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December 16, 2010

Hon. Donald S. Clark
Federal Trade Commission
Office of the Secretary
Room H-135 (Annex J)
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Re: *IMO NBTY, Inc., et al*, FTC File No. 1023080
Request for Public Comments, (Dec. 14, 2010)

Dear Secretary Clark,

The following comments are submitted in response to the FTC's request for public comments on a proposed Consent Decree that regards packaging and promotion of vitamins that contain DHA. Confidential treatment is not requested for any part of this paper or any of the comments.

The summary description of the matter in the agency's News Release, the Complaint and the exhibits, in summary, state that the respondents placed three, true statements on the packaging. The products contain "DHA" (Complaint, ¶11.A.), that two tablets contain "100 mcg of DHA" (Complaint, ¶11.B.), and that, there is substantiation that "100 mg" of DHA "promotes healthy brain and eye development." *Id*., and exhibits. The Complaint pleads that these three factual and/or substantiated statements, when printed together, are "false and misleading."

Enforcement action, indeed the allegation that true statements are false, might be viewed as the agency flexing hypertonic regulatory muscle. The tablets do contain DHA. The amount of DHA, per two tablet "serving" is, as indicated, 100 mcg. The representation that DHA promotes healthy brain and eye development is not incorrect, and has a basis in the journals.[1]

[1] "As the Institute of Medicine of the National Academies of Science (IOM) noted in a recent report, '[i]n the past several years, research has implicated … DHA [… omega-3 fatty acids], in various health benefits identified for the developing fetus and infants'". FDA Notices, 74 FR 3615-01 (Jan. 21, 2009) (releasing for comment, a draft document entitled "Summary of Published Research on the Beneficial Effects of Fish Consumption and Omega-3 Fatty Acids for Certain Neurodevelopmental and Cardiovascular Endpoints").

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The sparse details in the Complaint limit the public comments that may be made unreservedly. Some may wonder whether the alleged "misleading" impact from the three factual statements derives from a concern about the language comprehension skills of the intended consumers of children's vitamins, or is it the product of inferences about the math aptitude of those consumers, *viz*., cannot figure that a mg. is a multiple of a mcg.

Necessarily, to gauge the potentially misleading effect of labeling, the agency must assess the sophistication of the intended consumers who, presumably, can read the label and text.[1] Here, the three statements cited in the Complaint are not untrue, but are supposedly misleading or deceptive.[2] This provokes questions about what assumptions or suppositions have been made, which are not part of the administrative record, about the sophistication or education of the consuming public.[3]

The basic expectation should be that consumers are expected to evaluate facts on labeling. The goal is neutral regulation; and, not agency action that becomes an uber-mütter protective of those who do not read labels, or who do read and can understand the text and math on the labeling for dietary supplements.[4] Are these hypothetical deceits "reasonably avoidable by consumers themselves," and so, matters over which the FTC has "no authority." 15 U.S.C. §45(n). Further to the question of authority of FTC, it is fair to ask whether the labeling of vitamins is squarely within the province of the FDA[5], and too, within the confines of the labeling laws that agency is tasked to enforce.[6]

In conclusion, the Consent Decree engenders uncertainty among independent resellers of supplements and nutriceuticals, in part due to the thin allegations in the Complaint, the factual correctness of the statements on the labeling, the lack of details about how a fact misleads, and the overly-restrictive conditions in the proposed Decree.

Respectfully submitted,

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Lee Thomason

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[1] Are the DHA, mcg., and mg. statements "reasonably calculated to deceive persons of ordinary prudence and comprehension." *F.T.C. v. Solar Michigan, Inc*., 1988 WL 147604 (E.D.Mich. 1988).

[2] "Truthful advertising related to lawful activities is entitled" to legal protections. *In re R.M.J.*, 455 U.S. 191, 203, 102 S.Ct. 929, 71 L.Ed.2d 64 (1982).

[3] "[W]hen the claim is that a literally true statement has a tendency to mislead, confuse or deceive, evidence must be introduced to show what the person to whom the advertisement was addressed found to be the message." *Avis Rent A Car System, Inc. v. Hertz Corp*., 782 F.2d 381, 386 (2nd Cir. 1986).

[4] Courts may "reject the paternalistic assumption that" the intended purchasers reading these labels on vitamins containing DHA "are no more discriminating than the audience for children's television." *Peel v. Attorney Regis. & Discipl. Com'n of Ill*., 496 U.S. 91, 105, 110 S.Ct. 2281, 110 L.Ed.2d 83 (1990).

[5] "Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition." 21 CFR § 101.14(a)(1); see too, sub-section (d)(iii) as to FDA sanctioning the labeling of supplements that recite a health claim that "(iii) ...is complete, truthful, and not misleading."

[6] In 2004, the FTC published a proposed Consent Decree for the supplement "Senior Moment" that contained DHA, and among the proposed conditions were labeling consistent with "regulations promulgated by FDA." *IMO Nutramax*, 69 FR 45066-01 (July 28, 2004).