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REGULATORY UPDATE

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FDA SUES GNC

On Nov. 14, 1984, a Federal Grand Jury indicted General Nutrition Centers (GNC), three corporate officers and two retail store managers for conspiracy to defraud the FDA of its regulatory authority. FDA claims that GNC's Gamma Prim brand Evening Primrose Oil is being sold as a drug, but labeled as a dietary supplement. For several years FDA investigated GNC by sending investigators to purchase products at GNC stores and inquiring what they were good for. These agents were told that a certain book described the virtues of using Evening Primrose Oil for various conditions, including multiple sclerosis, hypertension and arthritis. GNC claims it has done nothing wrong, while the prosecuting attorney Salvatore Martoche states that this indictment is the most significant and far-reaching case to be brought by the FDA in recent years. Mr. Martoche is correct; this case is very significant.

The FDA has never before alleged that a health food company has intentionally tried to defraud the FDA by conspiring to sell dietary supplements as drugs through secondary literature. Should the FDA prevail in this case, it would throw into question the legality of books, literature, magazines, or other media that promote health benefits of specific products sold in health food stores.

This case does not concern the safety or efficacy of Evening Primrose Oil. It concerns the manner in which information can be disseminated about the health benefits of foods, herbs and dietary supplements. In effect, FDA is going for the home run. Before this case the FDA has never charged anyone with conspiring to defraud the agency's regulatory authority.

Conspiracy is a criminal offense punishable by up to 11 years in prison and a \$16,000 fine. It appears that FDA would like to help GNC president Gary Daum start a second career in the license plate making business. This would certainly have a chilling effect on the dissemination of information on health issues, both inside and outside of the health food industry.

At present, little is known about the specific allegations to be made at trial or the defense that will be put on by GNC. What is certain is that this case represents a major effort on the part of the FDA to clamp down on the health food industry. FDA spokesman Bruce Brown stated that this action against GNC should be viewed as a signal to the health food industry that the government is clamping down on the promotion of food supplements as medical treatments without FDA approval of their effectiveness or safety.

This case represents a much larger problem facing the American public and the health food industry: namely, the means by which the public is educated and informed as to the various benefits or uses of health products. The time is long overdue for the evaluation of the way in which we define foods, drugs, prevention, therapy and disease. The FDA should not be viewed as the nemesis of the health food industry; it merely carries out the regulation and laws as it understands them. What is needed is a well thought out position replacing current legislation based on 30 year-old information. (Example: the fiber/cancer controversy; the role of essential fatty acids in disease prevention, etc.). This is the ultimate solution to the problems currently faced by GNC, and indirectly, the health food industry. Such an effort is currently underway to propose answers to these difficult problems. The American Herbal Products Association, The Herb Research Foundation and other groups are currently preparing information to submit to both Congress and FDA. The purpose of this project is to establish a dialogue to promote long-term solutions beneficial to the American public.