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Supplement Industry Calls for NDI Draft Guidance Overhaul

The dietary supplement industry's trade associations—American Herbal Products Association (AHPA), Consumer Healthcare Products Association (CHPA), Council for Responsible Nutrition (CRN), Natural Products Association (NPA) and United Natural Products Alliance (UNPA)—joined together to call for an overhaul of the Food and Drug Administration's (FDA) Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, which in its current form undermines both the letter of the law and the intent of the Dietary Supplement Health & Education Act (DSHEA) of 1994, according to the associations.

The Draft Guidance issued by FDA in July, if implemented and enforced by FDA, would burden industry, placing unreasonable requirements on business, especially smaller firms, and create unreasonable barriers of entry for newer market entrants, without any related benefits for consumers, according to the five industry trade associations. While the groups submitted separate comments to reflect their own membership priorities, the five associations stressed that FDA should focus on the common themes in their respective submissions, rather than look for points of disparity as indicating any substantive differences of opinion among the groups. "We are all committed to seeing a substantial overhaul of the draft guidance and are united in our common belief that the document is overreaching and

contravenes DSHEA," the associations announced jointly.

Common key issues identified in the draft guidance by the trade groups include:

- Requiring submission of a notification for virtually every product that contains an NDI from every manufacturer
- A shift in the burden of proof that an ingredient is not an NDI from FDA to individual companies
- FDA's claim that there are no authoritative lists of "grandfathered" ingredients that can be used to establish that a dietary ingredient is an Old Dietary Ingredient (ODI), which dismisses the relevance of "grandfathered" lists submitted by the trade associations in 1996-98 for establishing that dietary ingredients are pre-DSHEA ingredients
- Misinterpreting the meaning of the term "chemically altered," which significantly expands the category of ingredients that would constitute an NDI
- Stating that human synthesized constituents of botanical ingredients are different from those synthesized by the plant
- Imposing a level of data necessary to demonstrate the safety of an NDI similar to what is required for food additives, a standard already rejected by Congress and the courts

Manufacturers and suppliers are supportive of the action. "We agree with the comments filed by the trade associations," said Shaheen Majeed, marketing director for Sabinsa Corporation (East Windsor, NJ). "It is this consistent nature of comments that

sends a clear message to FDA that the guidelines need to be revised. We believe in the safety of these ingredients in the marketplace, so we welcome such guidance, however, we do not feel the current draft guidelines actually deal with safety, rather they reflect the lack of understanding on many points by the FDA."

"The trades really looked at it from the point of view that political interpretation could have limited what was written," added Beth Lambert, CEO of Herbalist & Alchemist (Washington, NJ). "I think they gave really constructive responses to FDA."

Jarrow Formulas, Inc. (Los Angeles, CA) also called for a rewrite of the NDI Draft Guidance. "The Guidance goes directly against the grain of U.S. hopes and goals at this point in our history, and is truly an escort to the guillotine for the supplement industry and a gross violation and disrespect of the will of the American people," said Jarrow Rogovin, founder of the company.

The trade associations requested FDA to carefully consider the comments to the docket it has received and to issue guidance that addresses these serious concerns. They also urged for a timely response from the agency to provide industry with clarity and direction as the industry attempts to comply with the requirements of the law, and the associations offered to work with FDA to achieve that goal.

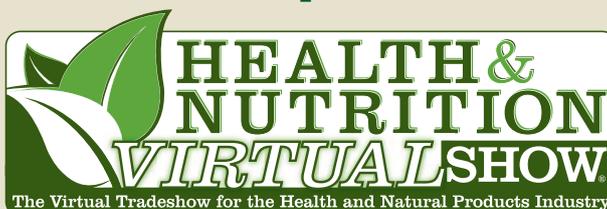
For more information, visit www.ahpa.org, www.chpa-info.org, www.crnusa.org, www.npainfo.org or www.unpa.com.

Virtual Trade Show Open Through January!

The Health and Nutrition Virtual Trade Show — a free online trade show and educational conference for all members of the natural products industry — made its internet debut in December and will remain "live" through the end of January, 2012.

Sponsored by *Vitamin Retailer* magazine, the Health and Nutrition Virtual Trade Show features virtual exhibits by leading industry manufacturers, along with an Auditorium, Learning Center and Library where attendees can watch educational health videos and download various articles and resource materials.

According to show management, the



virtual show has been an overwhelming success to date, with hundreds of natural product retailers and other industry members visiting during its first month.

Exhibitors featured at the Health and Nutrition Virtual Show include: North American Herb & Spice, Carotech, E.W. Packaging, Therapepe, Mother Earth Minerals, Once Again Nut Butter, Origenetics, Pain & Stress Center, Pines International, The Natural Dentist,

RU-Ved, Magnascent Iodine, Vaxa, Xlear and Life Extension. Various show specials, product information and video presentations by exhibitors can be viewed at the virtual booths

located in the show's Exhibition Hall.

Educational videos by such health experts as **Jacob Teitelbaum, M.D.**, Amber Lynn Vitse, Dr. Andrew Weil, and Dr. Virender Sodhi are featured in the show's Auditorium, with new educational materials being made available each week.

To attend the Health and Nutrition Virtual Trade Show, go to www.marketplace365.com/healthandnutritionshow.

Natural products get to the heart of the burn when addressing digestive distress.

BY SHARI BARBANEL



Reflux Defense

Anyone who has experienced heartburn knows how uncomfortable it can make a person. Eating something that “doesn’t agree” can cause a sensation of tightness, pain, discomfort or burning in the chest. The irritation caused by heartburn can make it difficult to concentrate on a task or sleep soundly.

Occasional heartburn is fairly common; in fact, in any six- to 12-month period, 20 to 40 percent of healthy people will experience heartburn symptoms, according to Cheryl Myers, head of education and scientific affairs for EuroPharma USA (Green Bay, WI). “In the past, we may all had an image of the typical heartburn sufferer as being

middle-aged and male, but heartburn and GERD (gastroesophageal reflux disease) affect people of a variety of backgrounds across the board,” she said. But if the pain becomes persistent, a person may be suffering from acid reflux.

Acid reflux disease (also known as GERD) occurs when stomach acid is regurgitated up into the esophagus. Health professionals at the American Gastroenterological Association estimate that 33 percent of people in the U.S. have acid reflux disease. Additionally, acid reflux disease is the most expensive chronic gastrointestinal disorder in the U.S., costing Americans approximately \$10 billion each year.

“The market for heartburn/acid reflux supplements is very large today with

approximately 65 million Americans experiencing heartburn daily. That’s a lot of people seeking relief,” said Brenda Watson, founder and president of ReNew Life Formulas (Palm Harbor, FL). “Many choose pharmaceutical products that either stop hydrochloric acid (HCl) production or simply neutralize stomach acids. Neither of these options addresses the real causes of heartburn such as poor digestion, overeating, alcohol consumption and more. Savvy consumers are increasingly turning to natural supplements for relief, creating exciting potential for real advancements and natural alternatives in this category.”

According to Watson, the standard American diet (SAD) is one of the

biggest contributors to poor digestive health. The SAD is high in calories, is filled with processed foods, and is low in nutrients and essential fiber found in fresh fruits and vegetables. "Most people do not consume nearly enough of the heart-healthy fats that are high in beneficial omega-3 and omega-9 fatty acids," she explained. "One of the many health implications of this imbalanced diet is an increase in poor digestion and heartburn, which exacerbate further health problems down the line."

Going Natural

While many consumers reach for an antacid when the symptoms of heartburn or acid reflux start to appear, they may be doing more harm than good. Taking antacids masks symptoms while suppressing a person's natural HCl levels and essential stomach acids, which can have negative effects on many systems in the body. "I think the overall market for heartburn relief is probably quite strong, once you can educate people to leave the common antacids and PPI's (proton pump inhibitors) alone," said Myers. "What many people don't realize is how dangerous long-term use of these products is. PPI's can double your risk of bone fractures by interfering with the body's natural nutrient absorption of beneficial minerals, deplete vitamin B12 and create a permanent state of too little stomach acid."

EuroPharma's Advanced Heartburn Rescue™ helps stop the symptoms of heartburn and promotes a healthier balance of stomach acid and overall digestive health. The company also offers Gut Soothe™, which features a clinically-studied DGL (deglycyrrhizinated licorice) extract that doesn't need to be chewed, combined with a highly-effective probiotic, *Lactobacillus paracasei*, for additional immune and digestive support.

Recently, EuroPharma partnered with Dr. Jacob Teitelbaum to launch Immediate Heartburn Relief™, a chewable tablet that can help provide relief while someone is also taking



Advanced Heartburn Rescue for a long-term regimen.

Enzymes play an essential role in every function in the human body, including eating and digestion. In the digestive tract, enzymes break down foods by breaking apart the bonds that hold nutrients together. "Enzymes have a direct impact on not only breaking down food to its simplest components, but also relieving stress on the digestive tract," said Dave Barton, director of education for Enzymedica Inc. (Port Charlotte, FL).

ReNew Life has a line of products that includes Digest More Ultra, a full-spectrum digestive blend that contains a high-dose 100,000 HUT protease blend, an important protein-digesting enzyme, plus 13 more enzymes designed to help digest an array of food types. The company recently introduced the STOP line of natural digestive solutions, featuring products such as GasSTOP, HeartburnSTOP and IndigestionSTOP. ReNew Life's newest formulation is HeartBURN OUT, a natural quick-spray mist that is sprayed into the throat for instant relief from the effects of occasional heartburn.

Enzymedica offers Acid Soothe capsules, which provide enzymes to help speed digestion of foods and move them out of the stomach as quickly as possible. This reduces

the body's need to make acid, and provides zinc carnosine to protect and fortify the damaged areas of the lining of the stomach. Additionally, Acid Soothe

capsules provide soothing herbs to calm the irritated stomach lining reducing the distress the consumer may be suffering. The company recently introduced chewable Acid Soothe tablets, which contain no fillers, and contain fast-acting, natural soothing ingredients plus digestive enzymes, according to the company.

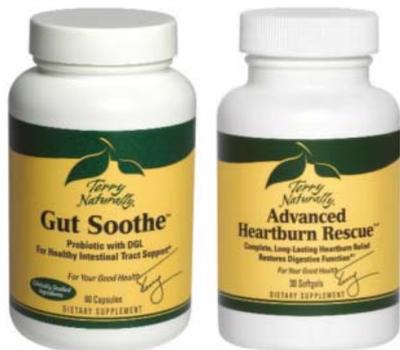
"Consumers are becoming more educated and more accustomed to seeking natural alternatives for maintaining optimal health," said Barton. "Enzymedica is committed to expanding on this consumer education so as to further drive them to their local health food stores."

Retail Tips

Offering customers samples to see the effectiveness of a product can go a long way. EuroPharma takes it a step further and offers a money back guarantee. Retailers can also place products by the register for customers to grab while checking out or create eye-catching displays around holidays when people are more likely to eat larger, heavier meals than usual.

But one of the most important things retailers can do is educate themselves so customers feel comfortable asking their advice. Shoppers may visit a store to explain the symptoms they are experiencing and want to be pointed in the right direction of what product they should be using. When speaking to a customer, Barton suggested that retailers "ask how often the consumer experiences digestive issues, [and] demonstrate the need for a product that may help their customers feel better with all natural ingredients."

"Most importantly, I think making your store a 'health info destination' is one of the best bets," said Myers. "Be a host to seminars. Reiterate how closely connected gut health and overall health really are—because I believe many people still think of them in terms of isolated systems." **VR**



i For More Information:

- Enzymedica, Inc., (888) 918-1118
- EuroPharma USA, (866) 598-5487
- ReNew Life Formulas, (800) 830-4778