FTC Action: False Probiotic Claims

On July 14th, the Federal Trade Commission announced a settlement in a case against Nestle Healthcare Nutrition for health claims made about a probiotic product. See http://www.ftc.gov/os/caselist/0923087/100714nestleorder.pdf for text of consent order. The product, BOOST Kid Essentials, is a children’s drink with a straw embedded with probiotics. In its complaint against the company FTC alleged that Nestle HCN made false claims in television, magazine, and print ads that their product prevents “upper respiratory tract infections in children, protects against colds and flu by strengthening the immune system, and reduces absences from daycare or school due to illness.” These statements went beyond simply claiming increased immunity to claiming that the product would prevent children from getting sick – a stronger claim that lacked substantiation. The FTC also asserted that claims must be based on a specific probiotic strain.

This is FTC’s first probiotics claims case and how the agency dealt with the issue is significant.

The FTC considers an express or implied nutrition or health benefit claim for food to be deceptive unless “at the time the claim is made the advertiser possesses and relies upon a reasonable basis substantiating the claim.” (FTC Enforcement Policy Statement on Food Advertising, May 1994). In response to Nestle HCN’s claims that BOOST prevents upper respiratory tract infections (URTIs), the consent order prohibits Nestle HCN from making claims that a product prevents or reduces the risk of URTIs “unless the FDA has issued a regulation authorizing the claim based on a finding that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, considering the totality of publicly available scientific evidence.” (This language is based on regulations promulgated by the FDA under the Nutrition Labeling and Education Act of 1990.) The FTC considers this “significant scientific agreement” standard to be what “experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim.” Although the FTC Enforcement Policy Statement does not require it, the FTC is requiring as proof that the company has met this standard, that Nestle HCN obtain FDA pre-approval before it makes a URTI risk-reduction claim for its products because this will “facilitate compliance with the order.” At least one commenter on this aspect of the consent order characterized it as an “unusual element of the settlement” and setting an “unusually high standard” for making claims. See Jeff Helles, “Bursting Nestle Boost’s bubble on ‘probiotic’ claims, available at http://www.philly.com/philly/blogs/consumer/FTC_bursts_BOOSTs_bubble_on_probiotic_claims.html.

FTC guidelines on advertising for dietary supplements states that the “FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with ‘competent and reliable scientific evidence,” defined in FTC cases as ‘tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” “There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration.”
As to Nestle HCN’s claims that BOOST reduces children’s absences from daycare and school due to illness, the FTC determined that “competent and reliable scientific evidence” means “at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence are sufficient to substantiate that the representation is true.”

The FTC has published its consent agreement in the Federal Register. See [http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm#IIb](http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm#IIb). It is open for public comment through August 16th, 2010 after which FTC will decide whether to make it final.

This case touches on a number of the issues raised at the working group meeting on June 14th. The broader issue of regulation of probiotic claims will be a focus of our project and we will be following this case and any others that FTC may bring. Any thoughts on this case or the issue of probiotic claims regulation would be welcome.