

**IPA Responds to
FDA Call for Comments**

**Gut Got You Down?
Ask About Probiotics**

**More Gut Stuff:
Irritable Bowel Syndrome
and Probiotics**

**Probiotics May Help People
with Chronic Fatigue Syndrome**

EXECUTIVE DIRECTOR

Ioannis Misopoulos

EXECUTIVE BOARD

Scott Bush
Vice President
Danisco, USA

S.K. Dash
Vice President
UAS Labs

Nancy Hamren
Treasurer
Nancy's Yogurt

Message from the President



Dear IPA Members,

Isn't it a wonderful time to be in the probiotic business? Consumer awareness is on the rise. The health care community is gaining in knowledge and acceptance. Lots of new food and supplement launches. Exciting mainstream news articles. And scientific studies that expand the horizon of new and innovative health benefits. This is certainly great news for all of us!

As I write to you a year has passed since we gathered in Beverly Hills for the 1st International Probiotics Association Symposium. While The Guess Jeans group with whom we shared the hotel may have bested us on the chic factor, our event was certainly noteworthy in its own right. The IPA Symposium afforded attendees a unique forum for education, knowledge exchange and networking. We were fortunate to have such an esteemed panel of presenters and I trust that attendees departed with an appreciation for this excellent event. Please put April 16-17, 2010 on your calendar for the 2nd International Probiotics Association Symposium, to be held in Miami, FL. The theme of next year's conference is "Probiotics: The Path from Bench to Bedside, Challenges and Achievements".

The IPA newsletter, this being our inaugural edition, is intended to deliver a flavor of new and noteworthy scientific, regulatory and industry news. It also serves as IPA's vehicle to keep you, our valuable members, informed of key IPA initiatives undertaken on your behalf. In this edition you can read about IPA's meeting with USP to promulgate uniform, validated testing standards and our commentary to FDA regarding the industry impact of certain regulations. Plus there are articles describing new and exciting research findings.

Your IPA Executive Committee convenes on a monthly basis via teleconference. We strive to advance the causes of our membership. Please feel free to bring to our attention issues that may be pertinent for the organization to address.

In closing, let me ask your assistance in expanding IPA's membership. There are many companies who are active in our industry and could benefit from IPA's efforts but do not currently belong to our organization. I encourage you to promote the benefits of IPA membership and assist us in growing our ranks.

Healthy Regards, Scott

IPA RESPONDS TO FDA CALL FOR COMMENTS
Warns that Act could jeopardize interstate shipping, access to probiotics

Last July the U.S. Food and Drug Administration (FDA) published a notice in the Federal Register calling for comments about a section of the Food and Drug Administration Amendments Act of 2007 (FDAAA) that could affect the interstate shipment and availability of probiotics. In response, the International Probiotics Association (IPA) has submitted comments signed by IPA Executive Director Ioannis Misopoulos that answer questions posed by the FDA and outline how a broad interpretation of the Act could jeopardize access to probiotics.

The section of the FDAAA in question is section 912. This section establishes section 310(l) in another FDA act called the Federal Food, Drug, and Cosmetic Act. According to the notice in the Federal Register, section 310(l) "prohibits the interstate shipment of foods containing an added drug or a biological product that has been the subject of substantial clinical investigations, the existence of which has been made public."

As noted in IPA's comments to the FDA, probiotic manufacturers, processors, suppliers, and marketers have conducted clinical studies to determine the health benefits of eating specific substances, like probiotics, in food. If section 310(l) is interpreted broadly, this may categorize probiotics as the aforementioned "biological products." What's more, these companies conducted their research after the FDA encouraged them to do so. In other words, the very studies that the FDA encouraged the probiotics industry to fund and perform may place probiotics in a category that restricts how probiotics may be shipped.

Another concern is that section 310(l) could be seen as dictating that a substance is either a food or a drug and cannot be both. This, says IPA, "would deprive consumers of access to a substance unless and until that substance successfully completes the lengthy and unpredictable pharmaceutical development process." In other words, probiotics, as substances that are added to food, would have to be developed and studied as drugs, an expensive proposition that many probiotics manufacturers would not be able to afford.

Neither interpretation of section 310(l) is desirable where IPA is concerned. As stated in the conclusion of IPA's comments, both interpretations "would discourage clinical research on the beneficial health effects of a wide range of substances, including probiotics, in conventional foods and dietary supplements." Furthermore, according to IPA, it would reduce the availability of products containing probiotics, "thereby unnecessarily depriving [consumers] of the associated health benefits."

To that end, IPA has made several suggestions to the FDA about interpreting section 310(l). IPA suggests, among other things, that the FDA exclude dietary supplements from its interpretation of section 310(l) altogether. IPA also suggests that the FDA interpret the term "drug" as it is defined in other FDA regulations, as "articles intended to diagnose, cure, mitigate, treat, or prevent a disease." Probiotics manufacturers make no such claims about their products.

Thus far, the FDA has not taken any action or announced any changes with respect to section 310(l), or to section 912 of the FDAAA.



GUT GOT YOU DOWN? ASK ABOUT PROBIOTICS

The cramping. The trips to the bathroom. The general unpleasantness. Whether it's the result of an infection in your digestive tract or a nasty side effect of taking antibiotics, diarrhea is a drag. But take heart: A recent review of medical research has revealed that taking probiotics can help.

Scientists at the Albert Einstein College of Medicine of Yeshiva University in the Bronx, N.Y. reviewed 19 studies and found that probiotics reduced the risk of developing antibiotic-associated diarrhea by 52%. The benefit was greatest when patients began taking probiotics within 72 hours of starting treatment with antibiotics. The scientists also found that probiotics can shorten the duration and severity of diarrhea from bacterial or viral infection.

Bacteria and viruses can cause diarrhea all by themselves, and antibiotics can cause diarrhea by killing the good bacteria in your gut along with the bad.

Probiotics, most notably *Lactobacillus sp.*, *Bifidobacterium sp.*, *Streptococcus thermophilus*, and *Saccharomyces boulardii*, are thought to combat antibiotic-related and infectious diarrhea by competing with the bad bacteria in the gut and by enhancing immunity.

If you're prone to getting diarrhea when you take antibiotics, or you're having trouble battling infectious diarrhea, ask your doctor about probiotics. The scientists at Einstein encourage doctors to recommend probiotics for their patients in these circumstances, and recommend probiotic doses of more than 5 billion colony-forming units per day for children and more than 10 billion colony-forming units per day for adults. The only caveat is that most insurance providers won't cover the cost: A one-month supply will run you between \$8 and \$22.

The Einstein review was published in the November 1, 2008 issue of *American Family Physician*.

MORE GUT STUFF: IRRITABLE BOWEL SYNDROME AND PROBIOTICS

Antibiotics and infection are not the only things that can bring woe to your gut. Irritable Bowel Syndrome (IBS) can cause cramping, bloating, gas, and bouts of diarrhea that alternate with bouts of constipation. However, unlike antibiotic-related and infectious diarrhea, IBS is not caused by any organisms, although it may be aggravated by them. Instead, IBS is a disorder of how your gut functions, and often the only way a doctor can diagnose it is to rule out other causes through testing. Fortunately, certain probiotics may help lessen symptoms of IBS.

In a review of medical research the American College of Gastroenterology Task Force on IBS found 11 studies in which probiotics were shown to reduce symptoms of IBS. The researchers note that effectiveness varied depending on which probiotic was studied, with a trend toward combinations of probiotics providing the greatest improvement.

This research was published in the January 2009 supplement to the *American Journal of Gastroenterology*.



PROBIOTICS MAY HELP PEOPLE WITH CHRONIC FATIGUE SYNDROME

If you have chronic fatigue syndrome (CFS), a debilitating illness marked by persistent fatigue for six months or more, you may get some relief by taking certain probiotics, say researchers in Stockholm and Umeå, Sweden.

In a small study of 10 women and 5 men with chronic fatigue syndrome, the participants took two deciliters of yogurt containing the probiotics belonging to the families *Lactobacillus*, *L. acidophilus*, and *B. lactis* twice a day for four weeks. The researchers assessed the participants' symptoms for two weeks before treatment, during the four weeks of treatment, and

for four weeks after treatment. Researchers measured the intensity of the participants' fatigue and muscle symptoms and asked participants about their short-term memory and ability to concentrate.

At the end of the study, six of the participants reported improvements in their symptoms. Four women and one man reported improvements in their physical health and two women and one man reported improvements in their mental health. Five women and three men reported no improvement, and one woman said her symptoms got worse.

The researchers caution that this is a pilot study, a smaller, preliminary version of a larger study to come that is conducted to test and refine the procedures. They also note that the variation in the participants' response to treatment is to be expected because CFS is a complex condition that affects each individual differently.

This study was published in the January 26, 2009 issue of *Nutrition Journal*.

News from the IPA Office

On October 28th 2008, IPA along with few of its member companies met with USP to discuss several issues pertaining to standardizing testing methods and a validation program. Prior to the discussions, USP gave an overall presentation of their verification program which is structured as an auditing cGMP program that individual companies can take advantage of. During the meeting IPA was presented with a sample probiotic monograph and the discussions were concentrated around the information that needs to go into that monograph. Since the last meeting nothing has moved forward since IPA is still in internal discussions of the most appropriate plan of action. Stay tuned for updates in the next issue of the IPA Pulse.

DON'T FORGET to mark your calendars for the next IPA WORLD CONGRESS 2010 to take place at the beautiful HILTON MIAMI on April 16th - 17th.

Details and other developments to be published on the next issue of the IPA Pulse.

Probiotics in the News

Probiotics are a hot topic in the media. To learn more about probiotics so that you can make well-informed choices, check out the following articles:

"Bug Crazy: Assessing The Benefits of Probiotics," in The Wall Street Journal, January 13, 2009. <http://online.wsj.com/article/SB12318083108177567.html>

"Probiotics: Good for Kids?" in The Mommy Files blog of The San Francisco Chronicle online, February 25, 2009. http://www.sfgate.com/cgi-bin/blogs/sfnoms/detailRentry_id=35332

"The Right Probiotics for Your Stomach Problems and More," in Health Magazine, online edition, February 13, 2009. <http://living.health.com/2009/02/13/right-probiotics-stomach/>

BOARD OF DIRECTORS

Claude Chevalier
BioK+
Henrik Dalboege
Chr. Hansen
Julie O'Sullivan
Fonterra
George Paraskevacos
Harmonium Int'l.
Jacques Milette
Institut Rosell/Lallemand
Jarrow Rogovin
Jarrow Formulas
Julie Smolyansky
Lifeway Foods

Hishashi Matsumura
Morinaga Milk Co
Don Brown
Nature's Way
Michael Shahani
Nebraska Cultures
Linda Hsieh
Nestle Nutrition
Thomas Blair
Nestle Purina
Tim Gamble
Nutraceutix, Inc.
Ted A. Nordquist
Whole Soy & Co.

SCIENTIFIC ADVISORY BOARD

Serge Carriere, M.D.
Biok+
Thomas Dymann Leser, PhD
Chr. Hansen
Eamonn Quigley, M.D.
Cork University, Ireland
Greg Leyer, PhD
Danisco, USA
Pramad Gopal, PhD
Fonterra
Thomas Tompkins, PhD
Institut Rosell/Lallemand
Gail Czarnacki-Maulden, PhD
Nestle Purina

Robert Martindale, M.D.
Oregon Health Sciences University
Christine Lang, PhD
Organobalance
Luba Shynkarenko-Sichel, PhD
Pure Research Products
S.K. Dash, PhD
UAS Labs
Robert Hutkins, PhD
University of Nebraska-Lincoln