Robert J. Schoenberg
RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP
Headquarters Plaza
One Speedwell Avenue
Morristown, New Jersey 07962-1981
Tel: (973) 451-8511
Email: rschoenberg@riker.com

M. Roy Goldberg (*Pro Hac Vice pending)*
Nathaniel Bruno (*Pro Hac Vice pending*)
SHEPPARD MULLIN RICHTER
& HAMPTON LLP
1300 I Street, N.W., Suite 1100 East
Washington, D.C. 20005-3314
Tel: (202) 218-0000
Email: rgoldberg@sheppardmullin.com
Email: nbruno@sheppardmullin.com

Attorneys for Plaintiff
Everett Laboratories, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVERETT LABORATORIES, INC., Plaintiff, v. ACELLA PHARMACEUTICALS, LLC, Defendant.	Civil Action No. _____ Hon. _____ U.S.D.J. **COMPLAINT FOR PATENT INFRINGEMENT AND JURY DEMAND** (Document Filed Electronically)

Plaintiff Everett Laboratories, Inc. ("Everett"), by its undersigned attorneys, for its Complaint against Defendant Acella Pharmaceuticals, LLC ("Acella" or "Defendant"), alleges as follows:

INTRODUCTION AND SUMMARY

1. This action seeks redress for Acella's deliberate and willful infringement of U.S. Patent No. 8,197,855 (the "'855 Patent") (a copy of which is attached as **Exhibit A** hereto) through Acella's manufacture, use, marketing, offering for sale, selling, and/or importing of its prescription-only, prenatal nutritional supplement called "Choice-OB+DHA," which is a willful exact copy of Everett's "Select-OB®+DHA" prescription-only, prenatal nutritional supplement. The claims of the '855 Patent are based on the caplet component of Select-OB®+DHA.

2. According to its package insert, Choice-OB+DHA contains the same vitamins and minerals, in the same amounts, as Everett's Select-OB®+DHA. Choice-OB+DHA hence directly infringes Claims 1, 4-13, and 15-18 of the '855 Patent. Additionally, because Acella sells and distributes Choice-OB+DHA with a package insert that instructs the method of using Choice-OB+DHA to provide nutritional supplementation to the patient, Acella is also inducing direct infringement of method claims 19, 22-31, and 33-36 of the '855 Patent by patients.

3. Because, on information and belief, leading computerized drug databases (such as First DataBank and/or Medi-Span) have "linked" Choice-OB+DHA to Select-OB®+DHA, which causes wholesalers that utilize information from the drug databases to offer the lower-priced copy product Choice-OB+DHA for the branded Select-OB®+DHA product and causes pharmacies that utilize information from the drug databases to substitute the lower-priced copy product Choice-OB+DHA for the branded Select-OB®+DHA product when presented with a prescription for Select-OB®+DHA, Everett is being and will continue to rapidly and increasingly be irreparably harmed as a result of the existence of the infringing Choice-OB+DHA product in the market. It can be expected that, within less than one year of Choice-OB+DHA being "linked" to Select-OB®+DHA, Choice-OB+DHA will have displaced 90 percent of the sales that otherwise would have been made by Everett of its Select-OB®+DHA product by virtue of the "linking."

4. The presence of the Choice-OB+DHA product in the market creates a huge dilemma – a "Hobson's Choice" for Everett. Either Everett stops marketing its Select-OB®+DHA product or continues to spend money to market it to the advantage of its infringing competitor, Acella. Yet, if Everett stops marketing Select-OB®+DHA, Everett will forfeit sales to other nutritional supplement companies which, unlike Everett, will still have an incentive to market and promote their products to doctors.

JURISDICTION AND VENUE

5. This Court has original and exclusive jurisdiction of this action, pursuant to 28 U.S.C. §§ 1331 and 1338(a), because the action arises under the Patent Laws of the United States, Title 35, United States Code. The Court also has original jurisdiction over the copyright infringement claim stated herein, pursuant to 28 U.S.C. § 1338(b), because that claim arises under Section 501(a) of the Copyright Act, 17 U.S.C. § 501(a).

6. The Court has personal jurisdiction over Defendant Acella in this action because Defendant regularly conducts business in New Jersey, has engaged in infringing acts in New Jersey, and specifically has offered to sell, offers to sell, has sold, and/or sells the product that is the subject of this Complaint in New Jersey and in this judicial district.

7. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to this Complaint occurred in this judicial district.

THE PARTIES

8. Everett is a corporation organized and existing under the laws of the State of New Jersey, having its headquarters and principal place of business at One Main Street, Suite 203, Chatham, New Jersey, 07928.

9. Upon information and belief, Acella is a Delaware limited liability company, having its principal place of business at 11675 Great Oaks Way, Suite 144, Alpharetta, GA 30022.

STATEMENT OF FACTS

Plaintiff Everett Laboratories, Inc. And Its Select-OB®+DHA Product

10. Plaintiff Everett is a pharmaceutical company that has been marketing and selling and continues to market and sell various prescription-only nutritional supplement products

throughout the United States. Everett's reputation has been and continues to be enviable both in the trade and to the general consuming public in the United States. Everett is well known to prescribers of prescription-only nutritional supplements and medicines as well as to retailers, wholesalers, physicians, pharmacists, patients, and distributors in the industry in the United States.

The Select-OB®+DHA Product

11. Since at least April 8, 2009, Everett has continuously and actively engaged in selling a nutritional supplement called Select-OB®+DHA which was formulated to deliver essential vitamins and minerals to the mother and her developing fetus. It is sold as a two-component kit in a blister pack. One component of the kit is a chewable caplet that contains specified quantities of the active ingredients vitamins A, B_1, B_2, B_6, B_{12}, C, D_3, E, folic acid and niacin, and minerals iron, magnesium and zinc. *See* Select-OB®+DHA 10/11 product insert attached hereto as **Exhibit B**, and original package insert attached hereto as **Exhibit C**. The other component is a softgel capsule containing DHA from algae, and Lauric Acid. *See* Select-OB®+DHA 10/11 product insert attached hereto as **Exhibit B**.

12. Select-OB®+DHA is a "branded product." The U.S. Food and Drug Administration ("FDA") regulates "branded" drugs. Although prescription-only prenatal vitamins are not regulated like drugs are by the FDA, the parallels are similar and hence this Complaint uses the term "branded" to refer to Everett's innovator products.

13. On June 12, 2012, the U.S. Patent and Trademark Office issued the '855 Patent (**Exhibit A** hereto) for the product formulation of the caplet component of Select-OB®+DHA and related methods of use.

14. Claim 1 of the '855 Patent recites the following:

> 1. A composition for supplementing nutritional deficiencies in a patient or person in need thereof, consisting of vitamin A, beta

> carotene, vitamin B_1, vitamin B_2, vitamin B_3, vitamin B_6, vitamin B_9, vitamin B_{12}, vitamin C, vitamin D_3, vitamin E, iron, magnesium, zinc and one or more inactive ingredients, wherein said composition is both swallowable and chewable.

15. The named inventors of the '855 Patent are John A. Giordano and Charles J. Balzer, who have assigned their rights in the '855 Patent to Everett, such that Everett is the assignee and owner of the '855 Patent.

16. Everett has engaged in extensive advertising and promotion of Select-OB®+DHA to gain goodwill and public recognition of its product. To that end, Everett has spent substantial sums of money and resources to develop, advertise, and market Select-OB®+DHA.

17. Everett has caused Select-OB®+DHA to be listed in online drug databases that pharmacies use in filling prescriptions for prenatal nutritional supplements, including the leading drug database, First DataBank, as well as Medi-Span, and Gold Standard.

Defendant Acella And Its Choice-OB+DHA Product

18. Acella is a Delaware limited liability company with offices in Alpharetta, Georgia. On information and belief, its business model includes formulating alternatives or substitutes for existing branded vitamin products and offering them for sale at lower prices.

19. Acella directly competes with Everett in the market for prescription-only, prenatal supplements containing DHA.

The Choice-OB+DHA Product

20. Upon information and belief, Acella uses, manufactures, markets, offers for sale, imports, and/or sells Choice-OB+DHA, which is a copy of, and hence competes directly with, Everett's Select-OB®+DHA product. A copy of the package insert for Choice-OB+DHA is attached as **Exhibit D** hereto. Acella sells its Choice-OB+DHA copy of Everett's Select-OB®+DHA product at a significantly lower price than Everett's Select-OB®+DHA product. Upon information and belief, Acella offers for sale and has sold its lower-cost Choice-OB+DHA

copy product at pharmacies in this judicial district.

21. According to the Choice-OB+DHA package insert, and as shown in the following Chart 1, Choice-OB+DHA directly infringes Claim 1 of the '855 Patent, as it contains the same vitamins and minerals listed in Claim 1 of the '855 Patent, and it further contains them in identical amounts as Select-OB®+DHA:

CHART 1

'855 Patent, Claim 1 Ingredients	Select-OB®+DHA Product Insert	Choice-OB+DHA Package Insert
Vitamin A Beta Carotene	1700 I.U. total	1700 I.U. total
Vitamin C	60 mg	60 mg
Vitamin D	400 I.U.	400 I.U.
Vitamin E	30 I.U.	30 I.U.
Vitamin B_1	1.6 mg	1.6 mg
Vitamin B_2	1.8 mg	1.8 mg
Niacin (Vitamin B_3)	15 mg	15 mg
Vitamin B_6	2.5 mg	2.5 mg
Folic Acid (Vitamin B_9)	1.0 mg	1.0 mg
Vitamin B_{12}	5 µg	5 µg
Iron	29 mg	29 mg
Magnesium	25 mg	25 mg
Zinc	15 mg	15 mg
Inactive ingredients	Other carriers or Excipients	Other carriers or Excipients

22. Choice-OB+DHA also directly infringes Claims 4-13 and 15-18 of the '855 Patent.

23. Additionally, because Acella sells and distributes Choice-OB+DHA with a package insert that instructs the method of using Choice-OB+DHA to provide nutritional supplementation to the patient, Acella is also inducing direct infringement of method Claims 19, 22-31, and 33-36 of the '855 Patent by the patients.

Linking And Automatic Substitution By Drug And Nutritional Supplement Databases

24. Computerized drug databases (also known as compendia) – such as First

DataBank, Medi-Span, and Gold Standard – link non-branded copy products to branded products by comparing the key active ingredients of each product. If the products match in terms of type, content, and amount of the key ingredients considered by the database, the products will be linked. If products are linked, there is typically automatic substitution by the pharmacies that are asked to fill the prescription by the copy product with the lower price. Indeed, many insurance companies and other third-party payers insist that the cheaper, copy product be substituted for the branded product.

25. First DataBank and Medi-Span categorize products for purposes of determining substitutability based upon labeling provided to them by manufacturers. Their customers include retail pharmacy chains, drug wholesalers, health management organizations, insurance companies, and Medicaid state agencies. These customers purchase data from First DataBank and Medi-Span for use in their own computer database systems (such as databases utilized by pharmacists at retail pharmacies). These data support pharmacy dispensing, formulary management, drug pricing analysis, and electronic prescribing. Most major retail pharmacies and pharmacy chains rely on data provided by First DataBank or Medi-Span to assist the pharmacist in making dispensing decisions about prescription products. Specifically, First DataBank data is utilized by Rite Aid®, CVS®, CVS Caremark®, Safeway®, Publix®, and Costco® pharmacy chains, and Medi-Span data is utilized by Walgreens® and Wal-Mart® pharmacy chains.

26. First DataBank and Medi-Span obtain data about new pharmaceutical products directly from the products' manufacturers and/or distributors. Prior to the launch of a new product, manufacturers and/or distributors submit new product information to First DataBank and Medi-Span. This information includes labels, product inserts or package inserts, and other

promotional materials that describe the product's ingredients, strength, dosage form, route of administration, and price.

27. Neither First DataBank nor Medi-Span performs or sponsors any independent testing of pharmaceutical products. Both databases rely strictly on information provided to them by product manufacturers and/or distributors concerning their products.

28. When First Databank first receives information about a new pharmaceutical product, it is reviewed by a research associate in the Editorial Services Department. The research associate will identify the product's key active ingredients and their strength, the dosage form, and the route of administration. If an existing product with the same key active ingredients in the same strengths, in the same dosage form, and with the same route of administration is found within the First DataBank database, the research associate will assign the new product to the same clinical formulation ID (also known as the "Generic Code Number" or "GCN code") as that assigned to the existing product in the database. The clinical formulation ID is the newly-formed identifier name for what was previously known as the Generic Code Number. Products which have the same GCN code are considered pharmaceutically equivalent to each other. Products having the same GCN code are also described as being "linked." If more than one product is assigned to the same GCN code, those products are described as "multiple source" products, *i.e.*, they are pharmaceutically equivalent products that are available from multiple sources.

29. Medi-Span has an analog to First DataBank's GCN code, which Medi-Span refers to as the "Generic Product Identifier" or "GPI code." Products assigned to the same GPI code in the Medi-Span database have the same key active ingredients in the same strengths, in the same dosage form, with the same route of administration, and are also considered pharmaceutically equivalent to each other. Products having the same GPI code are also said to be "linked."

30. When pharmacists at the retail pharmacies that utilize First DataBank and Medi-Span data process prescriptions written by doctors for Everett's Select-OB®+DHA prenatal vitamin supplement product, they will substitute defendant Acella's Choice-OB+DHA prenatal vitamin supplement product for Everett's Select-OB®+DHA prenatal vitamin supplement product due to the linking of those products in the First DataBank and Medi-Span databases.

31. Pharmacists will make substitutions in order to capitalize upon the advantage of the lower price of Defendant Acella's Choice-OB+DHA generic copy product that may inure to the benefit of the patients for whom the prescriptions are being filled and/or their insurance companies (based on lower co-payment rates typically set by insurance companies for lower-priced generic copy products in order to encourage their substitution for higher-priced brand-name products), and/or the pharmacy chain from which the patient is purchasing the product and potentially the pharmacy chain's wholesaler (based on incentives created by contracts in various potential combinations between the pharmacy chain, the wholesaler, and the generic copy manufacturer such as Acella that proliferate distribution and sales of lower-priced generic copy products). Everett's sales of its Select-OB®+DHA product will therefore immediately and rapidly be displaced by sales of Defendant Acella's Choice-OB+DHA product, respectively, due to the linking of Choice-OB+DHA to Select-OB®+DHA in the databases of First DataBank and/or Medi-Span as described hereinabove.

32. The practice of substitution is so common that displacement of sales and erosion of the market for a branded product begins to take place immediately upon a copy product being linked to it in the databases, and that sales displacement and market erosion continues to grow quickly over time, such that, in the case of Everett's innovative branded Select-OB®+DHA product and Acella's Choice-OB+DHA copy product, sales of Everett's Select-OB®+DHA

product will be 90 percent displaced by Acella's Choice-OB+DHA generic copy product, respectively, within one year.

Drug Databases Are Linking Choice-OB+DHA To Select-OB®+DHA

33. On information and belief, including based on certain "screen shots" obtained by Everett, wholesalers are listing and offering Choice-OB+DHA as a substitute for Select-OB®+DHA and pharmacies are substituting Choice-OB+DHA for Select-OB®+DHA, based on the "linking" of Choice-OB+DHA to Select-OB®+DHA in one or more of the leading drug databases. In fact, based on certain additional "screen shots" obtained by Everett, First DataBank is at least one specific leading drug database that is already "linking" Choice-OB+DHA to Select-OB®+DHA in its database, which information is available to the wholesalers and pharmacies who utilize First DataBank data. Accordingly, for instance, when pharmacists at the retail pharmacies that show Choice-OB+DHA as being linked to Select-OB®+DHA based on the "linking" of Choice-OB+DHA to Select-OB®+DHA in the drug databases utilized by those pharmacies (including at least First DataBank) fill a prescription for a customer with a prescription for Select-OB®+DHA, the pharmacists will substitute Choice-OB+DHA for customers with a prescription for Select-OB®+DHA. Pharmacists will make those substitutions in order to capitalize upon the advantage of the significantly lower price of the Acella copy product, Choice-OB+DHA. Everett's sales of its branded Select-OB®+DHA product will therefore be displaced by sales of Acella's Choice-OB+DHA product due to the linking of the products.

Everett's Irreparable Harm From Acella's Infringing Choice-OB+DHA Product

34. Everett faces substantial and irreparable harm as a result of Acella's infringing sales of its Choice-OB+DHA product. Each time that a pharmacy substitutes Choice-OB+DHA despite the physician's prescription having specified Select-OB®+DHA, Everett directly loses

that sale to Acella. Additionally, in the health care industry, there is significant (if not absolute) pressure on pharmacists (by, for example, insurance companies) to substitute the lower-cost copy version of a prescription drug or supplement for a higher-cost brand-name version.

35. Acella is currently selling and/or distributing its Choice-OB+DHA product to ultimately be sold through retail pharmacies, which, on information and belief, are selling Choice-OB+DHA as a substitute for Select-OB®+DHA. Acella will rapidly gain increasing market share with its Choice-OB+DHA product, which is causing and will continue to increasingly cause direct harm to Everett.

36. It can be expected that, within less than one year of Choice-OB+DHA being "linked" to Select-OB®+DHA, Choice-OB+DHA will have displaced 90 percent of the sales that otherwise would have been made by Everett of its Select-OB®+DHA product.

37. Many patients who have been prescribed prenatal nutritional supplements will not even realize that the pharmacy has substituted the lower-cost supplement for the branded product that their doctor prescribed. This has been and will continue to be the case with Choice-OB+DHA being substituted for Select-OB®+DHA. On other occasions, patients will be informed of the intended substitution and advised that if they insist on the prescribed, branded product, their "co-pay" will be significantly higher.

38. After a pharmacy has stocked up on the copy product, the pharmacy will naturally want to use up its inventory rather than see it go to waste. The critical harm to Everett in the present circumstances is evident: It is virtually impossible to "put the genie back in the bottle" once a copyist competitor (such as Acella and its infringing Choice-OB+DHA product) is able to get a foothold in the marketplace. The realities of the marketplace will in this manner make it impossible for Everett to overcome Acella's infringing activities.

39. Select-OB®+DHA and Choice-OB+DHA are not the only prescription-only nutritional supplements in the U.S. market. By having an innovative product and visiting thousands of doctors and spending significant sums in marketing and promotional efforts, Everett has created a brand awareness and excellent reputation for Select-OB®+DHA. However, to remain effective it is necessary that Everett continue to market and promote Select-OB®+DHA to prescribing doctors, so that they do not pass over Select-OB®+DHA in favor of some other nutritional supplement when writing prescriptions for their patients.

40. The presence of the Choice-OB+DHA product in the market creates a huge dilemma – a "Hobson's Choice" for Everett. Either Everett stops marketing the Select-OB®+DHA product or continues to spend money to market Select-OB®+DHA to the advantage of its infringing competitor, Acella. Yet, if Everett stops marketing Select-OB®+DHA Everett will forfeit sales to other nutritional supplement companies which, unlike Everett, will still have an incentive to market and promote their products to doctors. Moreover, it will not be possible to calculate how many such sales Everett will have lost to other sellers of prescription-only prenatal nutritional supplements.

41. As a result of Acella's infringement Everett will also suffer irreparable harm to its goodwill and reputation respecting its entire line of prenatal products (including Vitafol®-OB+DHA, Vitafol®-PN, Vitafol®-OB, and Select-OB®+DHA), especially as pharmacists become accustomed to using Choice-OB+DHA products as substitutes for Select-OB®+DHA and Everett's other nutritional supplement products. Select-OB®+DHA is not a retail product, but a product prescribed by doctors and dispensed by pharmacists. Over time, habits develop, and pharmacists associate Select-OB®+DHA and Everett's other products with cheaper copy versions. It is critical to Everett's business that pharmacists and doctors do not associate

Everett's products with cheaper copy versions, and that pharmacists do not routinely substitute Choice-OB+DHA for Select-OB®+DHA.

Copyright Registration of Everett's Product Insert for Select-OB®+DHA

42. Everett's Select-OB®+DHA product was originally sold with a package insert authored by Everett (the original version of which is attached as **Exhibit C**) – and is now sold with a product insert authored by Everett (the 10/11 version of which is attached **Exhibit B**) – which inserts have provided and continue to provide information about the product's vitamins and minerals, as well as substantial other information pertaining to the use of the product. Everett has registered its copyrights in the inserts for Select-OB®+DHA, specifically by registering the original package insert (a true and correct copy of which registration is attached hereto as **Exhibit E**, United States Copyright Office Registration No. VA 1-666-635), and by registering the 10/11 product insert version (a true and correct copy of which registration is attached hereto as **Exhibit F**, United States Copyright Office Registration No. TX 7-527-076).

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Infringement Of The '855 Patent)

43. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs, the same as if set forth at length.

44. Everett is the assignee and owner of the '855 Patent (which patent was duly and legally issued by the PTO on June 12, 2012).

45. Upon information and belief, Defendant has through the conduct described above, engaged in the manufacture, use, sale, offer for sale, and/or importation of products that infringed and continue to infringe, directly and/or indirectly by contributorily infringing and/or inducing to infringe, one or more of the claims of the '855 Patent, in violation of 35 U.S.C. § 271

and without Everett's authority. The infringing product embodying the claimed invention(s) is Defendant's Choice-OB+DHA prescription prenatal multivitamin product.

46. Defendant's willful acts of infringement are causing damages and irreparable harm to Everett and will continue to cause damages and irreparable harm unless enjoined by this Court.

SECOND CLAIM FOR RELIEF
(Copyright Infringement)

47. To the extent not inconsistent with the allegations herein, or in the alternative, Everett refers to and incorporates herein the allegations of the foregoing Paragraphs, the same as if set forth at length.

48. This cause of action arises under the federal Copyright Act, 17 U.S.C. §§ 101, *et seq.*

49. The Court has original jurisdiction over this matter pursuant to Everett's filing of, and the federal Copyright Office's subsequent issuance of, copyright registration certificates covering Everett's Select-OB®+DHA package and product inserts. A true and correct copy of the certificate specifically registering the copyrights for the original package insert for Everett's Select-OB®+DHA is attached hereto as **Exhibit E** (United States Copyright Office Registration No. VA 1-666-635). A true and correct copy of the certificate specifically registering the copyrights for the 10/11 version of Everett's Select-OB®+DHA product insert is attached hereto as **Exhibit F** (United States Copyright Office Registration No. TX 7-527-076).

50. Everett is the sole owner of all copyrights in the Select-OB®+DHA package insert and product insert and all corresponding text, layout, and other elements of expression encompassed therein, including the selection and arrangement of text and other elements of expression. The Select-OB®+DHA package insert and product insert are original. Further, the

U.S. Copyright Office issued Certificates of Registration identifying Everett as the copyright author and therefore owner. *See* **Exhibits E-F**.

51. Defendant has infringed Everett's copyrights in the Select-OB®+DHA package insert and product insert. Defendant has, among other things, copied, distributed, used, sold, displayed, and distributed virtually all of the Select-OB®+DHA package insert and product insert without approval or authorization from Everett.

52. Defendant had access to and copied copyright-protected elements of the Select-OB®+DHA package insert and product insert to create Defendant's infringing Choice-OB+DHA package insert.

53. Defendant's acts as alleged herein constitute copyright infringement under the U.S. Copyright Act, 17 U.S.C. § § 101, *et seq.* By its actions alleged above, Defendant has intentionally and willfully infringed, and will continue to intentionally and willfully infringe, Everett's copyrights in the Select-OB®+DHA package insert and product insert.

54. As a direct and proximate result of Defendant's unlawful acts of copyright infringement as set forth above, Everett has suffered and will continue to suffer injury to its business, goodwill, and property in an amount not presently known. Everett is entitled to recover from Defendant the damages it has sustained and will sustain as a result of Defendant's unlawful acts of copyright infringement as alleged herein, pursuant to 17 U.S.C. § 504. Everett is further entitled to recover from Defendant the gains, profits, and advantages that Defendant has obtained as a result of the wrongful conduct alleged herein, pursuant to 17 U.S.C. § 504. Everett at present is unable to ascertain the full extent of its damage, or the gains, profits and advantages that Defendant has obtained by reason of the wrongful conduct described herein.

55. Alternatively, as Everett's copyright registrations were issued before the infringement occurred, Everett may elect to seek statutory damages under 17 U.S.C. § 504(c) for Defendant's unlawful and willful acts of copyright infringement as set forth above.

56. Everett is also entitled, pursuant to 17 U.S.C. § 502, to an order for injunctive relief that prevents and restrains Defendant from continuing to infringe on the Select-OB®+DHA package insert and product insert and, pursuant to 17 U.S.C. § 503, to an order impounding any and all of Defendant's products that contain the infringing Choice-OB+DHA package insert. Everett is further entitled to an order compelling Defendant to recall and retrieve and all of Defendant's products that contain the infringing Choice-OB+DHA package insert that are in the marketplace. Everett has no adequate remedy at law for Defendant's wrongful and unlawful conduct because, among other things: (a) Everett's copyrights in its Select-OB®+DHA package insert and product insert are unique and valuable property which have no readily determinable market value; (b) Defendant's infringement harms Everett such that Everett could not be made whole by any monetary award for such infringement; and (c) Defendant's wrongful and unlawful conduct, and the resulting damage and harm to Everett, is continuing and irreparable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Everett Laboratories, Inc. asks that this Court enter judgment against Defendant Acella Pharmaceuticals, LLC, granting the following relief:

A. Judgment that Defendant has directly infringed U.S. Patent No. 8,183,855.

B. Judgment that Defendant has indirectly infringed U.S. Patent No. 8,183,855 by inducing the direct infringement of the '855 Patent.

C. Judgment that Defendant has indirectly infringed U.S. Patent No. 8,183,855 by contributing to the direct infringement of the '855 Patent.

D. That Defendant be held to have willfully engaged in copyright infringement in violation of Section 501 of the Copyright Act, 17 U.S.C. § 501.

E. That a preliminary and permanent injunction issue prohibiting Defendant and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them, from further direct and/or indirect copyright infringement of the Select-OB®+DHA package insert and/or product insert.

F. That Defendant be required to:

1. Deliver upon oath, to be impounded during the pendency of this action, and for destruction pursuant to judgment herein, all Choice-OB+DHA products;

2. Seek and obtain a full recall of all Choice-OB+DHA products that have been sold, consigned, or placed into inventory of a wholesaler or retailer;

3. Place all revenues generated from the sale of Choice-OB+DHA, as well as all future payments from the sale of Choice-OB+DHA, in a trust account during the pendency of this action;

4. Issue a recall and retrieve all Choice-OB+DHA products and/or any nutritional supplements or any other of Defendant's products that bear or contain the infringing Choice-OB+DHA package insert, or any other material that infringes on Everett's Select-OB®+DHA package insert and/or product insert, that are being or have been used, advertised, marketed, offered, distributed, or sold in the marketplace; and

5. Deliver upon oath, to be impounded during the pendency of this action, and for destruction pursuant to judgment herein, any and all Choice-OB+DHA package inserts and any other of Defendant's materials that infringe on Everett's copyrights.

G. That Defendant be required to file with the Court and serve on Everett, within 30 days after service of the Court's Order as herein prayed, a report in writing under oath stating in detail the manner and form in which Defendant has complied with the Court's Order.

H. That Defendant be required to account for and pay over to Everett all profits obtained by Defendant from its violations of law complained of herein.

I. That the Court grant a preliminary and permanent injunction enjoining Acella from manufacturing, marketing or selling, importing, or offering for sale, Choice-OB+DHA.

J. That the Court grant a preliminary and permanent injunction enjoining Acella from making claims that would cause Choice-OB+DHA to be listed as interchangeable with, or a substitute for, Select-OB®+DHA.

K. That the Court order Acella to pay compensatory damages to Everett in an amount to be determined at trial.

L. That the Court order Defendant to pay Everett's damages and Defendant's profits pursuant to 17 U.S.C. § 504(b) for Defendant's willful infringement of Everett's copyrights or, alternatively, if Everett elects, statutory damages pursuant to 17 U.S.C. § 504(c).

M. That Defendant pay Everett additional damages for willful infringement of the '855 Patent in an amount to be determined at trial pursuant to 35 U.S.C. § 284.

N. Judgment that this is an exceptional case under 35 U.S.C. § 285 and awarding Everett its costs, expenses and reasonable attorneys' fees incurred in this action.

O. Judgment awarding Everett its full costs and reasonable attorneys' fees incurred in this action under Section 505 of the Copyright Act, 15 U.S.C. § 505.

P. That Defendant be ordered to pay prejudgment interest to Everett.

Q. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38, Fed. R. Civ. P., Plaintiff Everett Laboratories, Inc. hereby demands a jury trial on all issues triable of right by a jury.

Respectfully submitted,

RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP

By s/ Robert J. Schoenberg

Headquarters Plaza
One Speedwell Avenue
Morristown, New Jersey 07962-1981
Telephone: (973) 451-8511
Email: rschoenberg@riker.com

M. Roy Goldberg (*Pro Hac Vice pending*)
SHEPPARD MULLIN RICHTER
& HAMPTON LLP
1300 I Street, N.W., Suite 1100 East
Washington, D.C. 20005-3314
Tel: (202) 218-0007
Email: rgoldberg@sheppardmullin.com

Attorneys for Plaintiff
Everett Laboratories, Inc.

Dated: June 5, 2013.

CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1(d)(2), the undersigned attorneys for Plaintiff, Everett Laboratories, Inc., certify that this action is not eligible for arbitration under Local Civil Rule 201.1 because the relief sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive relief, as well as damages believed to be in excess of $150,000.00, exclusive of interest, costs, and any claim for punitive damages, and involves complex issues of patent and copyright law.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiff, Everett Laboratories, Inc., certifies that, to the best of his knowledge, the matter in controversy is not the subject of another action pending in any court or of any arbitration or administrative proceeding.

RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP
Attorneys for Plaintiff
EVERETT LABORATORIES, INC.

By /s/ Robert J. Schoenberg

Dated: June 5, 2013.

4373297v2

Exhibit A

US008197855B2

(12) **United States Patent**
Giordano et al.

(10) **Patent No.: US 8,197,855 B2**
(45) **Date of Patent: Jun. 12, 2012**

(54) **COMPOSITIONS AND METHODS FOR NUTRITION SUPPLEMENTATION**

(75) Inventors: **John A. Giordano**, West Orange, NJ (US); **Charles J. Balzer**, Lavalette, NJ (US)

(73) Assignee: **Everett Laboratories, Inc.**, West Orange, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 538 days.

(21) Appl. No.: **11/928,610**

(22) Filed: **Oct. 30, 2007**

(65) **Prior Publication Data**

US 2008/0050454 A1 Feb. 28, 2008

Related U.S. Application Data

(63) Continuation of application No. 10/916,534, filed on Aug. 12, 2004, now Pat. No. 7,560,123.

(51) **Int. Cl.**

A61K 31/714	(2006.01)
A61K 31/07	(2006.01)
A61K 31/19	(2006.01)
A61K 31/34	(2006.01)
A61K 31/355	(2006.01)
A61K 33/26	(2006.01)
A61K 33/30	(2006.01)
A61K 33/06	(2006.01)
A61K 31/4415	(2006.01)
A61K 31/51	(2006.01)
A61K 31/525	(2006.01)
A61K 31/593	(2006.01)
A61P 3/02	(2006.01)

(52) **U.S. Cl.** **424/641**; 424/646; 424/682; 514/168; 514/251; 514/276; 514/458; 514/474; 514/52; 514/557; 514/574; 514/725

(58) **Field of Classification Search** ..... None
See application file for complete search history.

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Primary Examiner — Shanon A Foley
(74) *Attorney, Agent, or Firm* — Don J. Pelto, Esquire; Sheppard, Mullin, Richter & Hampton LLP

(57) **ABSTRACT**

The present invention relates to compositions that may be swallowable, chewable or dissolvable, comprising various vitamins and minerals, and in a specific embodiment comprising vitamin A, beta carotene, B-complex vitamins, vitamin C, vitamin D_3, vitamin E, iron, magnesium and zinc, and methods for using these compositions for nutritional supplementation in subjects undergoing physiologically stressful events, such as, for example and without limitation, pregnancy, lactation or any disease state.

36 Claims, No Drawings

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COMPOSITIONS AND METHODS FOR NUTRITION SUPPLEMENTATION

The present application is a continuation of and claims the benefit under 35 U.S.C. §120 of U.S. patent application Ser. No. 10/916,534, filed Aug. 12, 2004, and issued as U.S. Pat. No. 7,560,123.

FIELD OF THE INVENTION

The present invention relates to compositions, that may be swallowable, chewable and/or dissolvable, comprising various vitamins and minerals, and methods for using these compositions for nutritional supplementation in, for example, subjects in physiologically stressful states.

BACKGROUND OF THE INVENTION

Nutrition plays a critical role in maintaining good health. Proper nutrition prevents dietary deficiencies, and also protects against the development of disease. When the body faces physiological stress, proper nutrition plays an increasingly important role. For example, pregnancy and lactation are among the most nutritionally volatile and physiologically stressful periods and processes in the lifetimes of women. Vitamin and mineral needs are almost universally increased during these natural processes. Increased vitamin and mineral needs during these times are almost always due to elevated metabolic demand, increased plasma volume, increased levels of blood cells, decreased concentrations of nutrients, and decreased concentrations of nutrient-binding proteins.

When increased nutrient needs occur during pregnancy, lactation, or any other physiologically stressful state, nutritional supplementation serves a vital role in maintaining good health. Nutritional supplementation is especially pertinent to women contemplating conceiving a child because optimizing specific nutrients before, during, and after the physiological processes of pregnancy or lactation can have profound, positive, and comprehensive impacts upon the overall wellness of the developing and newborn child as well as on the safety and health of the mother. The present invention provides compositions and methods designed to supplement the nutritional needs of individuals in physiologically stressful states.

Further, while some patients may prefer swallowable dosage forms, it is estimated that 50% of the population has problems swallowing whole tablets. Seager, 50 J. PHARM. PHARMACOL. 375-82 (1998). These problems can lead to poor, or even noncompliance, with dosing regimens and thus have negative impacts on treatment efficiency. Id. Administration of vitamins and minerals through chewable or dissolvable compositions solves this problem because the compositions need not be swallowed whole.

SUMMARY OF THE INVENTION

The present invention provides compositions and methods of using these compositions for both prophylactic and therapeutic nutritional supplementation. Specifically, for example, the present invention relates to novel compositions of vitamins and minerals that can be used to supplement the nutritional deficiencies observed in patients undergoing physiologically stressful states such as, for example and without limitation, pregnancy, lactation, and any disease state. The compositions of the present invention may be in a swallowable, chewable or dissolvable form according to an individual patient's preference. Choice in dosage form promotes ease of administration and compliance with dosing regimens.

In one embodiment of the present invention, the compositions may comprise vitamin A, beta carotene, B-complex vitamins, vitamin C, vitamin D_3, vitamin E, iron, magnesium, and zinc.

In another embodiment, the compositions of the present invention may comprise one or more of vitamin A in the form of acetate; beta carotene; vitamin B_1 in the form of thiamine mononitrate; vitamin B_2 in the form of riboflavin; vitamin B_3 in the form of niacinamide or niacin; vitamin B_6 in the form of pyridoxine hydrochloride; vitamin B_9 in the form of folic acid, folacin, metafolin, folate and/or one or more natural isomers of folate including (6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5-methyl-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5-formyl-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 10-formyl-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5,10-methylene-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5,10-methenyl-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof and 5-formimino-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof; vitamin B_{12} in the form of cyanocobalamin; vitamin C in the form of ascorbic acid; vitamin D_3 in the form of cholecalciferol; vitamin E in the form of d-alpha tocopheryl acetate or d-alpha tocopheryl succinate; iron in the form of polysaccharide complex or ferrous fumarate; magnesium in the form of magnesium oxide; and/or zinc in the form of zinc oxide.

In another embodiment of the present invention, the compositions may be substantially free of any other added vitamins and minerals not described in the preceding paragraph. For example, the compositions of the present invention may be substantially free of added alpha carotene; substantially free of added lutein; substantially free of added lycopene; substantially free of added zeaxanthin; substantially free of added vitamin B_4; substantially free of added vitamin B_5; substantially free of added vitamin B_7; substantially free of added vitamin B_8; substantially free of added vitamin B_{10}; substantially free of added vitamin B_{11}; substantially free of added calcium; substantially free of added chromium; substantially free of added copper; substantially free of added manganese; substantially free of added selenium; substantially free of added boron; substantially free of added odorless garlic; substantially free of added coenzyme Q-10; substantially free of added l-carnitine; substantially free of added grape seed extract; substantially free of added green tea extract; substantially free of added quercetin; substantially free of added hawthorne berries; and/or substantially free of added alpha lipoic acid.

In another specific embodiment, the compositions of the present invention may be substantially free of added vitamin A; substantially free of added beta carotene; substantially free of added vitamin B_1; substantially free of added vitamin B_2; substantially free of added vitamin B_3; substantially free of added vitamin B_6; substantially free of added vitamin B_9; substantially free of added vitamin B_{12}; substantially free of added vitamin C; substantially free of added vitamin D_3; substantially free of added vitamin E; substantially free of added iron; substantially free of added magnesium; and/or substantially free of added zinc.

In another embodiment, the compositions of the present invention may comprise pharmaceutically acceptable carriers, such as one or more of binders, diluents, lubricants, glidants, colorants, emulsifiers, disintegrants, starches, water, oils, alcohols, preservatives, and sugars.

In another embodiment of the present invention, the compositions may comprise sweetening agents such as one or more of sucrose, fructose, high fructose corn syrup, dextrose,

saccharin sodium, maltodextrin, aspartame, potassium acesulfame, neohesperidin dihydrochalcone, sucralose, monoammonium glycyrrhizinate, and mixtures thereof.

In another embodiment of the present invention, the compositions may comprise flavorants such as one or more of anise oil, cinnamon oil, peppermint oil, oil of wintergreen, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, cedar leave oil, oil of nutmeg, oil of sage, oil of bitter almonds, cassia oil, lemon oil, orange oil, lime oil, grapefruit oil, grape oil, apple essence, pear essence, peach essence, berry essence, wildberry essence, date essence, blueberry essence, kiwi essence, strawberry essence, raspberry essence, cherry essence, plum essence, pineapple essence, apricot essence, natural mixed berry flavor, citric acid, malic acid, vanilla, vanillin, cocoa, chocolate, and menthol.

In another embodiment of the present invention, the compositions may comprise an alkyl polysiloxane in the form of dimethyl polysiloxane.

In another embodiment, the compositions of the present invention may comprise one or more of about 550 IU to about 1650 IU vitamin A; about 300 IU to about 900 IU beta carotene; about 1 mg to about 3 mg vitamin B_1; about 1 mg to about 3 mg vitamin B_2; about 7 mg to about 23 mg vitamin B_3; about 1 mg to about 4 mg vitamin B_6; about 500 μg to about 1500 μg vitamin B_9; about 2 μg to about 8 μg vitamin B_{12}; about 30 mg to about 90 mg vitamin C; about 200 IU to about 600 IU vitamin D_3; about 15 IU to about 45 IU vitamin E; about 14 mg to about 44 mg iron; about 12 mg to about 38 mg magnesium; and about 7 mg to about 23 mg zinc.

In another embodiment, the compositions of the present invention may comprise one or more of about 880 IU to about 1320 IU vitamin A; about 480 IU to about 720 IU beta carotene; about 1.3 mg to about 1.9 mg vitamin B_1; about 1.5 mg to about 2.2 mg vitamin B_2; about 12 mg to about 18 mg vitamin B_3; about 2 mg to about 3 mg vitamin B_6; about 800 μg to about 1200 μg vitamin B_9; about 4 μg to about 6 μg vitamin B_{12}; about 48 mg to about 72 mg vitamin C; about 320 IU to about 480 IU vitamin D_3; about 24 IU to about 36 IU vitamin E; about 23 mg to about 35 mg iron; about 20 mg to about 30 mg magnesium; and about 12 mg to about 18 mg zinc.

In another embodiment of the present invention, the compositions may comprise one or more of about 990 IU to about 1210 IU vitamin A; about 540 IU to about 660 IU beta carotene; about 1.5 mg to about 1.75 mg vitamin B_1; about 1.6 mg to about 2 mg vitamin B_2; about 13.5 mg to about 16.5 mg vitamin B_3; about 2.3 mg to about 2.8 mg vitamin B_6; about 900 μg to about 1100 μg vitamin B_9; about 4.5 μg to about 5.5 μg vitamin B_{12}; about 54 mg to about 66 mg vitamin C; about 360 IU to about 440 IU vitamin D_3; about 27 IU to about 33 IU vitamin E; about 26 mg to about 32 mg iron; about 22.5 mg to about 27.5 mg magnesium; and about 13.5 mg to about 16.5 mg zinc.

In another embodiment of the present invention, the compositions may comprise one or more of about 1100 IU vitamin A; about 600 IU beta carotene; about 1.6 mg vitamin B_1; about 1.8 mg vitamin B_2; about 15 mg vitamin B_3; about 2.5 mg vitamin B_6; about 1000 μg vitamin B_9; about 5 μg vitamin B_{12}; about 60 mg vitamin C; about 400 IU vitamin D_3; about 30 IU vitamin E; about 29 mg iron; about 25 mg magnesium; and about 15 mg zinc.

In another embodiment of the present invention, the compositions may be suitable for administration to subjects in physiologically stressful states, such as those resulting from pregnancy, lactation or disease states. Such compositions may be suitable for treating nutritional deficiencies resulting from such physiologically stressful states, which may result from, for example and without limitation, elevated metabolic demand, increased plasma volume, or decreased concentrations of nutrient-binding proteins such as, for example and without limitation, serum-ferritin, maltose-binding protein, lactoferrin, calmodulin, tocopheryl binding protein, riboflavin binding protein, retinol binding protein, transthyretin, high density lipoprotein-apolipoprotein A1, folic acid binding protein and 25-hydroxyvitamin D binding protein.

The present invention also includes methods of administering the compositions of the invention to patients to supplement nutritional deficiencies resulting from, for example and without limitation, pregnancy, lactation, and any disease state.

In one embodiment of the present invention, the methods may utilize compositions comprising vitamin A, beta carotene, B-complex vitamins, vitamin C, vitamin D_3, vitamin E, iron, magnesium and zinc. In another embodiment of the present invention, the methods may utilize compositions in a swallowable, chewable, or dissolvable form.

In another embodiment of the present invention, the methods may utilize compositions including vitamin A in the form of acetate; beta carotene; vitamin B_1 in the form of thiamine mononitrate; vitamin B_2 in the form of riboflavin; vitamin B_3 in the form of niacinamide or niacin; vitamin B_6 in the form of pyridoxine hydrochloride; vitamin B_9 in the form of folic acid, folacin, metafolin, folate and/or one or more natural isomers of folate including (6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5-methyl-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5-formyl-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 10-formyl-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5,10-methylene-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5,10-methenyl-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof and 5-formimino-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof; vitamin B_{12} in the form of cyanocobalamin; vitamin C in the form of ascorbic acid; vitamin D_3 in the form of cholecalciferol; vitamin E in the form of d-alpha tocopheryl acetate or d-alpha tocopheryl succinate; iron in the form of polysaccharide complex or ferrous fumarate; magnesium in the form of magnesium oxide; and zinc in the form of zinc oxide.

In another embodiment of the present invention, the methods may utilize compositions substantially free of any other added vitamins and minerals not described in the preceding paragraph. For example, the methods may utilize compositions that are substantially free of added alpha carotene; substantially free of added lutein; substantially free of added lycopene; substantially free of added zeaxanthin; substantially free of added vitamin B_4; substantially free of added vitamin B_5; substantially free of added vitamin B_7; substantially free of added vitamin B_8; substantially free of added vitamin B_{10}; substantially free of added vitamin B_{11}; substantially free of added calcium; substantially free of added chromium; substantially free of added copper; substantially free of added manganese; substantially free of added selenium; substantially free of added boron; substantially free of added odorless garlic; substantially free of added coenzyme Q-10; substantially free of added l-carnitine; substantially free of added grape seed extract; substantially free of added green tea extract; substantially free of added quercetin; substantially free of added hawthorne berries; and/or substantially free of added alpha lipoic acid.

In another specific embodiment, the methods may utilize compositions that are substantially free of added vitamin A; substantially free of added beta carotene; substantially free of added vitamin B_1; substantially free of added vitamin B_2;

substantially free of added vitamin B_3; substantially free of added vitamin B_6; substantially free of added vitamin B_9; substantially free of added vitamin B_{12}; substantially free of added vitamin C; substantially free of added vitamin D_3; substantially free of added vitamin E; substantially free of added iron; substantially free of added magnesium; and/or substantially free of added zinc.

In another embodiment of the present invention, the methods may utilize compositions comprising pharmaceutically acceptable carriers, such as one or more of binders, diluents, lubricants, glidants, colorants, emulsifiers, disintegrants, starches, water, oils, alcohols, preservatives, and sugars.

In another embodiment of the present invention, the methods may utilize compositions comprising sweetening agents such as one or more of sucrose, fructose, high fructose corn syrup, dextrose, saccharin sodium, maltodextrin, aspartame, potassium acesulfame, neohesperidin dihydrochalcone, sucralose, monoammonium glycyrrhizinate, and mixtures thereof.

In another embodiment of the present invention, the methods may utilize compositions comprising flavorants such as one or more of anise oil, cinnamon oil, peppermint oil, oil of wintergreen, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, cedar leave oil, oil of nutmeg, oil of sage, oil of bitter almonds, cassia oil, lemon oil, orange oil, lime oil, grapefruit oil, grape oil, apple essence, pear essence, peach essence, berry essence, wildberry essence, date essence, blueberry essence, kiwi essence, strawberry essence, raspberry essence, cherry essence, plum essence, pineapple essence, apricot essence, natural mixed berry flavor, citric acid, malic acid, vanilla, vanillin, cocoa, chocolate, and menthol.

In another embodiment of the present invention, the methods may utilize compositions comprising an alkyl polysiloxane in the form of dimethyl polysiloxane.

In another embodiment, the methods may utilize compositions comprising one or more of about 550 IU to about 1650 IU vitamin A; about 300 IU to about 900 IU beta carotene; about 1 mg to about 3 mg vitamin B_1; about 1 mg to about 3 mg vitamin B_2; about 7 mg to about 23 mg vitamin B_3; about 1 mg to about 4 mg vitamin B_6; about 500 μg to about 1500 μg vitamin B_9; about 2 μg to about 8 μg vitamin B_{12}; about 30 mg to about 90 mg vitamin C; about 200 IU to about 600 IU vitamin D_3; about 15 IU to about 45 IU vitamin E; about 14 mg to about 44 mg iron; about 12 mg to about 38 mg magnesium; and about 7 mg to about 23 mg zinc.

In another embodiment of the present invention, the methods may utilize compositions comprising one or more of about 880 IU to about 1320 IU vitamin A; about 480 IU to about 720 IU beta carotene; about 1.3 mg to about 1.9 mg vitamin B_1; about 1.5 mg to about 2.2 mg vitamin B_2; about 12 mg to about 18 mg vitamin B_3; about 2 mg to about 3 mg vitamin B_6; about 800 μg to about 1200 μg vitamin B_9; about 4 μg to about 6 μg vitamin B_{12}; about 48 mg to about 72 mg vitamin C; about 320 IU to about 480 IU vitamin D_3; about 24 IU to about 36 IU vitamin E; about 23 mg to about 35 mg iron; about 20 mg to about 30 mg magnesium; and about 12 mg to about 18 mg zinc.

In another embodiment of the present invention, the methods may utilize compositions comprising one or more of about 990 IU to about 1210 IU vitamin A; about 540 IU to about 660 IU beta carotene; about 1.5 mg to about 1.75 mg vitamin B_1; about 1.6 mg to about 2 mg vitamin B_2; about 13.5 mg to about 16.5 mg vitamin B_3; about 2.3 mg to about 2.8 mg vitamin B_6; about 900 μg to about 1100 μg vitamin B_9; about 4.5 μg to about 5.5 μg vitamin B_{12}; about 54 mg to about 66 mg vitamin C; about 360 IU to about 440 IU vitamin D_3; about 27 IU to about 33 IU vitamin E; about 26 mg to about 32 mg iron; about 22.5 mg to about 27.5 mg magnesium; and about 13.5 mg to about 16.5 mg zinc.

In another embodiment of the present invention, the methods may utilize compositions comprising one or more of about 1100 IU vitamin A; about 600 IU beta carotene; about 1.6 mg vitamin B_1; about 1.8 mg vitamin B_2; about 15 mg vitamin B_3; about 2.5 mg vitamin B_6; about 1000 μg vitamin B_9; about 5 μg vitamin B_{12}; about 60 mg vitamin C; about 400 IU vitamin D_3; about 30 IU vitamin E; about 29 mg iron; about 25 mg magnesium; and about 15 mg zinc.

In another embodiment of the present invention, the methods may utilize compositions suitable for administration to subjects in physiologically stressful states, such as those resulting from, for example and without limitation, pregnancy, lactation or disease states. Such compositions may be suitable for treating nutritional deficiencies resulting from such physiologically stressful states, which may result from, for example and without limitation, elevated metabolic demand, increased plasma volume, or decreased concentrations of nutrient-binding proteins such as serum-ferritin, maltose-binding protein, lactoferrin, calmodulin, tocopheryl binding protein, riboflavin binding protein, retinol binding protein, transthyretin, high density lipoprotein-apolipoprotein A1, folic acid binding protein and 25-hydroxyvitamin D binding protein.

Other objectives, features and advantages of the present invention will become apparent from the following detailed description. The detailed description and the specific examples, although indicating specific embodiments of the invention, are provided by way of illustration only. Accordingly, the present invention also includes those various changes and modifications within the spirit and scope of the invention that may become apparent to those skilled in the art from this detailed description.

DETAILED DESCRIPTION OF THE INVENTION

It is understood that the present invention is not limited to the particular methodologies, protocols, fillers, excipients, etc. . . . , described herein, as these may vary. It is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention. It must be noted that as used herein and in the appended claims, the singular forms "a," "an," and "the" include the plural reference unless the context clearly dictates otherwise. Thus, for example, a reference to "a vitamin" is a reference to one or more vitamins and includes equivalents thereof known to those skilled in the art and so forth.

Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which this invention belongs. Specific methods, devices, and materials are described, although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention.

The term "disease state" as used herein, may comprise any state in which one or more organs or components of an organism malfunction. The term "disease state" may refer to any deterioration of any component of a body. The term "disease state" may refer to any deficiency of any compound necessary for the maintenance or function of any component of any organism. The term "disease state" may refer to any condition in which a body contains toxins, produced by microorganisms that infect the body or by body cells through faulty metabolism or absorbed from an external source. "Disease states" may be adverse states caused by any diet, any virus, or

any bacteria. "Disease states" may comprise disorders associated with pregnant females such as, for example, osteomalacia and preeclampsia and disorders associated with a fetus such as, for example, neural tube defects and various fetal abnormalities. "Disease states" may comprise any pulmonary disorder such as, for example, bronchitis, bronchiectasis, atelectasis, pneunomia, diseases caused by inorganic dusts, diseases caused by organic dusts, any pulmonary fibrosis and pleurisy. "Disease states" may comprise any hematological/oncological disorder such as, for example, anemia, hemophilia, leukemia, and lymphoma. A "disease state" may comprise any cancer such as, for example and without limitation, breast cancer, lung cancer, prostate cancer, pancreatic cancer, liver cancer, stomach cancer, testicular cancer, ovarian cancer, skin cancer, cancer of the brain, cancer of the mouth, cancer of the throat, and cancer of the neck. "Disease states" may comprise any disorder of the immune system such as, for example, acquired immune deficiency syndrome (AIDS), AIDS-related complex, infection by any strain of any human immunodeficiency virus (HIV), and other viruses or pathogens such as bacteria. A "disease state" may comprise any cardiovascular disorder such as, for example, arterial hypertension, orthostatic hypotension, arteriosclerosis, coronary artery disease, cardiomyopathy, any arrhythmia, any valvular heart disease, endocarditis, pericardial disease, any cardiac tumor, any aneurysm and any peripheral vascular disorder. "Disease states" may comprise any hepatic/biliary disorder such as, for example and without limitation, jaundice, hepatic steatosis, fibrosis, cirrhosis, hepatitis, any hepatic granuloma, any liver tumor, cholelithiasis, cholecystitis and choledocholithiasis.

The term "physiologically stressful state," as used herein, comprises any state of an organism in which the organism faces one or more physiological challenges. A "physiologically stressful state" may comprise, for example and without limitation, pregnancy, lactation, or conditions in which an organism faces physiological challenges related to, for example and without limitation, elevated metabolic demand, increased plasma volume, or decreased concentrations of nutrient-binding proteins. A "physiologically stressful state" may result from one or more disease states.

The term "subject," as used herein, comprises any and all organisms and includes the term "patient." "Subject" may refer to a human or any other animal. "Subject" also may refer to a fetus.

The phrase "pharmaceutically acceptable," as used herein, refers to those compounds, materials, compositions and/or dosage forms which are, within the scope of sound medical judgment, suitable for use in contact with the tissues of human beings and animals without excessive toxicity, irritation, allergic response, or other problem or complication, commensurate with a reasonable benefit/risk ratio.

The phrase "swallowable form" refers to any compositions that do not readily dissolve when placed in the mouth and may be swallowed whole without any chewing or discomfort. Such compositions, in one embodiment, may have a shape containing no sharp edges and a smooth, uniform and substantially bubble free outer coating.

The phrase "chewable form" refers to any relatively soft compositions that are chewed in the mouth after oral administration, have a pleasant taste and mouthfeel, and quickly break into smaller pieces and begin to dissolve after chewing such that they can be swallowed substantially as a solution.

The phrase "dissolvable form" refers to any compositions that dissolve into a solution in the mouth. Such compositions, in one embodiment, may dissolve within about 60 seconds or less after placement in the mouth without any chewing.

The term "mouthfeel" refers to non-taste-related aspects of the pleasantness experienced by a person while chewing or swallowing a nutritional supplement. Aspects of mouthfeel include, for example and without limitation, the hardness and brittleness of a composition, whether the composition is chewy, gritty, oily, creamy, watery, sticky, easily dissolved, astringent, effervescent, and the like, and the size, shape, and form of the composition (tablet, powder, gel, etc. . . .).

The term "antioxidant" means an agent which inhibits oxidation and thus is used to prevent deterioration of preparations by the oxidative process. Such compounds include, by way of example and without limitation, ascorbic acid, ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, hypophosphorous acid, monothioglycerol, propyl gallate, sodium ascorbate, sodium bisulfite, sodium formaldehyde sulfoxylate and sodium metabisulfite and others known to those of ordinary skill in the art.

Proper nutrition is essential for maintaining health and preventing diseases. Adequate nutrition is especially critical during, for example, nutritionally volatile or physiologically stressful periods such as those including, by way of example and without limitation, pregnancy, lactation, or any disease state. Vitamin and mineral needs are almost universally increased throughout these periods. Increased needs during physiologically stressful states such as pregnancy, lactation or disease state may result from elevated metabolic demand, increased plasma volume, increased quantities of circulating red blood cells, decreased concentrations of nutrients, and decreased concentrations of nutrient-binding proteins such as, for example and without limitation, serum-ferritin, maltose-binding protein, lactoferrin, calmodulin, tocopheryl binding protein, riboflavin binding protein, retinol binding protein, transthyretin, high density lipoprotein-apolipoprotein A1, folic acid binding protein, and 25-hydroxyvitamin D binding protein. Lapido, 72 (Supp.) Amer. J. Clin. Nutr. 280S-90S (2000).

Optimizing specific nutrients before, during, and after the physiological processes of pregnancy and lactation can have profound, positive, and comprehensive impacts on the overall wellness of the developing and newborn child as well as on the safety and health of the mother. Black, 85 (Supp.) Brit. J. Nutr. S193-97 (2001); Scholl et al., 146 Amer. J. Epidem. 134-41 (1997). Nutrients provided to a mother reach the fetus. Specifically, it is established that substrates for growth and development, for example, circulate within the same pathways that carry drugs to and waste products from the fetus. Exchanges of material between mother and fetus occur primarily in the placenta, where villi containing fetal capillaries protrude into sinuses (intervillous spaces). Maternal arterial blood spurts into these spaces, then drains into maternal uterine veins to be returned to the maternal systemic circulation. Solutes in maternal blood cross the epithelial cells and connective tissue of the villi and the endothelium of the fetal capillaries; these solutes are then carried to the fetus by placental veins, which converge into the umbilical vein. The Merck Manual of Diagnosis and Therapy 2022 (Mark H. Beers, M.D. & Robert Berkow, M.D., eds., 17th ed. 1999).

The compositions and methods of the present invention provide the means to optimize good health by utilizing vitamin and mineral nutritional supplementation. The compositions and methods of the present invention may be administered to or directed to a subject such as a human or any other organism.

The compositions and methods of the present invention may include vitamin A. Vitamin A is involved in physiological processes that result in cellular differentiation, cellular maturity, and cellular specificity. Thus, vitamin A is an impor-

tant component of a nutritional supplement for subjects in physiologically stressful states, such as those caused by pregnancy, lactation or disease state. Zile et al., 131(3) J. Nutr. 705-08 (2001). In a specific embodiment of the present invention, vitamin A may be included in the form of acetate. In another specific embodiment, vitamin A may be included in amounts ranging from about 550 IU to about 1650 IU. In another specific embodiment, vitamin A may be included in amounts ranging from about 880 IU to about 1320 IU. In another specific embodiment, vitamin A may be included in amounts ranging from about 990 IU to about 1210 IU. In another embodiment, vitamin A may be included in an amount of about 1100 IU.

The compositions and methods of the present invention may include beta carotene. Beta carotene is converted to vitamin A within the body as needed. Mayne, 10 J. FASEB 690-701 (1996). Beta carotene also has powerful anti-oxidant properties. Antioxidants are important during physiologically stressful events for numerous reasons. For example, lipid peroxidation has been associated with over 200 disease processes. Rock et al., 96(7) J. Amer. Diet. Assoc. 693-702 (1996). Antioxidants are especially important during pregnancy because in the first trimester, establishment of blood flow into the intervillous space is associated with a burst of oxidative stress. The inability to mount an effective antioxidant defense against this burst results in early pregnancy loss. Myatt & Cui, Histochem. Cell Biol., DOI: 10.1007/s00418-004-0677-x (Jul. 10, 2004). Further, oxidative stress has been implicated in the pathophysiology of preeclampsia, a toxemia of pregnancy. Llurba et al., 37(4) Free Radic. Biol. Med. 557-70 (2004). Finally, oxidative stress during pregnancy plays an important role in fetal growth, and healthy antioxidant levels are positively correlated with birth weight and length. Lee et al., Eur. J. Clin. Nutr., DOI: 10.1038/sj.ejcn.160 (Mar. 31, 2004). In a specific embodiment of the present invention, beta carotene may be included in amounts ranging from about 300 IU to 900 IU. In another specific embodiment of the present invention, beta carotene may be included in amounts ranging from about 480 IU to 720 IU. In another specific embodiment of the present invention, beta carotene may be included in amounts ranging from about 540 IU to 660 IU. In another embodiment, beta carotene may be included in an amount of about 600 IU.

The compositions and methods of the present invention may comprise or use B-complex vitamins. This class of vitamins comprises water-soluble nutrients generally not stored in the body. They play roles in a variety of biological processes critical to the health of pregnant women, lactating women, and fetuses such as, for example, the metabolism of homocysteine. The B-complex vitamins that may be included in the compositions and methods of the present invention comprise one or more of vitamin B_1, vitamin B_2, vitamin B_3, vitamin B_6, vitamin B_9 and vitamin B_{12}.

The compositions and methods of the present invention may comprise or use vitamin B_1. Vitamin B_1 plays a role in carbohydrate metabolism and neural function. It is a coenzyme for the oxidative decarboxylation of alpha-ketoacids (e.g., alpha-ketoglutarate and pyruvate) and for transketolase, which is a component of the pentose phosphate pathway. National Research Council, Recommended Dietary Allowances 123 (10th ed. 1989) (hereinafter "RDA"). In a specific embodiment of the present invention, vitamin B_1 may be included in the form of thiamine mononitrate. In another specific embodiment, vitamin B_1 may be included in amounts ranging from about 1 mg to about 3 mg. In another specific embodiment, vitamin B_1 may be included in amounts ranging from about 1.3 mg to about 1.9 mg. In another specific embodiment, vitamin B_1 may be included in amounts ranging from about 1.5 mg to about 1.75 mg. In another embodiment, vitamin B_1 may be included in an amount of about 1.6 mg.

The compositions and methods of the present invention may comprise or use vitamin B_2. Vitamin B_2 is a component of two flavin coenzymes, flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). These flavoenzymes are involved in a number of oxidation-reduction reactions including the conversion of pyridoxine and niacin. RDA, supra at 132. Flavoenzymes also play a role in a number of metabolic pathways such as amino acid deamination, purine degradation and fatty acid oxidation and thus help to maintain carbohydrate, amino acid and lipid metabolism. In a specific embodiment of the present invention, vitamin B_2 may be included in the form of riboflavin. In another specific embodiment, vitamin B_2 may be included in amounts ranging from about 1 mg to about 3 mg. In another specific embodiment, vitamin B_2 may be included in amounts ranging from about 1.5 mg to about 2.2 mg. In another specific embodiment, vitamin B_2 may be included in amounts ranging from about 1.6 mg to about 2 mg. In another embodiment, vitamin B_2 may be included in an amount of about 1.8 mg.

The compositions and methods of the present invention may comprise or use vitamin B_3. Vitamin B_3, or "niacin" is the common name for two compounds: nicotinic acid (also called niacin) and niacinamide (also called nicotinamide). Vitamin B_3 is particularly important for maintaining healthy levels and types of fatty acids. It is also required for the synthesis of pyroxidine, riboflavin, and folic acid. RDA, supra at 137. Administration of vitamin B_3 also may effect a reduction in total cholesterol (LDL) and very low density lipoprotein (VLDL) levels and an increase in high density lipoprotein (HDL) cholesterol levels. Nicotinamide adenine dinucleotide (NAD) and NAD phosphate (NADP) are active coenzymes of niacin. These coenzymes are involved in numerous enzymatic reactions such as glycolysis, fatty acid metabolism, and steroid synthesis. Henkin et al., 91 Am. J. Med. 239-46 (1991). In a specific embodiment of the present invention, vitamin B_3 may be included in the form of niacinamide. In another specific embodiment, the present invention may include an equivalent molar amount of niacin. In another specific embodiment, vitamin B_3 may be included in amounts ranging from about 7 mg to about 23 mg. In another specific embodiment, vitamin B_3 may be included in amounts ranging from about 12 mg to about 18 mg. In another specific embodiment, vitamin B_3 may be included in amounts ranging from about 13.5 mg to about 16.5 mg. In another embodiment, vitamin B_3 may be included in an amount of about 15 mg.

The compositions and methods of the present invention may comprise or use vitamin B_6. The administration of vitamin B_6 may reduce the levels of homocysteine. Bostom et al., 49 Kidney Int. 147-52 (1996). The active forms of vitamin B_6, pyridoxal-5'-phosphate (PLP) and pyridoxamine-5'-phosphate, are coenzymes for numerous enzymes and as such, are important for gluconeogenesis, niacin formation, and erythrocyte metabolism. RDA, supra at 142-43. Vitamin B_6 is a coenzyme for both cystathionine synthase and cystathionase, enzymes that catalyze the formation of cysteine from methionine. Homocysteine is an intermediate in this process and elevated levels of plasma homocysteine are recognized as a risk factor for both vascular disease (Robinson et al., 94 Circulation 2743-48 (1996)) and neural tube defects (Locksmith & Duff, 91 Obstet. Gynecol. 1027-34 (1998)). In a specific embodiment of the present invention, vitamin B_6 may be included in the form of pyridoxine hydrochloride. In another specific embodiment, vitamin B_6 may be included in

amounts ranging from about 1 mg to about 4 mg. In another specific embodiment, vitamin B_6 may be included in amounts ranging from about 2 mg to about 3 mg. In another specific embodiment, vitamin B_6 may be included in amounts ranging from about 2.3 mg to about 2.8 mg. In another embodiment, vitamin B_6 may be included in an amount of about 2.5 mg.

The compositions and methods of the present invention may comprise or use vitamin B_9. This vitamin has demonstrated the ability to prevent neural tube defects such as spina bifida caused by disturbed homocysteine metabolism. Vanderput et al., Exp. Biol. Med. 243-70 (2001); DeFalco et al., 27 Clin. Exp. Obstet. Gynecol. 188-90 (2000); Eskes, 27 Clin. Exp. Obstet. Gynecol. 157-67 (2000); Locksmith & Duff, supra. Vitamin B_9 also is important for the formation of red and white blood cells within bone marrow and plays a role in heme formation. Further, folate deficiencies inhibit the activity of vitamin B_1. RDA, supra at 150. In a specific embodiment of the present invention, vitamin B_9 may be included in the form of folic acid. In another embodiment, vitamin B_9 may be included in the forms of folic acid, folacin, metafolin, folate and/or one or more natural isomers of folate including (6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5-methyl-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5-formyl-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 10-formyl-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5,10-methylene-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof, 5,10-methenyl-(6R)-tetrahydrofolic acid or a polyglutamyl derivative thereof and 5-formimino-(6S)-tetrahydrofolic acid or a polyglutamyl derivative thereof. In another specific embodiment, vitamin B_9 may be included in amounts ranging from about 500 μg to about 1500 μg. In another specific embodiment, vitamin B_9 may be included in amounts ranging from about 800 μg to about 1200 μg. In another specific embodiment, vitamin B_9 may be included in amounts ranging from about 900 μg to about 1100 μg. In another embodiment, vitamin B_9 may be included in an amount of about 1000 μg.

The compositions and methods of the present invention may comprise or use vitamin B_{12}. Vitamin B_{12} can be converted to the active coenzymes, methylcobalamin and 5'-deoxyadenosylcobalamin. These coenzymes are necessary for folic acid metabolism, conversion of coenzyme A and myelin synthesis. Methylcobalamin also catalyzes the demthylation of a folate cofactor which is involved in DNA synthesis. A lack of demethylation may result in folic acid deficiency. RDA, supra at 159-160. Deoxyadenosylcobalamin is the coenzyme for the conversion of methylmalonyl-CoA to succinyl-CoA, which plays a role in the citric acid cycle. Cobalamin, along with pyridoxine and folic acid, also are implicated in the proper metabolism of homocysteine, a breakdown product of the amino acid methionine, which is correlated with an increased risk of heart disease due to its negative effects on endothelial function. In one specific embodiment of the present invention, vitamin B_{12} may be included in the form of cyanocobalamin. In another specific embodiment, vitamin B_{12} may be included in amounts ranging from about 2 μg to about 8 μg. In another specific embodiment, vitamin B_{12} may be included in amounts ranging from about 4 μg to about 6 μg. In another specific embodiment, vitamin B_{12} may be included in amounts ranging from about 4.5 μg to about 5.5 μg. In another embodiment, vitamin B_{12} may be included in an amount of about 5 μg.

The compositions and methods of the present invention may comprise or use vitamin C. The major biochemical role of water-soluble vitamin C is as a co-substrate in metal catalyzed hydroxylations. Like beta carotene, vitamin C has antioxidant properties. It interacts directly with superoxide hydroxyl radicals and singlet oxygen, and also provides antioxidant protection for folate and vitamin E, keeping vitamin E in its most potent form. Vitamin C may afford protective effects against preeclampsia by participating in the scavenging of free radicals. Indeed, significantly lower levels of vitamin C have been observed in preeclamptic women than in controls. Woods et al., 185(1) Am. J. Obstet. Gynecol. 5-10 (2001); Kharb, 1 Euro. J. Obstet. Gynecol. Reprod. Biol. 37-39 (2000); Milczarek et al., 210 Mol. Cell. Biochem. 65-73 (2000).

Vitamin C also enhances the absorption of iron. RDA, supra at 115. In addition, vitamin C is required for collagen synthesis, epinephrine synthesis, and bile acid formation. Moreover, vitamin C has been implicated in inhibiting atherosclerosis by being present in extracellular fluid of the arterial wall and potentiating nitric oxide activity, thus normalizing vascular function. In a specific embodiment of the present invention, vitamin C may be included in the form of ascorbic acid. In another specific embodiment, vitamin C may be included in amounts ranging from about 30 mg to about 90 mg. In another specific embodiment, vitamin C may be included in amounts ranging from about 48 mg to about 72 mg. In another specific embodiment, vitamin C may be included in amounts ranging from about 54 mg to about 66 mg. In another embodiment, vitamin C may be included in an amount of about 60 mg.

The compositions and methods of the present invention may comprise or use vitamin D_3. Vitamin D_3 is a fat-soluble "hormone like" substance important for the maintenance of healthy bones. This vitamin increases the absorption of calcium and phosphorous from the gastrointestinal tract, and improves mineral resorption into bone tissue. Vitamin D can be converted to its active form from exposure of the skin to sunlight. This fact is among the reasons why vitamin D deficiency is common in the elderly, notably the institutionalized, who spend little or no time out of doors. Deficiencies in vitamin D_3 can lead to increased bone turnover and loss, and when severe, osteomalacia, or softening of the bones. Supplementation with vitamin D_3 has been shown to moderately reduce bone loss, increase serum 25-hydroxyvitamin D, and decrease serum parathyroid hormone levels. Dawson-Hughes et al., 337 NewEng. J. Med. 670-76 (1997); Lips et al., 86 J. Clin. Endocrinol. Metab. 1212-21 (2001). Vitamin D_3 also plays a role in the maintenance of calcium and phosphorus homeostasis, but it is also active in cell differentiation and immune function. In a specific embodiment of the present invention, vitamin D_3 may be included in the form of cholecalciferol. In another specific embodiment, vitamin D_3 may be included in amounts ranging from about 200 IU to about 600 IU. In another specific embodiment, vitamin D_3 may be included in amounts ranging from about 320 IU to about 480 IU. In another specific embodiment, vitamin D_3 may be included in amounts ranging from about 360 IU to about 440 IU. In another embodiment, vitamin D_3 may be included in an amount of about 400 IU.

The compositions and methods of the present invention may comprise or use vitamin E. Vitamin E is a fat-soluble vitamin antioxidant found in biological membranes where it protects the phospholipid membrane from oxidative stress. Vitamin E inhibits the oxidation of unsaturated fatty acids by trapping peroxyl free radicals. It is also an antiatherogenic agent, and studies have demonstrated a reduced risk of coronary heart disease with increased intake of vitamin E. Stampfer et al., 328 New Eng. J. Med. 1444-49 (1993). In addition, vitamin E, like beta carotene and vitamin C, may afford protective effects against preeclampsia by participat-

ing in the scavenging of free radicals. As with vitamin C, significantly lower levels of vitamin E have been observed in preeclamptic women than in controls. Woods et al., supra; Kharb, supra; Milczarek et al., supra. In a specific embodiment of the present invention, vitamin E may be included in the form of d-alpha-tocopheryl acetate. In another specific embodiment, vitamin E may be included in the form of an equivalent molar amount of d-alpha tocopheryl succinate. In another specific embodiment, vitamin E may be included in amounts ranging from about 15 IU to about 45 IU. In another specific embodiment, vitamin E may be included in amounts ranging from about 24 IU to about 36 IU. In another specific embodiment, vitamin E may be included in amounts ranging from about 27 IU to about 33 IU. In another embodiment, vitamin E may be included in an amount of about 30 IU.

The compositions and methods of the present invention may comprise or use iron. A primary function of iron is to carry oxygen to bodily tissues via the hemoglobin part of red blood cells. Supplemental intake of iron is critical to preventing anemia, a disorder associated with a variety of physiological states including, for example, pregnancy. Bothwell, 72(Supp.) Am. J. Clin. Nutr. 257S-64S (2000). Severe anemia may have adverse effects upon a mother and a fetus. Specifically, significant depression of hemoglobin has been associated with poor pregnancy outcome. Black, supra; Sifakis & Pharmakides, 900 Ann. N.Y. Acad. Sci. 125-36 (2000). The compositions and methods of the present invention may include iron in either chelated or nonchelated form. In a specific embodiment of the present invention, iron may be included in the form of polysaccharide iron complex. In another specific embodiment, iron may be included in the form of an equivalent molar amount of ferrous fumurate. In another specific embodiment, iron may be included in amounts ranging from about 14 mg to about 44 mg. In another specific embodiment, iron may be included in amounts ranging from about 23 mg to about 35 mg. In another specific embodiment, iron may be included in amounts ranging from about 26 mg to about 32 mg. In another embodiment, iron may be included in an amount of about 29 mg.

The compositions and methods of the present invention may comprise or use magnesium. Magnesium is found primarily in both bone and muscle and is important for over 300 different enzyme reactions. A primary function of magnesium is to bind to phosphate groups in adenosine triphosphate (ATP), thereby forming a complex that assists in the transfer of ATP phosphate. Magnesium also functions within cells as a membrane stabilizer. Magnesium plays roles in nucleic acid synthesis, glycolysis, transcription of DNA and RNA, amino acid activation, membrane transport, transketolase reactions, and protein synthesis. James L. L. Groff et al., Advanced Nutrition and Human Metabolism 341 (2d ed. 1996). It is also involved in the formation of cAMP, a cytosolic second messenger that plays a role in cell signaling mechanisms. Magnesium also functions both synergistically and antagonistically with calcium in neuromuscular transmission. RDA, supra at 188. Specifically, magnesium is critical for the maintenance of electrochemical potentials of nerve and muscle membranes and the neuromuscular junction transmissions, particularly important in the heart. Not surprisingly, magnesium deficiency is tied to cardiovascular disease and hypertension. Agus et al., 17 Crit. Care Clin. 175-87 (2001). Indeed, oral magnesium therapy improves endothelial function in patients with coronary disease. Shechter et al., 102 Circulation 2353-58 (2000).

Magnesium is available in a variety of salts and can be included in the compositions and methods of the present invention in either chelated or nonchelated form. In one specific embodiment of the present invention, magnesium may be included in the form of magnesium oxide. In another specific embodiment, magnesium may be included in amounts ranging from about 12 mg to about 38 mg. In another specific embodiment, magnesium may be included in amounts ranging from about 20 mg to about 30 mg. In another specific embodiment, magnesium may be included in amounts ranging from about 22.5 mg to about 27.5 mg. In another embodiment, magnesium may be included in an amount of about 25 mg.

The compositions and methods of the present invention may comprise or use zinc. Zinc plays a role in numerous metabolic activities such as nucleic acid production, protein synthesis, and development of the immune system. There are more than 200 zinc metalloenzymes including aldolase, alcohol dehydrogenase, RNA polymerase, and protein kinase C. Zima et al., 17 Blood Purif. 182-86 (1999). Zinc stabilizes RNA and DNA structures, forms zinc fingers in nuclear receptors, and is a component of chromatin proteins involved in transcription and replication. Deficiencies of zinc during pregnancy have been shown to contribute to severe fetal abnormalities. Srinivas et al., 68(6) Indian J. Pediatr. 519-22 (2001); Yang et al., 13(4) Biomed. Environ. Sci. 280-86 (2000); King, 71(Supp.) Am. J. Clin. Nutr. 1334S-43S (2000). Zinc is available in many forms and may be included in the compositions and methods of the present invention in chelated or nonchelated form. In a specific embodiment of the present invention, zinc may be included in the form of zinc oxide. In another specific embodiment, zinc may be included in amounts ranging from about 7 mg to about 23 mg. In another specific embodiment, zinc may be included in amounts ranging from about 12 mg to about 18 mg. In another specific embodiment, zinc may be included in amounts ranging from about 13.5 mg to about 16.5 mg. In another embodiment, zinc may be included in an amount of about 15 mg.

The compositions and methods of the present invention may comprise or use a combination of the included vitamins and minerals just described, in either chelated or non-chelated form. The active ingredients are available from numerous commercial sources, and in several active forms or salts thereof, known to those of ordinary skill in the art. Hence, the compositions and methods of the present invention are not limited to comprising or using any particular form of the vitamin or mineral ingredient described herein.

In a specific embodiment of the present invention, specific vitamins and/or minerals may be excluded. For example, in a specific embodiment, the compositions and methods of the present invention may be substantially free of added vitamin A; substantially free of added beta carotene; substantially free of added alpha carotene; substantially free of added lutein; substantially free of added lycopene; substantially free of added zeaxanthin; substantially free of added vitamin B_1; substantially free of added vitamin B_2; substantially free of added vitamin B_3; substantially free of added vitamin B_4; substantially free of added vitamin B_5; substantially free of added vitamin B_6; substantially free of added vitamin B_7; substantially free of added vitamin B_8; substantially free of added vitamin B_9; substantially free of added vitamin B_{10}; substantially free of added vitamin B_{11}; substantially free of added vitamin B_{12}; substantially free of added vitamin C; substantially free of added vitamin D_3; substantially free of added vitamin E; substantially free of added calcium; substantially free of added chromium; substantially free of added copper; substantially free of added magnesium; substantially free of added manganese; substantially free of added selenium; substantially free of added zinc; substantially free of added boron; substantially free of added odorless garlic; sub-

stantially free of added coenzyme Q-10; substantially free of added l-carnitine; substantially free of added grape seed extract; substantially free of added green tea extract; substantially free of added quercetin; substantially free of added hawthorne berries; and/or substantially free of added alpha lipoic acid. In another embodiment of the present invention, the compositions are substantially free of other added vitamins and minerals.

A specific embodiment of the present invention may comprise swallowable compositions. Swallowable compositions are well known in the art and are those that do not readily dissolve when placed in the mouth and may be swallowed whole without any chewing or discomfort. In a specific embodiment of the present invention the swallowable compositions may have a shape containing no sharp edges and a smooth, uniform and substantially bubble free outer coating.

To prepare the swallowable compositions of the present invention, each of the active ingredients may be combined in intimate admixture with a suitable carrier according to conventional compounding techniques. In a specific embodiment of the swallowable compositions of the present invention, the surface of the compositions may be coated with a polymeric film. Such a film coating has several beneficial effects. First, it reduces the adhesion of the compositions to the inner surface of the mouth, thereby increasing the patient's ability to swallow the compositions. Second, the film may aid in masking the unpleasant taste of certain drugs. Third, the film coating may protect the compositions of the present invention from atmospheric degradation. Polymeric films that may be used in preparing the swallowable compositions of the present invention include vinyl polymers such as polyvinylpyrrolidone, polyvinyl alcohol and acetate, cellulosics such as methyl and ethyl cellulose, hydroxyethyl cellulose and hydroxylpropyl methylcellulose, acrylates and methacrylates, copolymers such as the vinyl-maleic acid and styrene-maleic acid types, and natural gums and resins such as zein, gelatin, shellac and acacia. Pharmaceutical carriers and formulations for swallowable compounds are well known to those of ordinary skill in the art. See generally, e.g., WADE & WALLER, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (2^{nd} ed. 1994).

In a specific embodiment of the present invention, the compositions may comprise chewable compositions. Chewable compositions are those that have a palatable taste and mouthfeel, are relatively soft and quickly break into smaller pieces and begin to dissolve after chewing such that they are swallowed substantially as a solution.

In order to create chewable compositions, certain ingredients should be included to achieve the attributes just described. For example, chewable compositions should include ingredients that create pleasant flavor and mouthfeel and promote relative softness and dissolvability in the mouth. The following discussion describes ingredients that may help to achieve these characteristics.

Chewable compositions preferably have a pleasant or palatable flavor. Palatable flavors may be achieved by including sweetening agents and/or flavorants. Sweetening agents that may be included in the compositions of the present invention include, by way of example and without limitation, sucrose, fructose, high fructose corn syrup, dextrose, saccharin sodium, maltodextrin, aspartame, potassium acesulfame, neohesperidin dihydrochalcone, sucralose, monoammonium glycyrrhizinate, and others known to those of ordinary skill in the art. As used herein, the term "flavorant" means natural or artificial compounds used to impart a pleasant flavor and often odor to a pharmaceutical preparation. Flavorants that may be used in the present invention include, for example and without limitation, natural and synthetic flavor oils, flavoring aromatics, extracts from plants, leaves, flowers, and fruits and combinations thereof. Such flavorants include, by way of example and without limitation, anise oil, cinnamon oil, vanilla, vanillin, cocoa, chocolate, natural chocolate flavor, menthol, grape, peppermint oil, oil of wintergreen, clove oil, bay oil, anise oil, eucalyptus, thyme oil, cedar leave oil, oil of nutmeg, oil of sage, oil of bitter almonds, cassia oil; citrus oils, such as lemon, orange, lime and grapefruit oils; and fruit essences, including apple, pear, peach, berry, wildberry, date, blueberry, kiwi, strawberry, raspberry, cherry, plum, pineapple, and apricot. All of these flavorants are commercially available. In a specific embodiment of the present invention, flavorants that may be used include natural berry extracts and natural mixed berry flavor, as well as citric and malic acid. The amount of flavorants used may depend on a number of factors, including desired taste characteristics. While not necessary, one or more of these sweetening agents and/or flavorants also may be included in the swallowable compositions of the present invention.

In addition to having a palatable flavor, chewable compositions also should have a pleasant mouthfeel. A variety of ingredients can be included in the compositions of the present invention to enhance mouthfeel.

In the chewable compositions of the present invention, sugars such as white sugar, corn syrup, sorbitol (solution), maltitol (syrup), oligosaccharide, isomaltooligosaccharide, sucrose, fructose, lactose, glucose, lycasin, xylitol, lactitol, erythritol, mannitol, isomaltose, dextrose, polydextrose, dextrin, compressible cellulose, compressible honey, compressible molasses and mixtures thereof may be added to improve mouthfeel and palatability. Further, by way of example and without limitation, fondant or gums such as gelatin, agar, arabic gum, guar gum, and carrageenan may be added to improve the chewiness of the compositions. Fatty materials that may be included in the present invention include, by way of example and without limitation, vegetable oils (including palm oil, palm hydrogenated oil, corn germ hydrogenated oil, castor hydrogenated oil, cotton-seed oil, olive oil, peanut oil, palm olein oil, and palm stearin oil), animal oils (including refined oil and refined lard whose melting point ranges from 30° to 42° C.), Cacao fat, margarine, butter, and shortening.

Alkyl polysiloxanes (commercially available polymers sold in a variety of molecular weight ranges and with a variety of different substitution patterns) also may be used in the present invention to enhance the texture, the mouthfeel, or both of the chewable nutritional supplement compositions described herein. By "enhance the texture" it is meant that the alkyl polysiloxane improves one or more of the stiffness, the brittleness, and the chewiness of the chewable supplement, relative to the same preparation lacking the alkyl polysiloxane. By "enhance the mouthfeel" it is meant that the alkyl polysiloxane reduces the gritty texture of the supplement once it has liquefied in the mouth, relative to the same preparation lacking the alkyl polysiloxane.

Alkyl polysiloxanes generally comprise a silicon and oxygen-containing polymeric backbone with one or more alkyl groups pending from the silicon atoms of the back bone. Depending upon their grade, they can further comprise silica gel. Alkyl polysiloxanes are generally viscous oils. Exemplary alkyl polysiloxanes that can be used in the swallowable, chewable or dissolvable compositions of the present invention include, by way of example and without limitation, monoalkyl or dialkyl polysiloxanes, wherein the alkyl group is independently selected at each occurrence from a C_1-C_6-alkyl group optionally substituted with a phenyl group. A specific alkyl polysiloxane that may be used is dimethyl pol-

ysiloxane (generally referred to as simethicone). More specifically, a granular simethicone preparation designated simethicone GS may be used. Simethicone GS is a preparation which contains 30% simethicone USP. Simethicone USP contains not less than about 90.5% by weight $(CH_3)_3$—$Si\{OSi(CH_3)_2\}CH_3$ in admixture with about 4.0% to about 7.0% by weight SiO_2.

To prevent the stickiness that can appear in conventional chewable compositions and to facilitate conversion of the active ingredients to emulsion or suspension upon taking, the compositions of the present invention, may further comprise emulsifiers such as, by way of example and without limitation, glycerin fatty acid ester, sorbitan monostearate, sucrose fatty acid ester, lecithin and mixtures thereof. In a specific embodiment, one or more of such emulsifiers may be present in an amount of about 0.01% to about 5.0%, by weight of the administered compositions. If the level of emulsifier is lower or higher than the said range, the emulsification cannot be realized, or wax value will rise.

Chewable compositions should begin to break and dissolve in the mouth shortly after chewing begins such that the compositions can be swallowed substantially as a solution. The dissolution profile of chewable compositions may be enhanced by including rapidly water-soluble fillers and excipients. Rapidly water-soluble fillers and excipients preferably dissolve within about 60 seconds of being wetted with saliva. Indeed, it is contemplated that if enough water-soluble excipients are included in the compositions of the present invention, they may become dissolvable rather than chewable composition forms. Examples of rapidly water soluble fillers suitable for use with the present invention include, by way of example and without limitation, saccharides, amino acids and the like. In a specific embodiment, the saccharide may be a mono-, di- or oligosaccharide. Examples of saccharides which may be added to the compositions of the present invention include, by way of example and without limitation, sorbitol, glucose, dextrose, fructose, maltose and xylitol (all monosaccharides); and sucrose, lactose, glucose, galactose and mannitol (all disaccharides). Other suitable saccharides are oligosaccharides. Examples of oligosaccharides are dextrates and maltodextrins. Other water soluble excipients that may be used with the present invention include, by way of example and without limitation, amino acids such as alanine, arginine, aspartic acid, asparagine, cysteine, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine.

Disintegrants also may be included in the compositions of the present invention in order to facilitate dissolution. Disentegrants, including permeabilising and wicking agents, are capable of drawing water or saliva up into the compositions which promotes dissolution from the inside as well as the outside of the compositions. Such disintegrants, permeabilising and/or wicking agents that may be used in the present invention include, by way of example and without limitation, starches, such as corn starch, potato starch, pre-gelatinized and modified starches thereof, cellulosic agents, such as Acdi-sol, montmorrilonite clays, cross-linked PVP, sweeteners, bentonite, microcrystalline cellulose, croscarmellose sodium, alginates, sodium starch glycolate, gums, such as agar, guar, locust bean, karaya, pectin, Arabic, xanthan and tragacanth, silica with a high affinity for aqueous solvents, such as colloidal silica, precipitated silica, maltodextrins, beta-cyclodextrins, polymers, such as carbopol, and cellulosic agents, such as hydroxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.

Finally, dissolution of the compositions may be facilitated by including relatively small particles sizes of the ingredients used.

In addition to those described above, any appropriate fillers and excipients may be utilized in preparing the swallowable, chewable and/or dissolvable compositions of the present invention so long as they are consistent with the objectives described herein. For example, binders are substances used to cause adhesion of powder particles in granulations. Such compounds appropriate for use in the present invention include, by way of example and without limitation, acacia, compressible sugar, gelatin, sucrose and its derivatives, maltodextrin, cellulosic polymers, such as ethylcellulose, hydroxypropylcellulose, hydroxypropylmethyl cellulose, carboxymethylcellulose sodium and methylcellulose, acrylic polymers, such as insoluble acrylate ammoniomethacrylate copolymer, polyacrylate or polymethacrylic copolymer, povidones, copovidones, polyvinylalcohols, alginic acid, sodium alginate, starch, pregelatinized starch, guar gum, polyethylene glycol and others known to those of ordinary skill in the art.

Diluents also may be included in the compositions of the present invention in order to enhance the granulation of the compositions. Diluents can include, by way of example and without limitation, microcrystalline cellulose, sucrose, dicalcium phosphate, starches, lactose and polyols of less than 13 carbon atoms, such as mannitol, xylitol, sorbitol, maltitol and pharmaceutically acceptable amino acids, such as glycin, and their mixtures.

Lubricants are substances used in composition formulations that reduce friction during composition compression. Lubricants that may be used in the present invention include, by way of example and without limitation, stearic acid, calcium stearate, magnesium stearate, zinc stearate, talc, mineral and vegetable oils, benzoic acid, poly(ethylene glycol), glyceryl behenate, stearyl fumarate, and others known to those of ordinary skill in the art.

Glidants improve the flow of powder blends during manufacturing and minimize composition weight variation. Glidants that may be used in the present invention include, by way of example and without limitation, silicon dioxide, colloidal or fumed silica, magnesium stearate, calcium stearate, stearic acid, cornstarch, talc and others known to those of ordinary skill in the art.

Colorants also may be included in the nutritional supplement compositions of the present invention. As used herein, the term "colorant" includes compounds used to impart color to pharmaceutical preparations. Such compounds include, by way of example and without limitation, FD&C Red No. 3, FD&C Red No. 20, FD&C Yellow No. 6, FD&C Blue No. 2, D&C Green No. 5, FD&C Orange No. 5, D&C Red No. 8, caramel, and ferric oxide, red and others known to those of ordinary skill in the art. Coloring agents also can include pigments, dyes, tints, titanium dioxide, natural coloring agents, such as grape skin extract, beet red powder, beta carotene, annato, carmine, turmeric, paprika and others known to those of ordinary skill in the art. It is recognized that no colorant is required in the nutritional supplement compositions described herein.

If desired, the compositions of the present invention may be sugar coated or enteric coated by standard techniques. The unit dose forms may be individually wrapped, packaged as multiple units on paper strips or in vials of any size, without limitation. The swallowable, chewable or dissolvable compositions of the present invention may be packaged in unit dose, rolls, bulk bottles, blister packs and combinations thereof, without limitation.

The swallowable, chewable or dissolvable compositions of the present invention may be prepared using conventional methods and materials known in the pharmaceutical art. For example, U.S. Pat. Nos. 5,215,754 and 4,374,082 relate to methods for preparing swallowable compositions. U.S. Pat. No. 6,495,177 relates to methods to prepare chewable nutritional supplements with improved mouthfeel. U.S. Pat. No. 5,965,162, relates to compositions and methods for preparing multi-vitamin comestible units which disintegrate quickly in the mouth, especially when chewed. Further, all pharmaceutical carriers and formulations described herein are well known to those of ordinary skill in the art, and determination of workable proportions in any particular instance will generally be within the capability of the person skilled in the art. Details concerning any of the excipients of the invention may be found in WADE & WALLER, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (2nd ed. 1994). All active ingredients, fillers and excipients are commercially available from companies such as Aldrich Chemical Co., FMC Corp, Bayer, BASF, Alexi Fres, Witco, Mallinckrodt, Rhodia, ISP, and others.

Other objectives, features and advantages of the present invention will become apparent from the following specific examples. The specific examples, while indicating specific embodiments of the invention, are provided by way of illustration only. Accordingly, the present invention also includes those various changes and modifications within the spirit and scope of the invention that may become apparent to those skilled in the art from this detailed description. The invention will be further illustrated by the following non-limiting examples.

EXAMPLES

Without further elaboration, it is believed that one skilled in the art, using the preceding description, can utilize the present invention to the fullest extent. The following examples are illustrative only, and not limiting of the remainder of the disclosure in any way whatsoever.

Example 1

A composition of the following formulation was prepared in chewable form:

Vitamin A (acetate)	1100 IU
Beta Carotene	600 IU
Vitamin B_1 (thiamine mononitrate)	1.6 mg
Vitamin B_2 (riboflavin)	1.8 mg
Vitamin B_3 (niacinamide)	15 mg
Vitamin B_6 (pyridoxine hydrochloride)	2.5 mg
Vitamin B_9 (folic acid)	1000 µg
Vitamin B_{12} (cyanocobalamin)	5 µg
Vitamin C (ascorbic acid)	60 mg
Vitamin D (cholecalciferol)	400 IU
Vitamin E (d-alpha-tocopheryl acetate)	30 IU
Iron (polysaccharide complex)	29 mg
Magnesium (magnesium oxide)	25 mg
Zinc (zinc oxide)	15 mg

Example 2

A study is undertaken to evaluate the effectiveness of the compositions of the present invention in the treatment of patients. The objective of the study is to determine whether oral intake of the compositions results in an improvement of the nutritional status of patients with regard to the specific vitamins and minerals contained in the administered compositions.

A double-blind, placebo controlled study is conducted over a six-month period. A total of 120 subjects (60 pregnant women entering the second trimester of pregnancy and 60 lactating women), aged 20-35 years, are chosen for the study. An initial assessment of the nutritional status of each woman is conducted. Vitamin A, beta carotene and vitamin B_6 are measured using high performance liquid chromatography. Erythrocyte transketolase activity is used to measure vitamin B_1 levels. Vitamin B_2 levels are determined by assessment of erythrocyte glutathione reductase activity. Vitamin B_3 levels are assessed by measuring urinary excretion of N'methylnicotinamide and its pyridone. Vitamin B_9 is measured by radioimmunoassay (RIA), specifically The Solid Phase No Biol Folic Acid Kit (Diagnostic Products, Los Angeles, Calif.). Vitamin B_{12} is measured by RIA using human intrinsic factor as a binder. Vitamin C levels are measured by spectrophotometric and colorimetric methods. Vitamin D is measured using an extraction double-antibody RIA (Dia Sorin, Inc., Stillwater, Minn.). The peroxide hemolysis test is used to determine vitamin E status. Iron levels are measured using standard spectrophotometry. Similarly, magnesium levels are measured by absorbance of a magnesium chelate with xylidl blue at 660 nM. Zinc levels are assessed using flame atomic absorption spectrometry (Perkins Elmer 460, Norwalk, Conn.).

The 120 subjects are separated into four separate groups of 30 women. In a first group comprising only pregnant women and in a second group comprising only lactating women, each subject is administered one dosage form of the composition as described in Example 1 twice a day. In a third group comprising only pregnant women and in a fourth group comprising only lactating women, each subject is administered one placebo dosage form twice a day. Thus, dosage form administration occurs every 12 hours. No other nutritional supplements are taken by the subjects during the assessment period.

An assessment of the nutritional status of each woman is conducted utilizing the methods described above at one month intervals for a six month period. The data is evaluated using multiple linear regression analysis and a standard t-test. In each analysis, the baseline value of the outcome variable is included in the model as a covariant. Treatment by covariant interaction effects is tested by the method outlined by Weigel & Narvaez, 12 CONTROLLED CLINICAL TRIALS 378-94 (1991). If there are no significant interaction effects, the interaction terms are removed from the model. The regression model assumptions of normality and homogeneity of variance of residuals are evaluated by inspection of the plots of residuals versus predicted values. Detection of the temporal onset of effects is done sequentially by testing for the presence of significant treatment effects at 1, 2, 3, 4, 5, and 6 months, proceeding to the earlier time in sequence only when significant effects have been identified at each later time period. Changes from the baseline within each group are evaluated using paired t-tests. In addition, analysis of variance is performed on all baseline measurements and measurable subject characteristics to assess homogeneity between groups. All statistical procedures are conducted using the Statistical Analysis System (SAS Institute Inc., Cary, N.C.). An alpha level of 0.05 is used in all statistical tests.

A statistically significant improvement in the nutritional status of all vitamin and mineral levels measured is observed in the treated subjects over the controls upon completion of the study. Therefore, the study confirms that oral administra-

tion of the compositions of the present invention is effective in improving the nutritional status of patients.

While specific embodiments of the present invention have been described, other and further modifications and changes may be made without departing from the spirit of the invention. All further and other modifications and changes are included that come within the scope of the invention as set forth in the claims. The disclosure of all publications cited above are expressly incorporated by reference in their entireties to the same extent as if each were incorporated by reference individually.

What is claimed is:

1. A composition for supplementing nutritional deficiencies in a patient or person in need thereof, consisting of vitamin A, beta carotene, vitamin B_1, vitamin B_2, vitamin B_3, vitamin B_6, vitamin B_9, vitamin B_{12}, vitamin C, vitamin D_3, vitamin E, iron, magnesium, zinc and one or more inactive ingredients, wherein said composition is both swallowable and chewable.

2. The composition of claim **1** wherein said vitamin A is present in an amount of about 550 IU to about 1650 IU; said beta carotene is present in an amount of about 300 IU to about 900 IU; said vitamin B_1 is present in an amount of about 1 mg to about 3 mg; said vitamin B_2 is present in an amount of about 1 mg to about 3 mg; said vitamin B_3 is present in an amount of about 7 mg to about 23 mg; said vitamin B_6 is present in an amount of about 1 mg to about 4 mg; said vitamin B_9 is present in an amount of about 500 μg to about 1500 μg; said vitamin B_{12} is present in an amount of about 2 μg to about 8 μg; said vitamin C is present in an amount of about 30 mg to about 90 mg; said vitamin D_3 is present in an amount of about 200 IU to about 600 IU; said vitamin E is present in an amount of about 15 IU to about 45 IU; said iron is present in an amount of about 14 mg to about 44 mg; said magnesium is present in an amount of about 12 mg to about 38 mg; and said zinc is present in an amount of about 7 mg to about 23 mg.

3. The composition of claim **1** wherein said vitamin A is present in an amount of about 1100 IU; said beta carotene is present in an amount of about 600 IU; said vitamin B_1 is present in an amount of about 1.6 mg; said vitamin B_2 is present in an amount of about 1.8 mg; said vitamin B_3 is present in an amount of about 15 mg; said vitamin B_6 is present in an amount of about 2.5 mg; said vitamin B_9 is present in an amount of about 1000 μg; said vitamin B_{12} is present in an amount of about 5 μg; said vitamin C is present in an amount of about 60 mg; said vitamin D_3 is present in an amount of about 400 IU; said vitamin E is present in an amount of about 30 IU; said iron is present in an amount of about 29 mg; said magnesium is present in an amount of about 25 mg; and said zinc is present in an amount of about 15 mg.

4. The composition of any of claims **1-3**, wherein said iron is in the form of polysaccharide iron complex.

5. The composition of claim **1**, wherein said vitamin A is in the form of acetate.

6. The composition of claim **1**, wherein said vitamin B_1 is in the form of thiamine mononitrate.

7. The composition of claim **1**, wherein said vitamin B_2 is in the form of riboflavin.

8. The composition of claim **1**, wherein said vitamin B_3 is in the form of niacinamide.

9. The composition of claim **1** wherein said vitamin B_6 is in the form of pyridoxine hydrochloride.

10. The composition of claim **1**, wherein said vitamin B_9 is in the form of folic acid.

11. The composition of claim **1**, wherein said vitamin B_{12} is in the form of cyanocobalamin.

12. The composition of claim **1**, wherein said vitamin C is in the form of ascorbic acid.

13. The composition of claim **1**, wherein said vitamin D_3 is in the form of cholecalciferol.

14. The composition of claim **1**, wherein said vitamin E is in the form of d-alpha tocopheryl acetate.

15. The composition of claim **1**, wherein said magnesium is in the form of magnesium oxide.

16. The composition of claim **1**, wherein said zinc is in the form of zinc oxide.

17. The composition of claim **1**, wherein said inactive ingredients are selected from one or more of the group consisting of binders, diluents, lubricants, glidants, colorants, emulsifiers, disintegrants, starches, water, oils, alcohols, preservatives, sweetening agents, flavorants and sugars.

18. The composition of claim **1**, wherein said inactive ingredients are selected from one or more of the group consisting of fructose, stearic acid, natural mixed berry flavor, croscarmellose sodium, citric acid, magnesium stearate, silicon dioxide, and malic acid.

19. A method consisting of administering to a patient the composition of claim **1**.

20. The method of claim **19** wherein said vitamin A is present in, an amount of about 550 IU to about 1650 IU; said beta carotene is present in an amount of about 300 IU to about 900 IU; said vitamin B_1 is present in an amount of about 1 mg to about 3 mg; said vitamin B_2 is present in an amount of about 1 mg to about 3 mg; said vitamin B_3 is present in an amount of about 7 mg to about 23 mg; said vitamin B_6 is present in an amount of about 1 mg to about 4 mg; said vitamin B_9 is present in an amount of about 500 μg to about 1500 μg; said vitamin B_{12} is present in an amount of about 2 μg to about 8 μg; said vitamin C is present in an amount of about 30 mg to about 90 mg; said vitamin D_3 is present in an amount of about 200 IU to about 600 IU; said vitamin E is present in an amount of about 15 IU to about 45 IU; said iron is present in an amount of about 14 mg to about 44 mg; said magnesium is present in an amount of about 12 mg to about 38 mg; and said zinc is present in an amount of about 7 mg to about 23 mg.

21. The method of claim **19** wherein said vitamin A is present in an amount of about 1100 IU; said beta carotene is present in an amount of about 600 IU; said vitamin B_1 is present in an amount of about 1.6 mg; said vitamin B_2 is present in an amount of about 1.8 mg; said vitamin B_3 is present in an amount of about 15 mg; said vitamin B_6 is present in an amount of about 2.5 mg; said vitamin B_9 is present in an amount of about 1000 μg; said vitamin B_{12} is present in an amount of about 5 μg; said vitamin C is present in an amount of about 60 mg; said vitamin D_3 is present in an amount of about 400 IU; said vitamin E is present, in an amount of about 30 IU; said iron is present in an amount of about 29 mg; said magnesium is present in an amount of about 25 mg; and said zinc is present in an amount of about 15 mg.

22. The method of any of claims **19-21**, wherein said iron is in the form of polysaccharide iron complex.

23. The method of claim **19**, wherein said vitamin A is in the form of acetate.

24. The method of claim **19**, wherein said vitamin B_1 is in the form of thiamine mononitrate.

25. The method of claim **19**, wherein said vitamin B_2 is in the form of riboflavin.

26. The method of claim **19**, wherein said vitamin B_3 is in the form of niacinamide.

27. The method of claim **19**, wherein said vitamin B_6 is in the form of pyridoxine hydrochloride.

28. The method of claim **19**, wherein said vitamin B_9 is in the form of folic acid.

29. The method of claim **19**, wherein said vitamin B_{12} is in the form of cyanocobalamin.

30. The method of claim **19**, wherein said vitamin C is in the form of ascorbic acid.

31. The method of claim **19**, wherein said vitamin D_3 is in the form of cholecalciferol.

32. The method of claim **19**, wherein said vitamin E is in the form of d-alpha tocopheryl acetate.

33. The method of claim **19**, wherein said magnesium is in the form of magnesium oxide.

34. The method of claim **19**, wherein said zinc is in the form of zinc oxide.

35. The method of claim **19**, wherein said inactive ingredients are selected from one or more of the group consisting of binders, diluents, lubricants, glidants, colorants, emulsifiers, disintegrants, starches, water, oils, alcohols, preservatives, sweetening agents, flavorants and sugars.

36. The method of claim **19**, wherein said inactive ingredients are selected from one or more of the group consisting of fructose, stearic acid, natural mixed berry flavor, croscarmellose sodium, citric acid, magnesium stearate, silicon dioxide, and malic acid.

* * * * *

Exhibit B

NDC 0642-0075-30
SELECT-OB®+DHA
Prenatal Supplement with DHA
Rx only

COMPOSITION:
Each SELECT-OB® caplet contains:

Vitamin A (as acetate & beta carotene)	1700 IU
Vitamin C (as ascorbic acid)	60 mg
Vitamin D3 (as cholecalciferol)	400 IU
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU
Thiamine mononitrate (Vitamin B1)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	15 mg
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folic acid	1 mg
Vitamin B12 (as cyanocobalamin)	5 mcg
Iron (as polysaccharide iron complex)	29 mg
Magnesium (as magnesium oxide)	25 mg
Zinc (as zinc oxide)	15 mg

Each DHA softgel capsule contains:

OMEGA-3 FATTY ACID	
DHA from Algal (crypthecodinium) Oil	250 mg
Lauric Acid	20 mg

Other Ingredients in Select-OB® caplet: Fructose, Stearic Acid, Mono and Diglycerides, Croscarmellose Sodium, Mixed Berry Flavor WONF, Gelatin (Porcine), Silicon Dioxide, Citric Acid, Magnesium Stearate, Modified Food Starch, Malic Acid, Corn Starch, Sucrose, Dicalcium Phosphate, Sodium Ascorbate, Medium Chain Triglycerides, Sorbic Acid, Tocopherol Concentrate, Sodium Benzoate, dl-Alpha-Tocopherol, Butylated Hydroxytoluene (BHT), Tricalcium Phosphate. Coating: Hypromellose, Titanium Dioxide, Polydextrose, Hydroxypropyl Cellulose, Triacetin, Polyethylene Glycol, FD&C Blue #1 / Brilliant Blue FCF Aluminum Lake, FD&C Blue #2 / Indigo Carmine Aluminum Lake.

Other Ingredients in DHA softgel capsule: Gelatin, Glycerin USP, Water, Orange Flavor.

INDICATIONS AND USAGE:
SELECT OB®+DHA is indicated to provide vitamin, mineral, and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother, including individuals with known allergies to fish. SELECT-OB®+DHA does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS:
SELECT-OB®+DHA is contraindicated in patients with hypersensitivity to any of its components or color additives. Folic acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid. Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver.
Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (vitaminB12).

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or a Poison Control Center immediately.

WARNINGS/PRECAUTIONS:
SELECT-OB®+DHA should be used with caution in patients with known sensitivity or allergy to soy.
Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur. Prolonged use of iron salts may produce iron storage disease.
Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive. The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency. Consumption of more than 3 grams of omega-3 fatty acids per day from all sources may lead to excessive bleeding.
Supplemental intake of omega-3 fatty acids such as DHA exceeding 2 grams per day is not recommended.
Avoid overdosage. Keep out of the reach of children.

Drug Interactions: High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs.
Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones.
Zinc can inhibit the absorption of certain antibiotics; take at least 2 hours apart to minimize interactions. Consult appropriate references for additional specific vitamin-drug interactions.
Information for Patients: Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breastfeeding.
Pediatric Use: Not for pediatric use.

ADVERSE REACTIONS:
Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in SELECT-OB®+DHA.

DOSAGE AND ADMINISTRATION:
Before, during and after pregnancy, chew or swallow one blue SELECT®-OB caplet and swallow one DHA softgel capsule daily, or as directed by a physician.

HOW SUPPLIED:
SELECT-OB®+DHA is available as a light blue caplet debossed EV0077 and one amber-colored DHA softgel capsule. Available in Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5 Select-OB® caplets and 5 DHA softgel capsules each), (NDC 0642-0075-30).
Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat and moisture.

Rx only

Manufactured for:
EVERETT LABORATORIES, INC.
West Orange, NJ 07052
1-877-324-9349

U.S. Patent No. 7,560,123
Select-OB® is a trademark of Everett Laboratories, Inc.
Life's DHA™ is a trademark of Martek Biosciences Corporation.
U.S. Patent No. 5,407,957; 5,492,938; 7,163,811
(Rev. 10/11)

Exhibit C

NDC 0642-0075-30

Select-OB®+DHA

Rx ONLY

One SELECT-OB® caplet daily provides:

VITAMINS:

Fat-soluble Vitamins	
A (Acetate & Beta Carotene)	1700 IU
D3 (Cholecalciferol)	400 IU
E (as d-Alpha Tocopheryl Acetate)	30 IU
Water-soluble Vitamins	
C (Ascorbic Acid)	60 mg
Folic Acid (Pteroylglutamic Acid)	1 mg
B1 (Thiamine Mononitrate)	1.6 mg
B2 (Riboflavin)	1.8 mg
B6 (Pyridoxine Hydrochloride)	2.5 mg
B12 (Cyanocobalamin)	5 mcg
Niacin (as Niacinamide)	15 mg

MINERALS:

Iron (Polysaccharide Iron Complex)	29 mg
Magnesium (Magnesium Oxide)	25 mg
Zinc (Zinc Oxide)	15 mg

One DHA gelatin capsule daily provides:

Docosahexaenoic Acid (DHA)	250 mg

DHA is an omega-3 fatty acid contained in oil derived from microalgae.

Other ingredients in DHA gelatin capsule: Gelatin, Glycerin USP, orange flavor, water.

INACTIVE INGREDIENTS: Fructose, Stearic Acid, Croscarmellose Sodium, Natural Berry Mix Flavor, Silicon Dioxide, Citric Acid, Magnesium Stearate, Hypromellose, Malic Acid, Maltodextrin, Titanium Dioxide, Polydextrose, Triacetin, Polyethylene Glycol, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, Hydroxypropyl Cellulose.

DESCRIPTION: 30 SELECT-OB® caplets and 30 DHA capsules are co-packaged in child-resistant blister cards for prescription use. SELECT-OB® is a light blue caplet, imprint "EV0077". DHA is contained in an amber-colored gelatin capsule.

INDICATIONS AND USAGE: SELECT-OB®+DHA is indicated to provide vitamin, mineral, and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother, including individuals with known allergies to fish. SELECT-OB®+DHA does not contain fish, fish oils, fish proteins or fish byproducts. SELECT-OB®: Contains 1 mg folic acid. Some women may reduce their risk of a neural tube defect pregnancy by maintaining adequate intakes of folate during childbearing years..

CONTRAINDICATIONS: SELECT-OB®+DHA is contraindicated in patients with hypersensitivity to any of its components. Folic acid (pteroylglutamic acid) is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid. Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver. Vitamin B12 is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin. Resistance to treatment may be due to depressed hematopoiesis, alcoholism, the presence of anti-metabolic drugs, and to deficiencies of vitamins. Prolonged use of iron salts may produce iron storage disease.

WARNINGS:

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or a Poison Control Center immediately.

(continued from back)

Pernicious anemia should be ruled out before starting treatment. While folic acid corrects the blood picture of pernicious anemia, it does not ameliorate the attendant neurologic involvement.

PRECAUTIONS: Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia associated with vitamin B12 deficiency, in that hematologic remission may occur while neurological manifestations remain progressive. Folic acid may lower the serum concentration of phenytoin resulting in increased seizure frequency. Folic acid may decrease a patient's response to methotrexate. DHA may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive. Consumption of >3 grams per day of omega-3 fatty acids from all sources may lead to excessive bleeding. Supplemental intake of omega-3 fatty acids such as DHA exceeding 2 grams per day is not recommended.

INFORMATION FOR PATIENTS: Patients should be informed to disclose all medicines, vitamins, and supplements used and to take the prescribed dose. Overdose or interactions can lead to side effects including birth defects.

ADVERSE REACTIONS: Allergic sensitivity reactions and gastrointestinal disturbances may occur.

DOSAGE AND ADMINISTRATION: Before, during and after pregnancy, chew or swallow one blue SELECT-OB® caplet and swallow one DHA gel capsule daily, or as directed by a physician.

HOW SUPPLIED: Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5 Select-OB® caplets and 5 DHA gel capsules each), NDC 0642-0075-30.

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat. **RX ONLY.**

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Select-OB® is a trademark of Everett Laboratories

U.S. Patent No. 6,977,167; 5,407,957; 5,462,938 and other patents pending

Manufactured for
EVERETT LABORATORIES, INC.
West Orange, NJ 07052

Lot No.

Exp. Date:

Rx ONLY NDC 0642-0075-30

Select-OB®+DHA

Prenatal Multivitamin Caplets that can be CHEWED or SWALLOWED and omega-3 (DHA) Gelcaps

Natural berry flavored BLUE Select-OB® Caplet can be chewed or swallowed

Natural orange flavored DHA Gelcap leaves no fishy aftertaste

30 DAY SUPPLY
- 30 CAPLETS
- 30 GELCAPS

Unit Dose Pack

- *Free of ocean borne contaminants*
- *All natural plant source DHA*

DOES NOT CONTAIN FISH OIL

life's DHA™

LACTOSE, GLUTEN AND FISH BY-PRODUCT FREE U.S. PATENTED

Rx ONLY NDC 0642-0075-30

Select-OB®+DHA

Prenatal Multivitamin Caplets that can be CHEWED or SWALLOWED and omega-3 (DHA) Gelcaps

Natural berry flavored BLUE Select-OB® Caplet can be chewed or swallowed

Natural orange flavored DHA Gelcap leaves no fishy aftertaste

- *Lactose, Gluten and Fish By-Product Free*
- *Free of ocean borne contaminants*
- *All natural plant source DHA*

DOES NOT CONTAIN FISH OIL

life's DHA™

life's DHA™ is a trademark of Martek Biosciences Corporation

Select-OB® + DHA
(DAILY DOSE)

N 3 0642-0075-30 8

Exhibit D

HOW SUPPLIED: 42192-353-60. Choice - OB + DHA is supplied in child-resistant blister cards containing 30 doses per carton (1 tablet and 1 golden - colored DHA softgel capsule equals 1 daily dose). Each dispensing carton contains 5 cards with 6 unit-doses per card which is a 30-day supply. The beige, oval tablet is imprinted with "353" on one side and is blank on the other. The golden - colored DHA softgel capsule is not imprinted. The listed product number is not a National Drug Code, but has merely been formatted to comply with standard industry practice for pharmacy and insurance computer systems.

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature.]

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical information provided herein.
THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

MANUFACTURED FOR:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
1-800-541-4802
Rev 0313

Choice - OB + DHA

Prenatal/Multivitamin Tablets that can be Chewed or Swallowed and Omega-3 (DHA) Gelcaps

42192-353-60

Choice - OB + DHA

Prenatal/Multivitamin Tablets that can be Chewed or Swallowed and Omega-3 (DHA) Gelcaps

Rx Only

Natural berry flavored tablet

30 day supply - 30 tablets and 30 softgel capsules

Acella PHARMACEUTICALS, LLC

LOT 3030 EXP 1-2015

Rx Only

SUPPLEMENT FACTS

Each tablet contains:

A (acetate and beta carotene)	1700 IU
D_3 (cholecalciferol)	400 IU
C (ascorbic acid)	60 mg
E (dl-alpha tocopheryl acetate)	30 IU
Folic Acid (Pteroylglutamic Acid)	1 mg
B_1 (thiamine mononitrate)	1.6 mg
B_2 (riboflavin)	1.8 mg
B_6 (pyridoxine hydrochloride)	2.5 mg
B_{12} (cyanocobalamin)	5 mcg
Niacin (niacinamide)	15 mg
Iron (polysaccharide iron complex)	29 mg
Magnesium (magnesium oxide)	25 mg
Zinc (zinc oxide)	15 mg

Each softgel capsule contains:

Docosahexaenoic Acid (DHA)	250 mg
Lauric Acid	20 mg

OTHER INGREDIENTS (softgel): bovine gelatin, glycerin USP and water.

DHA is an omega-3 fatty acid contained in oil derived from microalgea.

OTHER INGREDIENTS (tablet): cherry flavor, citric acid, crosscarmelose sodium, fructose, magnesium stearate, microcrystalline cellulose, silicon dioxide, sorbitol, stevia and strawberry flavor.

INDICATIONS: Choice - OB + DHA is indicated to provide vitamin, mineral and omega-3 fatty acid supplementation prior to conception, throughout pregnancy and during the postnatal period for the lactating and non-lactating mother, including those individuals with known allergies to fish. Choice - OB + DHA does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS: Folic acid (pteroylglutamic acid) is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid. Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficencies, etc.), pyridoxine responsive anemia or cirrhosis of the liver. Cyanocobalamin is contra-indicated in patients with sensitivity to cobalt or to cyanocobalamin (vitamin B12). Resistance to treatment may be due to depressed hematopoiesis, alcoholism, the presence of anti-metabolic drugs and to deficiencies of vitamins. Prolonged use of iron salts may produce iron storage disease.

WARNING: Pernicious anemia should be ruled out before starting treatment. While folic acid corrects the blood picture of pernicious anemia, it does not ameliorate the attendant neurologic involvement.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS: Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia associated with vitamin B_{12} deficiency in that hematologic remission may occur while neurological manifestations remain progressive. Folic acid may lower the serum concentration of phenytoin resulting in increased seizure frequency. Consumption of greater than 3 grams per day of omega-3 fatty acids from all sources may lead to excessive bleeding. Supplemental intake of omega-3 fatty acids such as DHA exceeding 2 grams per day is not recommended.

INFORMATION FOR PATIENT: Patients should be informed to disclose all medicines, vitamins and supplements used and to take the prescribed dose. Overdose or interactions can lead to side effects including birth defects.

ADVERSE REACTIONS: Allergic sensitivity reactions and gastrointestinal disturbances may occur.

DOSAGE AND ADMINISTRATION: Before, during and after pregnancy, one tablet and one gel capsule daily, or as directed by a physician.

Choice - OB + DHA

Prenatal/Multivitamin Tablets that can be Chewed or Swallowed and Omega-3 (DHA) Gelcaps

Exhibit E

Certificate of Registration

This Certificate issued under the seal of the Copyright Office in accordance with title 17, *United States Code*, attests that registration has been made for the work identified below. The information on this certificate has been made a part of the Copyright Office records.

Maria A. Pallante

Register of Copyrights, United States of America

Registration Number:

VA 1-666-635

Effective date of registration:

April 9, 2009

Title

Title of Work: Select-OB+DHA Package

Completion/ Publication

Year of Completion: 2009

Date of 1st Publication: April 8, 2009 **Nation of 1st Publication:** United States

Author

- **Author:** Everett Laboratories, Inc.

Author Created: 2-D artwork, photograph(s), text

Work made for hire: Yes

Citizen of: United States **Domiciled in:** United States

Copyright claimant

Copyright Claimant: Everett Laboratories, Inc.

29 Spring Street, West Orange, NJ, 07052, United States

Limitation of copyright claim

Material excluded from this claim: photograph(s)

New material included in claim: 2-D artwork, text

Certification

Name: Don J. Pelto

Date: April 9, 2009

Applicant's Tracking Number: 14ME-147259

Correspondence: Yes

Exhibit F

Certificate of Registration

This Certificate issued under the seal of the Copyright Office in accordance with title 17, *United States Code*, attests that registration has been made for the work identified below. The information on this certificate has been made a part of the Copyright Office records.

Maria A. Pallante

Register of Copyrights, United States of America

Registration Number
TX 7-527-076

Effective date of registration:
May 31, 2012

Title

Title of Work: Select-OB+DHA 10/11 Product Insert

Completion/Publication

Year of Completion: 2011

Date of 1st Publication: November 18, 2011 **Nation of 1st Publication:** United States

Author

- **Author:** Everett Laboratories, Inc.

Author Created: text, editing

Work made for hire: Yes

Citizen of: United States **Domiciled in:** United States

Copyright claimant

Copyright Claimant: Everett Laboratories, Inc.
29 Spring Street, West Orange, NJ, 07052, United States

Limitation of copyright claim

Material excluded from this claim: text, photographs, artwork, Earlier versions of packaging

Previous registration and year: VA 1-666-635 2009

New material included in claim: text, editing

Rights and Permissions

Organization Name: Sheppard, Mullin, Richter & Hampton LLP

Name: Nathaniel Bruno

Email: nbruno@sheppardmullin.com **Telephone:** 202-741-8424

Address: 1300 I Street, NW
11th Floor East
Washington, DC 20005 United States

Certification

Name: Nathaniel Bruno

Date: May 31, 2012