed GRAS. This was achieved through the presentation of scientific literature, detailing the multiple benefits of the bergamot fruit, its unique flavonoids and	<a href="https://bergamonte.net/faqs/"><u>https://bergamonte.net/faqs/</u></a> <b>Note: in the webpage FAQs to the question “Is bergamonte BPE complex GRAS?” the answer is “Yes,</b>



			<p>polyphenols, and pre-clinical and clinical studies showing cardiovascular and cardiometabolic support benefits. HPI CEO Annie Eng said: “We have been able to prove its safety and its efficacy for the claims on the ingredient, and now with self affirmed</p> <p>GRAS status, our brand partners and their consumers can enjoy knowing that Bergamonte is, without a doubt, safe for consumption. Obtaining self-affirmed GRAS for Bergamonte was years in the making.”</p>	<p><b>bergamot is on the FDA GRAS list. It is the same Bergamot found in Earl Grey Tea.”</b></p> <p><a href="https://www.wholefoodsmagazine.com/articles/16089-weekly-news-briefs">https://www.wholefoodsmagazine.com/articles/16089-weekly-news-briefs</a></p>
Vitamin D3 from lichen	<a href="#">Vegadelight</a>	<a href="#">Nutraland USA</a>	<p>Nutraland USA announces that its Natural Vegan Vitamin D3 ingredient from lichen, VEGADELIGHT®, has achieved self-affirmed GRAS (Generally Recognized As Safe) status. An independent panel of scientific experts concluded that Nutraland’s VEGADELIGHT® Natural Vegan Vitamin D3 was safe within the terms of Federal Food, Drug and Cosmetic Act and GRAS according to Title 21 Code of Federal Regulations (21 CFR).</p>	
Biosynthetic Pure salidroside (Salidroside is a naturally occurring	<a href="#">LANDKIND® Pure Salidroside</a>	<a href="#">Gnosis by Lesaffre</a>	<p>Landkind, a subsidiary of DoubleRainbow Biosciences leveraging advances in synthetic biology to deliver precision-engineered supplements to advance human</p>	<p><a href="https://ca.finance.yahoo.com/news/landkind-reaches-significant-regulatory-milestone-130000208.html">https://ca.finance.yahoo.com/news/landkind-reaches-significant-regulatory-milestone-130000208.html</a></p>

compound found in the Rhodiola rosea)			health, today announced it has achieved Generally Recognized as Safe (GRAS) status for its revolutionary LK-01™ Pure Salidroside.	
Fava bean protein hydrolysate	<a href="#">PeptiStrong</a>	<a href="#">Nuritas</a>	Nuritas, the world leader in Artificial Intelligence-based peptide discovery, has announced that it has achieved self-affirmed GRAS (Generally Recognized As Safe) status. GRAS status of PeptiStrong was achieved after an intensive review of safety by an independent panel of scientific experts. The panel concluded that the fava bean protein hydrolysate was safe in accordance with the US Food and Drug Administration for proposed food and beverage uses.	<a href="https://www.bevnet.com/news/supplier-news/2022/nuritas-obtains-self-affirmed-gras-status-for-peptistrong/">https://www.bevnet.com/news/supplier-news/2022/nuritas-obtains-self-affirmed-gras-status-for-peptistrong/</a>
Active flavonoid component extracted from Erigeron Breviscapus, containing more than 90 percent of scutellarin	<a href="#">Lifeflower (Breviscapini Extract)</a>	<a href="#">Farlong Nutraceutical</a>	Lifeflower Breviscapine is manufactured according to current good manufacturing practices and is GRAS (generally recognized as safe) for use as an ingredient in yogurt, nutritional bars, smoothies at 84 mg per serving, and dietary supplements at 200 mg per person per day.	<a href="https://www.nutritionaloutlook.com/view/farlong-nutraceutical-is-conducting-study-on-lifeflower-breviscapine-to-determine-its-effectiveness-on-cognitive-health">https://www.nutritionaloutlook.com/view/farlong-nutraceutical-is-conducting-study-on-lifeflower-breviscapine-to-determine-its-effectiveness-on-cognitive-health</a>
Immobilized microorganisms which contain active enzymes that		<a href="#">Better Juice</a>	Better Juice has obtained self-affirmed GRAS (Generally Recognized as Safe) status in the US, meaning products using its technology can be sold in the country.	<a href="https://www.greenqueen.com.hk/better-juice-fruit-juice-reduced-sugar-gras-ingredion/">https://www.greenqueen.com.hk/better-juice-fruit-juice-reduced-sugar-gras-ingredion/</a>

convert sugar into non-digestible				
Mushroom extracts	<a href="#"><u>Realturkeytail™ – turkey tail mushroom extract</u></a>	<a href="#"><u>Nammex</u></a>	<p>Mushroom ingredient supplier Nammex (Gibsons, BC, Canada) announced self-affirmed Generally Recognized as Safe (GRAS) status for two more of its trademarked mushroom ingredients: RealTurkeyTail and Mushroom Immune Complex, which is a blend of chaga, maitake, reishi, shiitake, and turkey tail. These now join other concentrated organic mushroom extracts in the Nammex portfolio with GRAS status, which indicates safe use for foods and beverages.</p> <p>Other trademarked Nammex ingredients with self-affirmed GRAS status include RealChaga, RealCordyceps, RealLionsMane, RealMaitake, RealReishi, and RealShiitake.</p>	<a href="https://www.nutritionaloutlook.com/view/nammex-adds-self-affirmed-gras-status-to-additional-trademarked-mushroom-ingredients"><u>https://www.nutritionaloutlook.com/view/nammex-adds-self-affirmed-gras-status-to-additional-trademarked-mushroom-ingredients</u></a>
Bonded arginine silicate and magnesium biotinate	<a href="#"><u>Lustriva</u></a>	<a href="#"><u>Nutrition21</u></a>	Nutrition21 (Saddle Brook, NJ) announced that its Lustriva beauty-from-within ingredient has been self-affirmed Generally Recognized as Safe (GRAS) for food and beverages. Lustriva was granted self-affirmed GRAS status after submitting a comprehensive dossier of information regarding proposed uses, estimated consumer intakes, chemistry, specifications,	<a href="https://www.nutritionaloutlook.com/view/nutrition21-s-lustriva-beauty-from-within-ingredient-now-self-affirmed-gras"><u>https://www.nutritionaloutlook.com/view/nutrition21-s-lustriva-beauty-from-within-ingredient-now-self-affirmed-gras</u></a>

			and a comprehensive review of its safety information,”	
Naturally occurring hydrolyzed Collagen type II peptides, chondroitinsulfate, and hyaluronic acid.	<a href="#">BioCell Collagen®</a>	<a href="#">Biocell Technology</a>	BioCell Collagen® is self-affirmed GRAS (Generally Recognized As Safe).	
Cinnamon extract ingredient	Cinsulin	CINA  <b>Note: webpage not found</b>	CINA Corp announced today its Generally Recognized as Safe (GRAS) status for its patented nutraceutical ingredient CinSulin®. GRAS status means that CinSulin is considered safe for use in a wide range of food and beverage applications. The GRAS status reviews and analyzes research data including the in vivo and in vitro studies, the methodology, the proposed uses, estimated consumer intakes, active ingredients, specifications, and a comprehensive review of safety data.  “Having GRAS status opens opportunities for CinSulin to be included in functional foods and beverages that support healthy glucose metabolism”	<a href="https://www.prweb.com/releases/cina-corp-announces-gras-status-for-its-patented-nutraceutical-ingredient-cinsulin-r--820004997.html">https://www.prweb.com/releases/cina-corp-announces-gras-status-for-its-patented-nutraceutical-ingredient-cinsulin-r--820004997.html</a>
Amarita Muscaria mushroom extract	<a href="#">Calm</a>	<a href="#">Psyched Wellness Ltd</a>	Psyched Wellness, a life sciences company focused on the production and distribution of artisanal functional and psychedelic mushrooms, is pleased to announce that an	<a href="https://psyched-wellness.com/blogs/press/psyched-wellness-gras-dossier-approved-by-panel-of-experts-">https://psyched-wellness.com/blogs/press/psyched-wellness-gras-dossier-approved-by-panel-of-experts-</a>

			<p>independent review panel of scientific experts has concluded that Psyched's key proprietary extract of Amanita Muscaria, AME-1, is Generally Recognized As Safe (GRAS) as a bulk ingredient.</p> <p><b>Note: On December 2024, <a href="#">FDA determined</a> that the use of this ingredient and its constituents do not meet the GRAS standard and that they are unapproved food additives.</b></p>	<a href="#">providing-green-light-to-market-products-in-the-united-states</a>
Plant proteins	Organic Pumpkin Protein; Organic Unroasted Pumpkin Protein; Organic Heliaflor; Sunflower Protein 45	<a href="#">Austrade Inc.</a>	<p>The self-affirmed GRAS status was obtained through an assessment completed by a panel of qualified experts. The review included a thorough analysis of each product's manufacturing process, nutrition profile and an evaluation of prior research studies and toxicological data. The panel unanimously concluded the listed ingredients are manufactured in accordance with current Good Manufacturing Practices and meet all regulatory and safety requirements to be deemed "Generally Recognized as Safe".</p>	<a href="https://austradeinc.com/ingredients/plant-proteins/">https://austradeinc.com/ingredients/plant-proteins/</a>
Pomegranate extract	<a href="#">Pomella</a>	<a href="#">Verdure Sciences</a>	<p>"The self-affirmed GRAS status is yet another indication of our commitment to continuously improve our scientific initiatives on our branded ingredients, the foundation of which lies in safety and efficacy," the company said in a statement. Backed by human clinical substantiation,</p>	<a href="https://www.nutraingredients-usa.com/Article/2017/10/26/Pomegranate-extract-ingredient-Pomella-gets-self-affirmed-GRAS">https://www.nutraingredients-usa.com/Article/2017/10/26/Pomegranate-extract-ingredient-Pomella-gets-self-affirmed-GRAS</a>

			safety, and efficacy, Pomella Extract is available in a variety of grades, including Pomella FG (food grade) and Pomella Organic. All varieties of Pomella have received self-GRAS status.	
Extract from the brown seaweeds <i>Ascophyllum nodosum</i> and <i>Fucus vesiculosus</i>	<a href="#">InSea2</a>	<a href="#">innoVactic</a>	Canada-based innoVactic has announced that its InSea2 ingredient obtained self-affirmed Generally Recognized as Safe (GRAS) status following a comprehensive evaluation by an independent panel of experts.	<a href="http://www.nutraingredients-usa.com/content/view/print/1449153">http://www.nutraingredients-usa.com/content/view/print/1449153</a>
Sustained release beta-alanine	<a href="#">SR CarnoSyn</a>	<a href="#">Natural Alternatives International</a>	The Generally Recognized as Safe (GRAS) status of Natural Alternatives International's sustained release beta-alanine (SR CarnoSyn) has been affirmed by a panel of independent experts.	<a href="http://www.nutraingredientsusa.com/content/view/print/1396189">http://www.nutraingredientsusa.com/content/view/print/1396189</a>
Fenugreek extract	<a href="#">Testofen</a> and <a href="#">Libifem</a> .	<a href="#">Gencor</a>	Botanical ingredient supplier Gencor has announced that its standardized Fenugreek extract has been affirmed generally recognized as safe (GRAS) by an independent panel of toxicologists.	<a href="https://www.nutraingredients-usa.com/Article/2017/02/08/Gencor-self-affirms-GRAS-status-for-fenugreek-extract">https://www.nutraingredients-usa.com/Article/2017/02/08/Gencor-self-affirms-GRAS-status-for-fenugreek-extract</a>