



No.F.10-16/2021-DD (H&OTC) (M-100)  
DIVISION OF HEALTH & OTC PRODUCTS  
DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-6  
[(See rule 7(16))]

PROVISIONAL CERTIFICATE FOR ENLISTMENT AS IMPORTER


E. No. 01250

Dated: 21-12-2021

M/s Nature's Line Pvt Ltd., 283-B, Block Johar Town, Lahore, agent of M/s Bomuca International Corporation, 9375, Custom House Plz., Suite F, San Diego, California, USA (Principal Manufacturer: M/s Captek Softgel International Inc., 2710, Progress Street, Vista, CA 92081, USA, is hereby enlisted in the enlistment register as importer, by the Authority [approved in 100<sup>th</sup> Meeting of EEC, held on 16<sup>th</sup> December, 2021 and vide F. No. 4-76/2021-(H&OTC)] subject to the following conditions namely:-

- The importer shall be responsible for the quality, efficacy and safety of all the therapeutic goods manufactured and sold by him.
- He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) except those exempted under the said Act.
- He shall immediately recall the defected therapeutic goods within 15 days after intimation to him and report the compliance to the Authority.
- He shall be responsible to withdraw the unsafe therapeutic goods from the market if so declared by the Authority. He shall also report adverse affect reports, (if any), to the Authority within 15 days period and notify focal person for such reporting.
- Any other relevant condition imposed by the Authority in future.
- This certificate shall not be valid after the date notified by the Authority through official gazette.
- Certificate of enlistment shall be surrendered to the Authority within 7 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

Dated: 21-12-2021

  
(AYYAZ AHMAD)  
Secretary, Enlistment Evaluation Committee  
Division of Health and OTC,  
Drug Regulatory Authority of Pakistan





F.No. 10-17/2021-DD(H&OTC)(M-101)  
DIVISION OF HEALTH & OTC PRODUCTS  
DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-7

[(See Rule 7(17))]

PROVISIONAL CERTIFICATE FOR ENLISTMENT OF PRODUCTS

Following products of M/s Nature's Line Pvt Ltd., 283-B, Block Johar Town, Lahore, agent of M/s Bomuca International Corporation, 9375, Custom House Plz., Suite F, San Diego, California, USA (Principal Manufacturer: M/s Captek Softgel International Inc., 2710, Progress Street, Vista, CA 92081, USA (Enl. No.01250) are manufactured at the mentioned site are enlisted [as approved in 101<sup>st</sup> meeting of EEC held on 23<sup>rd</sup> December, 2021].

E.No	Products Name and composition	Common Name	Recommended Use	Pack Size	Maximum Retail Price
012501010031	<b>Nature's Line's</b> <b>Vivioptal Softgel Multi</b> Each Softgel capsule contains: Vitamin A (as Retinol Palmitate) (USP)....5000IU Cholecalciferol (USP).....400IU Vitamin E (as d-α tocopherol) (USP)...10mg Vitamin B1 as Thiamin mononitrate (USP).....5mg Riboflavin (USP).....3mg Vitamin B6 (as Pyridoxine HCl) (USP).....6.08mg Folic Acid (USP).....400 mcg Biotin (USP).....50 mcg Adenosine Triphosphate Disodium (USP).....150 mcg Cyanocobalamin (USP).....3 mcg Niacinamide (USP).....25mg Conjugated Linoleic Acid 80% (USP)...40 mg Rutin (USP).....20 mg d-Calcium Pantothenate (USP) .....10 mg Orotic Acid (USP).....30 mg Inositol (USP) .....30 mg L-Lysine HCL (USP).....25 mg Calcium Ascorbate Dihydrate (USP)...72.62mg Choline as Choline Bitartrate (USP).....20.75 mg Calcium (as Dicalcium Phosphate Anhydrous) (USP).....11.1mg Copper (as Copper Sulfate Pentahydrate) (USP).....178mcg Manganese (as Manganese Sulfate Monohydrate) (USP).....162mcg Molybdenum (as Sodium Molybdate) (USP)...37mcg Zinc (as Zinc Oxide) (USP).....401mcg Potassium (as Potassium Chloride) (USP)...3.58 mg Iron (as Ferrous Fumarate) (USP).....3.7 mg Magnesium (as Magnesium Glycinate) (USP)...5mg Lecithin (USP).....60 mg	Vitamin A Vitamin D3 Vitamin E Vitamin B1 Vitamin B2 Vitamin B6 Folic Acid Biotin Adenosine Vitamin B12 Niacinamide Conjugated Linoleic Acid Rutin Calcium Pantothenate Orotic Acid Inositol L-Lysine Calcium Choline Calcium Copper Manganese Molybdenum Zinc Potassium Iron Magnesium Lecithin	Supplements for maintenance of good health.	30's	".."
012501010032	<b>Nature's Line's</b> <b>Vivioptal Softgel Active</b> Each Softgel capsule contains:- Calcium Ascorbate dihydrate (USP)... 145.24mg Cholecalciferol (USP).....220IU d-α Tocopherol (USP).....11.9mg Thiamin mononitrate (USP).....0.986mg Riboflavin (USP).....1.3 mg Niacinamide (USP).... 15mg Pyridoxin HCL (USP)..... 2.43mg Folic Acid (USP).....300mcg Cyanocobalamin (USP)... 3 mcg Biotin (USP).... 50 mcg d-Calcium Pantothenate (USP).....10.87mg	Vitamin C Vitamin D3 Vitamin E Vitamin B1 Vitamin B2 Niacinamide Vitamin B6 Folic Acid Vitamin B12 Biotin Pantothenic	Supplements for maintenance of good health.	30's	".."



	Inositol (USP)... 30 mg Lecithin (USP)... 60 mg Rutin (USP)... 20 mg Choline bitartrate (USP)... 120.48mg L-Lysine HCL (USP)... 31.23mg L-Cysteine Monohydrate (USP)... 28.99mg Zinc as Zinc Oxide (USP)... 0.5 mg Potassium as Potassium Sulfate (USP)... 3.5 mg Magnesium as Magnesium Oxide (USP)... 40 mg Selenium as L-Selenomethionine (USP)... 10 mcg Sodium Molybdate (USP)... 25 mcg Manganese as Manganese sulfate (USP)... 0.5 mg Chromium as Chromium Yeast (USP)... 25 mcg Copper as Cupric Oxide (USP)... 0.5 mg Betatene (USP)... 0.75 mg Lutein (USP)... 1 mg Zeaxanthin (USP)... 60 mcg Omega 3 Fatty Acids (USP)... 100 mg EPA (Eicosapentaenoic Acid) (USP)... 59.94 mg DHA (Docosahexaenoic Acid) (USP) ... 39.96 mg Ginseng Extract (USP)... 40 mg	Acid Inositol Lecithin Rutin Choline Lysine Cysteine Zinc Potassium Magnesium Selenium Molybdenum Manganese Chromium Copper Betatene Lutein Zeaxanthin Omega-3 EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid) Korean Ginseng			
012501010033	<b>Nature's Line's</b> <b>Vivioptal Softgel Women</b> Each Softgel capsule contains:- Beta-Carotene (USP)... 315 mcg Ascorbic Acid (USP)... 37.5 mg Calcium Carbonate (USP)... 40 mg Cholecalciferol (USP)... 20 mcg d-α tocopherol (USP)... 35.5 mg Thiamin (USP)... 1 mcg Riboflavin (USP)... 1.5 mg Niacinamide (USP)... 15 mg Pyridoxine HCL (USP)... 5 mg Folic Acid (USP)... 667 mcg DFE (400 mcg) Cyanocobalamin (USP)... 20 mcg Biotin (USP)... 200 mcg d-Calcium Pantothenate (USP)... 9.2 mg Magnesium Oxide (USP)... 40 mg Zinc Oxide (USP)... 8 mg Selenium (USP)... 80 mcg Lentinus edodes (fruit body) (Shiitake mushroom) (USP)... 5 mg CoQ10 (USP)... 15 mg Curcuma Longa (root) (USP)... 50 mg Fish Oil (USP)... 150 mg	Vitamin A Vitamin C Calcium Vitamin D Vitamin E Vitamin B1 Vitamin B2 Niacinamide Vitamin B6 Folate Vitamin B12 Biotin Pantothenic Acid Magnesium Zinc Selenium Shiitake mushroom CoQ10 Turmeric Root Powder Fish Oil	Supplements for maintenance of good health.	30's	" "
012501010034	<b>Nature's Line's</b> <b>Vivioptal Softgel Protect</b> Each Softgel capsule contains:- Retinol Palmitate (USP)... 545mcg Cholecalciferol (USP)... 10 mcg d-α Tocopherol (USP)... 20.13 mg (30 IU) Thiamin (USP)... 220 mcg Pyridoxine HCL (USP)... 5 mg Cyanocobalamin (USP)... 12 mcg Biotin (USP)... 27.7 mcg Zinc Oxide (USP)... 10 mg Selenium Yeast (USP)... 80 mcg Lycopene (USP)... 5 mg L-Arginine HCL (USP)... 15 mg L-Lysine HCL (USP)... 15 mg CoQ10 (USP)... 20 mg	Vitamin A Vitamin D Vitamin E Vitamin B1 Vitamin B6 Vitamin B12 Biotin Zinc Selenium Lycopene L-Arginine L-Lysine CoQ10	Supplements for maintenance of good health.	30's	" "



	Vitis Vinifera (Grape Powder) (Fruit) (USP)...50 mg Paullinia Cupana (Guarana Powder) (Seed)...100 mg	Grape Powder Guarana Powder			
012501010035	Nature's Line's PreCarb + Capsule Each Capsule contains:- White Kidney Bean Extract (USP).... 600mg Chromium (USP).....32mcg Calcium Carbonate (USP).....119mg	White Kidney Bean Extract Chromium Calcium	Supplements for maintenance of good health.	36's	" "

#### Conditions for Enlistment:

- The product(s) shall be tested for microbial contamination and it is verified that these products does not contain any type of pathogenic microbial contamination. Provided that disinfectants and homeopathic medicines containing 50% or above concentration of ethanol shall be exempted from such microbial testing.
- The content the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.
- The product shall not contain any toxic or dangerous materials which are injurious to health.
- The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.
- The products shall remain safe, effective and retain its quality during the whole shelf life.
- The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI) of 2012.
- The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.
- The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.
- The manufacturer/ importer shall be responsible for all the liabilities or damage occurred due to usage of enlisted products.
- The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.
- Label claim of prohibited diseases shall not be made in any case, as required under the rules.
- Maximum Retail Price (MRP) shall be as per policy finalized by the Authority.
- This certificate shall not be valid after the date notified by the Authority through official gazette.
- Certificate of enlistment shall be surrendered to the Authority within 7 days if it is suspended, revoked, becomes invalid or its holder winds up his business.
- Recommended (label claim of manufacturer) conditions for use as per standard package insert or leaflet shall be reviewed by the Authority which shall be part of finished product label.
- Shelf life of alternative medicines and health products shall be upto two years provided liquid preparations containing vitamins shall have shelf life upto eighteen months.
- Finished alternative medicines and health products shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form.

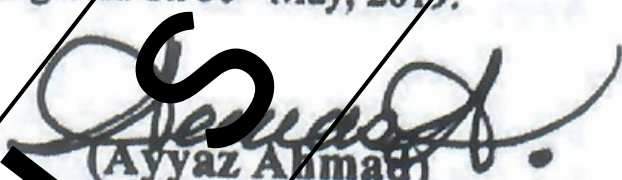


r) Product enlistment holder has undertaken to change the brand name, if it resembles with the already registered products.

(1) Finished alternative medicines and health products shall conform to the guidelines described in the specifications monographs prescribed in the relevant category and dosage form, as per EEC decision (14<sup>th</sup> meeting held on 31<sup>st</sup> August, 2016).

(2) The manufacturer will be responsible for immediate submission of copies of Method of Testing of finished product to the Division of Health & OTC, Drug Regulatory Authority of Pakistan and all Provincial Testing Laboratories, Health Department of all Provincial Government as per decision of the EEC in its 62<sup>nd</sup> meeting held on 30<sup>th</sup> May, 2019.

Dated 28-12-2021

  
(Ayyaz Ahmad)  
Secretary, Enlistment Evaluation Committee

Not For Use