BEFORE THE
UNITED STATES FOOD AND DRUG ADMINISTRATION
Rockville, Maryland

In re Comments in Response to Proposed Rule, Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements

FDA Docket No.
FDA-2013-N-0067

SUPPLEMENTAL COMMENT OF YOUNGEVITY, INC.

Youngevity, Inc. (hereinafter “Youngevity”), by counsel, hereby supplements its prior Comment (Dkt. No. 0002) in the above-referenced proceeding with this supplement. Youngevity supports FDA’s proposed rule entitled, “Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements.”

This supplemental comment is supported by an expert report from an expert in the study of selenium, Dr. G.N. Schrauzer, Ph.D.

Youngevity has provided innovative health enhancing products, including dietary supplements, to customers worldwide since 1991. It is the only company of its kind to have obtained a qualified health claim for selenium following submission of a health claim petition in 2002 and again in 2008. Youngevity markets selenium-containing dietary supplements.


In its proposed rule, the FDA seeks to amend regulations on nutrient specifications and labeling for infant formula by requiring the inclusion of selenium at certain minimum and maximum levels. Specifically, the FDA proposes a minimum level of 2.0 µg selenium/100kcal and a maximum level of 7.0 µg selenium/100kcal.

Youngevity supports the FDA’s proposed new rule, which will enable infants and young children to receive the important health benefits that come from selenium. On May 9, 2013, Youngevity filed its initial comment in this proceeding.\(^3\) Youngevity herein provides a supplemental comment, which incorporates recommendations made by Dr. Schrauzer (Attached as Exhibit 2). Dr. Schrauzer is uniquely qualified to offer expert insight concerning FDA’s proposed rule. Based on his education, training, and experience, Dr. Schrauzer is one of the foremost authorities on trace elements, trace minerals, and vitamins in the world. See Ex. 1, Curriculum Vitae of Dr. G.N. Schrauzer. Dr. Schrauzer supports the inclusion of selenium in infant formula as proposed by the FDA. He urges FDA to encourage supplementation of infant formula with the organic form of selenium, selenomethionine, as opposed to the inorganic form, sodium selenate. He does so based on the superior qualities of the organic form that allow for greater health benefits. See Ex. 2.

**Supplementation of Infant Formula With Organic Selenium**

Youngevity agrees with the FDA that selenium is an essential trace element in human nutrition. See Ex. 3 at 355-56. It is present in foods consumed daily in the United States. The Institute of Medicine lists selenium’s known biological functions to include defense against oxidative stress, regulation of thyroid hormone action, and regulation of the redox status of vitamin C and other molecules. See Ex. 4. In addition, the PDR on Nutritional Supplements references selenium’s antioxidant activity, noting that selenium may have immunomodulatory, anti-carcinogenic, and anti-atherogenic activities. See Ex. 3 at 356.

Without FDA’s proposed supplementation of infant formula with selenium, the amount of selenium an infant receives is dependent on maternal intake of selenium. See Ex. 7 at 15, ¶ 2. Maternal intake is dependent on multiple factors, and accordingly, maternal selenium levels are largely insufficient to ensure adequate selenium intake by infants. See Ex. 5 at 152 (“The wide range of breast milk selenium concentrations depends on selenium consumed in natural foods, which reflects the content of the soils where they are grown”). Youngevity urges FDA to encourage supplementation with selenium in its organic form, selenomethionine, as opposed to its inorganic form, sodium selenate.

Selenomethionine is the main nutritional source of selenium. See Ex. 2 at 1. Selenomethionine is the only naturally occurring selenium compound which is significantly incorporated into body proteins. Id. L-selenomethionine is a dietary supplement in many formulations sold in the United States and is found in the United States Pharmacopoeia. See Ex.

Brewer’s Yeast is an inexpensive source of selenomethionine available in powder or tablet form and can be added to infant formula. See Ex. 2 at 2. High-selenium yeast contains L-selenomethionine in proteins. See Ex. 3 at 356. Humans enzymatically digest these proteins into amino acids, oligopeptides, and L-selenomethionine. Id. The body then absorbs L-selenomethionine from the small intestine into the liver where a percentage is ultimately transported by circulation to various tissues. Id. The kidney’s regulation of selenium excretion produces selenium homeostasis. Increased excretion of selenide metabolites is directly proportional to increased selenium consumption.

Conversely, selenate is not incorporated into proteins to any significant extent. Id. Selenate’s half-life is approximately 60% shorter than that of L-selenomethionine. See Ex. 8 at 2. Some studies demonstrate that “the bioavailability of selenium from L-selenomethionine has been shown to be approximately 1.5 to 2 fold higher than that of inorganic forms of selenium.” Ex. 8 at 1-2. Accordingly, infant formulas with added sodium selenate cannot fully reproduce the health benefits of the organic selenium found in breast milk. See Ex. 2 at 2. To truly improve the selenium status of children and to allow the necessary build-up of selenium reserves in the body, selenomethionine should be recommended. Id.

**Proposed Levels of Selenium**

FDA proposes a minimum level of 2.0 µg/100 kcal and a maximum level of 7.0µg/100kcal for infant formulas. Excessive selenium deficiencies in infants are associated with Keshan disease. See Ex. 6 at 5. While some organizations in Europe have recommended slightly higher levels,4 Youngevity agrees with the levels suggested by the FDA unless a pediatrician otherwise recommends an alternative dosage because of a peculiar deficiency of selenium. See Ex. 2 at 2.

**Conclusion**

Based on the foregoing reasons, Youngevity respectfully urges the FDA to adopt the proposed rule with a recommendation that urges use of selenomethionine in preference to selenate in infant formulas. The proposed rule is necessary to protect against selenium deficiencies in infants, whose intake otherwise is solely dependent upon maternal intake, which may be deficient.

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4 See Ex. 6 at 2, ¶ 2.5, available at http://www.who.int/water_sanitation_health/dwq/chemicals/selenium.pdf. Also, in 2003, the European Commission’s Scientific Committee on Food recommended that the minimum and maximum selenium levels in infant formula should be 3 µg/100kcal and 9 µg/100kcal respectively. See Ex. 8 at 153. Such levels correspond with the Food and Nutrition Board’s (Institute of Medicine) findings of the average daily intake of breast milk and average concentrations of selenium present in breast milk. Id. Essentially, the Committee cautiously recommended a daily intake of supplemented formula that would mirror concentrations in equivalent volumes of breast milk with naturally present selenium levels.
Respectfully submitted,

YOUNGEVITY, INC.

By:  /s/ Jonathan W. Emord
     Jonathan W. Emord
     Peter A. Arhangelsky
     Lou F. Caputo
     Counsel to Youngevity, Inc.

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