

October 20, 2004

Dockets Management Branch
US Food and Drug Administration
Department of Health & Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

CITIZEN PETITION

The undersigned, on behalf of a client, submits this petition under section 403(q) and section 701(a) of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and/or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to amend 21 CFR, Part 101, Subpart C: Specific Nutrition Labeling Requirements and Guidelines, specifically Nutrition Labeling of Dietary Supplements 101.36(d)(1), to require the source of the dietary ingredient lycopene to be identified as from tomato, fungus, or synthetic.

A. Action Requested

The current Food & Drug Administration (FDA) regulation 21 CFR § 101.36(d)(1) requires source ingredients to be identified by their common and usual name, and for botanicals, the listing shall specify the part of the plant from which the ingredient is derived. This petition is requesting that the Agency amend 101.36(d)(1) to make it clear that the dietary ingredient lycopene, when derived from a botanical source, be identified as to that source and that all other lycopene dietary supplement ingredients be identified as to a stated source. The petition is requesting that the following statement be added to 101.36(d)(1):

When the source of the dietary ingredient lycopene is botanical, the source shall be listed (e.g., lycopene (from tomatoes)), or if the source of the dietary ingredient lycopene is not botanical, the source shall be listed (e.g., synthetic lycopene or lycopene (from fungus)).

The revised section would read as follows:

101.36(d)(1) The source . . .

(1) Source ingredients shall be identified in accordance with 101.4 (i.e., shall be listed by common or usual name, and the listing of botanicals shall specify the part of the plant from which the ingredient is derived) regardless of whether they are listed in an ingredient statement or in the nutrition label. When the source of the dietary ingredient lycopene is botanical, the source shall be listed (e.g., lycopene (from tomatoes)), or if the source of the dietary ingredient lycopene is not botanical, the source shall be listed (e.g., synthetic lycopene or lycopene (from fungus)).

B. Statement of Grounds

1. Congressional Intent to Make More Information Available to Consumers Regarding Dietary Supplements

In 1994, the Dietary Supplement Health and Education Act (DSHEA) amended the Federal Food Drug and Cosmetic Act to provide, among other items, that a manufacturer of a dietary supplement may include in the nutritional labeling of the dietary supplement source information for the dietary ingredient.¹ 21 USC § 343(q)(5)(F)(iii) states:

The listing of dietary ingredients may include the source of a dietary ingredient.

By including this provision, Congress recognized how important consumers found the source information. By this language, Congress empowered consumers to make choices regarding their preventive health care. The FDA's regulation 21 CFR § 101.36(d)(1) explains how industry can comply with this provision of DSHEA and states that the source ingredient that supplies a dietary ingredient may be identified within the nutrition label.² The problem with the regulations as written is that the decision to provide source information on the nutrition label of a dietary supplement is left to the discretion of the manufacturer. The permissive language in FDA's regulation results in labeling that does not fulfill Congress' recognized wish that consumers know more. Consumers have less knowledge about their dietary supplements than they need, and

¹ 21 U.S.C. § 343(q)(5)(F)(iii).

² 21 C.F.R. § 101.36(d).

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this leads to confusing or possibly misleading consumers contrary to the expressed intent of Congress speaking through its enactment of DSHEA.

The overarching goal of DSHEA is to empower consumers with information to enable them to make informed decisions regarding their preventive health care. The legislative history of DSHEA does not shed any light on why providing source ingredients is not mandatory and therefore to be included on the nutrition label. Unfortunately, the permissive nature of the agency regulation results in consumers having less information regarding their dietary supplements. This results in confusion among consumers and the possibility of consumers being deliberately misled. Consumer confusion is absolutely contrary to the Congressional intent of DSHEA and can be easily remedied by amending FDA's regulation as proposed in this petition.

As will be discussed at length below, most manufacturers of dietary supplements containing lycopene are opting to not disclose the source of the lycopene contained in their products. As such, the intent of DSHEA, as expressly communicated by Congress, of empowering consumers with more information is not being met in the marketplace for dietary supplements containing lycopene. In fact, Congressional intent may be deliberately frustrated in this case either by the consumer not receiving information necessary to make informed decisions or by unscrupulous manufacturers who display tomatoes on the labeling of a dietary supplement containing synthetic lycopene or lycopene derived from fungi and then opt to not include the source information on the nutrition label. The result of not requiring source information is not only that consumers are not receiving the information they need to make informed choices about their preventive health care, but they are also being either confused or deliberately misled.

As will also be discussed below, ingestion of lycopene from tomatoes may be more beneficial to consumers than synthetic lycopene. As information relating to the health benefits of lycopene from tomatoes over synthetic lycopene is developed and reaches the consumer, informing the consumer of the source of lycopene through the nutrition label of a dietary supplement becomes increasingly more important so that consumers can make informed decisions regarding the products that they purchase.

The permissive language of FDA's regulations regarding source information frustrates the very intent of DSHEA. Regardless of whether consumers are confused, lack sufficient information to make informed decisions, or are being deliberately misled, the only solution is to amend FDA's regulations to require source information on the nutrition label of dietary supplements as proposed by the Petitioner.

2. USP Position on this Issue

In a recent decision, the U.S. Pharmacopeia recognized that a labeling requirement is necessary in order to eliminate consumer confusion over the source of lycopene. The following briefing is found in the Pharmacopeial Forum Vol. 30(2) [Mar-Apr 2004], pg. 574:

Lycopene, page 851 of PF 29(3) [May-June 2003]. This new monograph, which previously appeared in *Pharmacopeial Previews*, is now being forwarded to *In-Process Revision* with modifications based on comments received. The existence of lycopene from different sources in the market created confusion among the consumers and manufacturers of dietary supplements. To clarify the situation, the USP Expert Committee on Nomenclature and Labeling proposed the addition of a Labeling section requiring the indication of whether the article is obtained from natural sources or prepared synthetically.

Like the Petitioner, USP recognizes the confusion of consumers resulting from the existence of lycopene from different sources. As a result, USP is proposing a similar solution, source labeling for dietary supplements containing lycopene.

3. Health Benefits of Lycopene

To fully understand the consumer's need to know as to the source of lycopene, one needs to understand the current status of the scientific literature concerning lycopene from certain sources.

Consumers are exposed to a wealth of information on the potential health benefits derived from inclusion of tomatoes and tomato-based products containing lycopene in the diet. Examples of the proliferation of health information are found in consumer magazines and in newspapers.³ Both print and broadcast media are

³ You say tomato, I say sunscreen", *Energy*, July 2003, p.37; Yaggi, S., "A tomato a day", *Platinum*, Mar/Apr 2003, p.68; "Slather on the tomato paste", *The Boston Globe*, Mar 2003, p. C3; "Tomato lycopene proves to be powerful antioxidant for treating cancer", *The Chicago Crusader*, Feb 8, 2003, p.18; Salvucci, A., "Saucy Benefits: Eat tomatoes to reduce cancer risk", *Living Well*, Mar 2003, p. 9; London, C, "Tomatoes and natural tomato complex may be the ultimate women's health food", *Awareness*,

regularly citing the results of epidemiological studies of populations ingesting tomato and cooked tomato products and clinical studies in which the study population's diet was supplemented with measured doses of lycopene in traditional tomato food sources or tomato extract. Relying upon this scientific information, which is proliferated by the media, consumers are acutely interested in both their consumption of tomato food products and dietary supplements containing lycopene and the other important health promoting constituents of tomato.

The following summaries highlight the results of just some of the studies that consumers are exposed to by the media. There is a significant body of work dealing with prostate cancer. A review by Giovannucci⁴ found that recent epidemiological studies have suggested that a potential benefit against the risk of prostate cancer is derived from lycopene from tomato-based products. Five studies supported a 30%-40% reduction in risk associated with high tomato or lycopene consumption, three are consistent with a 30% reduction in risk, but the results were not statistically significant and seven were not supportive of an association. The largest relevant dietary study, a prospective study in male health professionals found that consumption of two to four servings of tomato sauce per week was associated with approximately a 35% risk reduction of total prostate cancer and a 50% reduction of advanced extra-prostatic prostate cancer. The authors of the review conclude that "although not definitive, the available data suggest that increased consumption of tomatoes and tomato-based products may be prudent." In other work, also investigating prostate cancer risk, Dr. Giovannucci and colleagues at the Harvard School of Public Health found that some data from the Health Professional Follow-Up Study (HPFS) from 1986-1992 suggest that frequent intake

Jan/Feb 2004, p. 24; Stephens, A., "When time is ripe, try tasty tomato treats", *Tucson Citizen*, May 19, 2004 (reprint of newspaper article obtained from www.tucosoncitizen.com); Levy, J. and Sharoni, Y., "The Functions of Tomato Lycopene and It's Role in Human Health", *Herbalgram*, June 2004; Lawrence, D., "The Prostate Puzzle", *Vegetarian Times*, May 2004, pgs.83-84; Hasler, C., "A tomato a day", *Taste for Life*, June 2004, pgs. 28-29; Weingarden-Dubin, J., "Eat more Spaghetti sauce and lower your breast cancer risk!", *Women's World*, June 1, 2004; Carper, J., "Have you heard the latest news? If not, find out why tomatoes are suddenly today's hottest health food", *USA Today*, Aug 26, 2001 (reprint of newspaper article obtained from www.usaweekend.com); "Whole Tomatoes Cut Prostate Cancer Risk", *Connecticut Post*, Nov 6 2003; Cloutre, D., "The power of lycopene", *Let's Live*, June 2004, pgs. 28-29; and Rosenfeld, I., MD, "How Tomatoes Save Lives", *Parade*, May 16, 2004, pg. 19.

⁴ Giovannucci, E., A review of epidemiologic studies of tomatoes, lycopene and prostate cancer, *Experimental Biology and Medicine*, Vol. 227:852-859, 2002.

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of tomato products or lycopene, a carotenoid from tomatoes, is associated with reduced risk of prostate cancer.⁵ This data, however, was inconclusive. The researchers then evaluated additional data from the HPFS to determine if the association would persist. They found that frequent consumption of tomato products is associated with a lower risk of prostate cancer.

In a study examining a population of black and white males, Vogt et al. analyzed the serum levels of individual carotenoids in 209 cases and 228 controls in a US multi-center, population-based, case-control study.⁶ The results, though not statistically significant, suggest that serum lycopene is inversely related to prostate cancer risk in US Blacks and Whites. Clinical trial results coincide with epidemiological findings on prostate cancer prevention and demonstrate the positive effects of tomato lycopene in tomato products on the progression of prostate cancer.

Researchers at the Karmanos Cancer Institute in Detroit, Michigan, investigated the effects of supplementation with lycopene in tomato extract in 26 patients with newly diagnosed, clinically localized prostate cancer.⁷ The patients received either tomato extract supplements containing 15 mg lycopene twice daily for 3 weeks before radical prostatectomy, or no supplementation. Seventy-three percent of the subjects in the intervention group, and 18% of the control group subjects, had no involvement of surgical margins and/or extra-prostatic tissues with cancer. Eighty-four percent of the intervention group and 45% of the control group had tumors, less than 4 ml in size. The results suggest that lycopene supplementation may decrease the growth of prostate cancer.

A nested, case-control study used plasma samples obtained from healthy men enrolled in the Physicians' Health Study, a randomized, placebo-controlled trial of

⁵ Giovannucci, E., Rimm, E.B., Liu, Y., Stampfer, M.J. and Willett, W.C., A prospective study of tomato products, lycopene, and prostate cancer risk, *Journal of the National Cancer Institute*, Vol. 94(5): 391-397, 2002.

⁶ Vogt, T., Mayne, ST., Graubard, B.I., Swanson, C.A., Sowell, A.L., Schoenberg, J.B., Swanson, G.M., Greenberg, R.S., Hoover, R.N., Hayes, R.B. and Ziegler, R.G., Serum lycopene, other carotenoids and risk of prostate cancer in US Blacks and Whites, *American Journal of Epidemiology*, Vol. 155(11): 1023-1032, 2002.

⁷ Kucuk, O., Sarkar, F.H., Sakr, W., Djuric, Z., Pollak, M.N., Khachik, F., Li, Y.W., Banerjee, M., Grignon, D., Bertram, J.S., Crissman, J.D., Pontes, E.J. and Wood, D.P., Phase II randomized clinical trial of lycopene supplementation before radical prostatectomy, *Cancer Epidemiology, Biomarkers & Prevention* Vol. 10:861-868, 2001.

aspirin and beta-carotene.⁸ Subjects included 578 men who developed prostate cancer within 13 years of follow-up. Data from the study provided further evidence that increased consumption of tomato products and other lycopene-containing foods might reduce the occurrence or progression of prostate cancer.

Results of a study by Chen et al. from the University of Illinois at Chicago indicate a possible role for a tomato sauce constituent, possibly lycopene, in the treatment of prostate cancer.⁹ In this study, researchers examined the effects of consumption of tomato sauce-based pasta dishes on lycopene uptake, oxidative DNA damage, and prostate-specific antigen levels in 32 patients already diagnosed with prostate cancer. Patients consumed 30 mg lycopene per day from tomato sauce-based pasta dishes for 3 weeks preceding radical prostatectomy. After the dietary intervention, serum and prostate lycopene concentrations were significantly increased. Compared with pre-intervention levels, leukocyte oxidative DNA damage was statistically significantly reduced after the intervention, and prostate tissue oxidative DNA damage was also significantly lower in men who had the intervention.

New work is exploring the role of tomato and tomato constituents in cardiovascular health. In the face of growing evidence suggesting that lycopene has significant *in vitro* antioxidant potential, Sesso et al. examined the association between plasma lycopene and risk of cardiovascular disease in middle-aged and elderly women.¹⁰ In this prospective, nested, case-control study conducted in 39,876 women free of CVD and cancer, researchers found higher plasma lycopene concentrations are associated with a lower risk of CVD in women.

Increased thickness of the intima-media of the common carotid artery has been shown to predict coronary events; thus, lycopene intakes and serum concentrations may have clinical and public health relevance. Rissanen et al. tested the hypothesis that the intima-media thickness would be greater in men with low serum lycopene

⁸ Gann, P., Ma, Giovannucci, E., Willett, W., Sacks, P.M., Hennekens, C.H. and Stampfer, M.J., Lower prostate cancer risk in men with elevated plasma lycopene levels: Results of a prospective analysis, *Cancer Research*, Vol. 39:1225-1230, 1999.

⁹ Chen, L., Stacewicz-Sapuntzakis, M., Duncan, C., Sharifi, R., Ghosh, L., van Breemen, R., Ashton, D. and Bowen, P.E., Oxidative DNA damage in prostate cancer patients consuming tomato sauce-based entrees as a whole-food intervention. *Journal of the National Cancer Institute*, Vol. 93(24):1872-1879, 2001.

¹⁰ Sesso, H.D., Buring, J.E., Norkus, E.P. and Gaziano, J.M., Plasma lycopene, other carotenoids and retinol and the risk of cardiovascular disease in women, *American Journal of Clinical Nutrition*, Vol. 79:47-53, 2004.

concentration.¹¹ The study involved 1028 middle-aged men who were participants in the Kuopio Ischaemic Heart Disease Risk Factor study. Low serum lycopene concentration was found to be associated with a higher intima-media thickness of the carotid artery. This finding suggests that the serum lycopene concentration may play a role in the early stages of atherosclerosis.

Oxidized LDL cholesterol deposited in the arteries is a cardio health risk factor. A human intervention study was conducted to assess whether a moderately increased consumption of carotenoid-rich vegetables would influence the antioxidant status in 23 healthy men.¹² In one phase of the study, after a 2-week depletion period, the men received tomato juice containing 40 mg lycopene daily. In the other two phases, the men were supplemented with carrot juice and spinach powder. In evaluating the low carotenoid diet, researchers concluded that the additional consumption of carotenoid-rich vegetable products enhanced lipoprotein carotenoid concentrations, but only tomato juice reduced LDL oxidation in healthy men.

Oxidative stress and DNA damage have been implicated as risk factors in degenerative diseases including cancer. Porrini and Riso (2000) evaluated 9 women consuming tomato puree containing 7 mg lycopene daily for two weeks and found that small amounts of tomato puree added to the diet over a short period can increase carotenoid concentrations and the resistance of lymphocytes to oxidative stress.¹³

Analysis of data collected in a study conducted by Pool-Zobel et. al. found that supplementation of the diet with tomato juice containing 40 mg lycopene daily resulted in significant decreases in endogenous levels of strand breaks in lymphocyte DNA.¹⁴ The findings support the hypothesis that carotenoid containing

¹¹ Rissanen, T.H., Voutilainen S., Nyyssonen, K., Salonen, R., Kaplan, G.A. and Salonen, J.T., Serum lycopene concentration and carotid atherosclerosis; The Kuopio Ischaemic Heart Disease Risk Factor Study, *American Journal of Clinical Nutrition* Vol. 77:133-138, 2003.

¹² Bub, A., Watzl, B., Abrahamse, L, Delincee, H., Adam, S., Wever, J., Muller, H. and Rechkemmer, G., Moderate intervention with carotenoid-rich vegetable products reduces lipid peroxidation in *men*, *Journal of Nutrition*, Vol. 130:2200-2206, 2000.

¹³ Porrini, M. and Riso, P., Lymphocyte lycopene concentration and DMA protection from oxidative damage is increased in women after a short period of tomato consumption, *Journal of Nutrition*, Vol. 130:189-192, 2000.

¹⁴ Pool-Zobel, B., Bub, A., Muller, H., Wollowski, I. and Rechkemmer, G.,

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plant products exert a cancer-protective effect via a decrease in oxidative and other damage to DNA in humans.

Protection of the skin via ingestion of tomato products containing lycopene is a promising area of research. Stahl et al. investigated whether intervention with tomato paste containing 16 mg/day of lycopene protects against ultra-violet induced erythema.¹⁵ Ten control subjects received a daily dose of olive oil, whereas the other 9 volunteers received tomato paste mixed in olive oil for 10 weeks. At week 10 of the study, dorsal erythema formation was 40% lower in the group that consumed tomato paste compared to the controls. The data demonstrate that it is feasible to obtain protection against UV light-induced erythema by ingestion of a commonly consumed dietary source of lycopene.

Lastly, in a double-blind placebo controlled trial, twenty patients with exercise-induced asthma (EIA) received either Lyc-O-Mato® brand tomato extract providing 30 mg lycopene per day for one week, or a placebo.¹⁶ Fifty-five percent of the patients receiving the tomato extract were significantly protected against EIA. Serum analyses detected an elevated level of lycopene, compared to the placebo group, with no change in retinol, tocopherols or in the other carotenoids. The researchers state that their results indicate that a daily dose of lycopene from tomato extract exerts a protective effect against EIA in some patients, most probably through an *in vivo* antioxidative effect.

All of these studies and reports support the fact that the tomato ingredient lycopene may play a very important role in health maintenance. This was the very reason that DSHEA was passed, to provide consumers with dietary supplements and an opportunity to maintain or improve their health. As a consumer, there are two keys to any purchasing decision, one is do they ingest the amount of lycopene they wish, and two is the source, is the lycopene tomato based or synthetic. Congress saw the labeling as to source important and FDA can only fulfill Congress' vision by requiring source labeling as to lycopene.

Consumption of vegetables reduces genetic damage in humans: first results of a human intervention trial with carotenoid-rich foods, *Carcinogenesis*, Vol. 18(9): 1847-1850, 1997.

¹⁵ Stahl, W., Heinrich, U., Wiseman, S., Eichler, O., Sies, H. and Tronnier, H., Dietary tomato paste protects against ultra-violet light induced erythema in Humans, *Journal of Nutrition*, Vol. 131:1449-1451, 2001.

¹⁶ Neuman, I, Nahum, H. and Ben-Amotz, A., Reduction of exercise-induced asthma oxidative stress by lycopene, a natural antioxidant, *Allergy*, Vol. 55:1184-1189, 2000.

4. Labeling of Dietary Supplements Containing Lycopene in the Marketplace

The successful penetration of the media message spun from the results of studies including those summarized above is apparent in a Consumer Awareness Study on Attitudes towards Lycopene Health Claims.¹⁷ This study found that 45% of the representative population are aware of lycopene and, of the "aware" group, 60% believe that it is an ingredient found in tomato products. The petitioner believes that a significant percentage of consumers will assume that a dietary supplement labeled as containing lycopene will have derived that lycopene from tomatoes. The consumer will conclude that the health benefits that scientific studies suggest are associated with tomato-containing products, will be associated with that product. This "assumption" by the consumer that all the lycopene in dietary supplement products is derived from tomatoes is supported by manufacturers of products containing synthetic lycopene who deceptively market their products with tomato imagery and statements about the health benefits of tomatoes. Exhibit One shows five different brands of dietary supplements of lycopene. It is not possible from the principal display panel to determine which of the supplements are sourced from tomatoes. Product 5 in Exhibit One, the Nature's Bounty lycopene product label, is decorated with tomatoes. This product, however, contains only synthetic lycopene. The Wyeth Company manufactures Centrum®, a dietary supplement containing lycopene. See Exhibit Two. Wyeth spent over \$15.2 million dollars in 2003 to generate 3.86 billion advertising impressions in a print and television consumer ad campaign that promoted "Centrum *with* lycopene". Every night on national television, millions of Americans watched a Centrum® ad, in which a woman surrounded by tomatoes talks about the benefits of lycopene. A print ad for Centrum® that appeared in consumer publications suggests that the "something" that is in the tomato, that may help protect against heart disease, is the very same "something" that is in Centrum®. The intended inference in Wyeth's broadcast, website and print advertising is obvious; however, in fact, the lycopene in Centrum® is not derived from tomatoes at all, but rather, it is an isolated molecule that has been chemically synthesized.

5. Health Benefits of Lycopene from Tomatoes over Other Sources of Lycopene

A review of publicly available databases has not yielded any clinical studies characterizing the efficacy of synthetic lycopene. Boileau et al. studied the effects of

¹⁷ Consumer Awareness Study on Attitudes towards Lycopene Health Claims, conducted for HJ Heinz Co., Oct 2003.

a diet of either tomato powder (containing 13 mg lycopene/kg diet) or lycopene beadlets (a synthetic lycopene containing 161 mg lycopene/kg diet) on prostatic carcinogenesis and survival time in a rat model and found that consumption of tomato powder, but not synthetic lycopene, inhibited prostate carcinogenesis and increased survival time.¹⁸ Interestingly, although the tomato powder contained less than a tenth the amount of lycopene than the synthetic lycopene, the amount of lycopene found in the plasma was equivalent in both the tomato powder-fed rats and the synthetic lycopene-fed rats. A 2003 study found that natural lycopene and synthetic lycopene are both absorbed into the body to attain equivalent levels, as did a study conducted in humans.¹⁹ However, the study by Boileau et al. also suggests that the synthetic form of lycopene does not have the same effect on the body as from a tomato-based product containing lycopene.

In order to enable consumers to make informed choices regarding the source of lycopene and to avoid confusion or the possibility of consumers being misled, FDA must amend its regulation to require source information on the nutrition label of dietary supplements.

C. Environmental Impact

This petition is categorically excluded from the requirement of an environmental impact statement under 21 C.F.R. § 25.30(k), "Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), petitioner will submit the following information if requested by the Commissioner of Food and Drugs following review of this petition: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.

¹⁸ Boileau, T., Liao, Z., Kim, S., Lemeshow, S., Erdman, Clinton, S., Prostate carcinogenesis in N-methyl-N-nitrosourea (NMU)-testosterone-treated rats fed tomato powder, lycopene or energy restricted diets, *Journal of the National Cancer Institute*, Vol. 95:1578-1586, 2003.

¹⁹ Hoppe, PP., Kramer, K., van den Berg, H., Steenge, G., van Vliet, T., Synthetic and tomato-based lycopene have identical bioavailability in humans, *European Journal of Nutrition*, Vol. 42(5):272-8, October, 2003 (abstract, PubMed).

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E. Certification

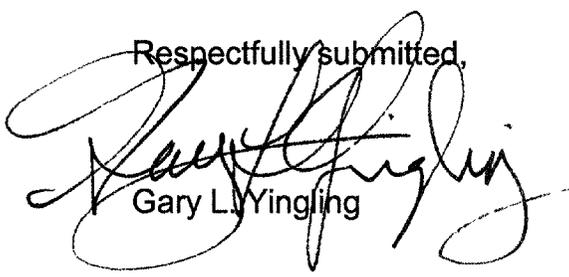
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it included representative data and information known to the petitioner which are unfavorable to the petition.

F. Conclusion

The Petitioner requests that the Commissioner of Food and Drugs amend FDA's regulation at 21 C.F.R. § 101.36(d)(1) to require the nutrition label inform the consumer of the source of the dietary ingredient contained in the dietary supplement. Specifically, Petitioner requests that, in dietary supplements containing lycopene, the nutrition label on a dietary supplements should identify that the source of the lycopene is either "from tomato," "from fungus," or "synthetic."

The clear intent of DSHEA is to provide information to consumers to empower them to make informed decisions regarding their preventive health care. FDA's regulations should further this intent; however, in their current form, FDA's regulations do not. The permissive nature of the labeling requirements for source ingredients in dietary supplements in FDA's regulations have the practical effect of keeping information from consumers, fostering confusion, and enabling manufacturers to mislead consumers. All of these results are contrary to the Congressional intent of DSHEA and could be easily remedied by amending FDA's regulation as proposed by the Petitioner.

Respectfully submitted,



Gary L. Yingling

Enclosure(s)