

## Minutes of the 10th Meeting of EEC held on 29-04-2016

No. F. 10-04/2016-DDC (Health & OTC)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
**DRUG REGULATORY AUTHORITY OF PAKISTAN**  
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Islamabad, the 29<sup>th</sup> April, 2016

### MINUTES OF THE 10<sup>TH</sup> MEETING OF ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

**10<sup>th</sup>** Meeting of the Enlistment Evaluation Committee (EEC), constituted under Rules 7 of the Alternative Medicines and Health Products (Enlistment) Rules, 2014, was held in the office of the Chairman of the Committee on **29<sup>th</sup> April, 2016**. Meeting of Committee was attended by the following:-

S. #.	Name & Designation	Position in the Committee
1.	<b>Abdul Samad Khan,</b> Director Health & OTC	Ex-Officio Chairman
2.	<b>Abdul Sattar Sohrani,</b> Deputy Drug Controller Health & OTC	Ex-Officio Member / Secretary
3.	<b>Homeopathic Dr. Muhammad Tariq Khan,</b> Assistant Professor, Department College of Pharmacy, Margalla Institute of Health Sciences, Rawalpindi.	Expert Member
4.	<b>Hafiz Muhammad Asif,</b> Assistant Professor Faculty of Health and medical Sciences Department of Eastern Medicines and Surgery, University of Poonch (Rawala Kot), AJ&K.	Expert Member
5.	<b>Dr. Lajbar Khan,</b> Ex-Chief Scientific Officer, Medicinal Botanic Centre, PCSIR Laboratories Complex, Peshawar.	Expert Member
6.	<b>Dr. Farnaz Malik,</b> Chief, DC & TMD, NIH	Ex-Officio Member <b>-Not Present-</b>
7.	<b>Dr. Amjad Ali,</b> Chief, Nutrition Division, NIH	Ex-Officio Member
8.	<b>Mr. Akhtar Abbas,</b> Deputy Director (PER Division)	Observer

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**ITEM NO. 1.** Meeting started with recitation of the Holy Quran and Darud on the Prophet (PBUH). Secretary of the Committee presented agenda of the meeting and following decisions were made by the Committee.

### **ITEM NO. 2. GRANT OF ENLISTMENT CERTIFICATE TO THE MANUFACTURERS**

Enlistment Evaluation Committee (EEC) examined and discussed the record / panel inspection reports of the following firms on the basis of recommendations of the panel of inspectors for the grant of enlistment certificates for manufacturing authorization.

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	<b>M/s. Z-JANS Pharmaceuticals (Pvt.) Ltd.</b> , 148-A, Hayatabad Industrial Estate, Peshawar.	1. Tablet 2. Capsule 3. Sachet 4. Ointment/ Cream 5. Topical liquids
2.	<b>M/s. Rochdale Homoeo Pharma</b> (Veterinary), 43-B, Small Industrial Estate, Sahiwal.	1. Oral liquid (Homoeopathic / Veterinary) 2. Oral powder (Homoeopathic / Veterinary)
3.	<b>M/s Helix Pharma Pvt Ltd.</b> , A-58/B, S.I.T.E, Manghopir Road, Karachi	1. Tablet 2. Capsule 3. Oral liquid
4.	<b>M/s Best Laboratories Pakistan</b> , Plot No.17, Ahbab Colony Road, Canal View Phase-II, Lahore.	1. Tablet 2. Oral liquid 3. Sachet 4. Capsule
5.	<b>M/s Phar-Man Services</b> , Plot No.226, Sector 27, Korangi Industrial Area, Karachi.	1. Homoeopathic Drops
6.	<b>M/s Cosmo Pharma International (Pvt) Ltd.</b> , Plot No.883, Block-2, Azizabad Bangoria Town, Industrial Area, FB Area, Karachi.	1. Oral liquid 2. Tablet 3. Sachet 4. Capsule 5. Cream/ Ointment It was also decided that the applicant firm can manufacture either Homoeopathic medicine or Nutraceutical and Herbal products but homoeopathic and Nutraceutical could not be manufactured in the same sections. Written option will be obtained from the applicant.
7.	<b>M/s Alpha Nutraceutical Research Laboratories</b> , 21/S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	1. Oral liquid 2. Tablet 3. Capsule 4. Sachet 5. Cream/ Ointment

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8.	<b>M/s Rax Laboratories (Homoeopathic),</b> 14 Allama Iqbal Road, Lahore.	<b>Homoeopathic Sections: -</b> 1. Oral liquid 2. Tablet 3. Capsule 4. Semisolid (Ointment/ Cream)
9.	<b>M/s Nutrasource International,</b> D-237, SITE, Karachi.	1. Oral liquid 2. Liquid suspension
10.	<b>M/s Zaiam Pharma Nutraceuticals &amp; Cam Division,</b> 4-B, Industrial Estate, Multan.	1. Oral liquid 2. Tablet 3. Sachet 4. Topical
11.	<b>M/s. Ammer Labs (Pvt.) Ltd.,</b> 60-61/C Small Industrial Estate, Sahiwal.	1. Oral liquid (Unani) 2. Oral liquid (Nutraceuticals) 3. Tablet 4. Dry Powder Sachet 5. Topical Semisolid (Cream/ ointment) 6. Capsule
12.	<b>M/s Meal Neutricia Nutraceutical,</b> 32-B, Industrial Estate, Hayatabad, Peshawar.	1. Tablet 2. Capsule 3. Oral liquid (Syrup)
13.	<b>M/s SHMZ International,</b> 101-Sunder Industrial Estate, Lahore.	1. Tablet 2. Sachet 3. Oral liquid (Syrup) 4. Capsule

### 2. INSPECTION REPORT NOT RECOMMENDED BY THE PANEL:-

1.	<b>M/s. Nutrimac Laboratories,</b> 5-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	01-04-2016	01. Ms. Aisha Irfan, FID, DRAP, Lahore.  02. Syed Zia Hussain, FID, DRAP, Lahore.	Not Good	Committee rejected the application due to the reasons given in the Inspection Report by the panel.
2.	<b>M/s Botanica Herbal Laboratories,</b> Imtiaz Market Main Lakho Road, Chakra, Rawalpindi.	28-03-2016	01. Mr. Naveed Anwer, PID/ Drugs Controller, Rawalpindi.  02. Mr. Khalid Mehmood, FID, DRAP, Islamabad.	Not Good	Committee deferred the case for Re-inspection by a Panel of Inspector.

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### **ITEM NO. 3. GRANT OF ENLISTMENT CERTIFICATES TO IMPORTERS AS AN AGENT OF PRINCIPLE MANUFACTURER.**

**The Enlistment Evaluation Committee considered the applications/ record and evaluated the case of enlistment of the following firms and granted approval for Enlistment Certificates on Form-6**

#### **(A) Application for Enlistment as agent of abroad Principal Manufacturer meeting the prescribed criteria**

1. **M/s Herbal Valley**, 69 Chanab Block, Allama Iqbal Town, Lahore. As agent **M/s Health Genesis Corporation**, 13165 NW 47th Ave, Opa-Locka, Florida. 33054-4309, **USA**.
2. **M/s Opal Laboratories (Pvt.) Ltd.**, LC-41, LITE, Landhi, Karachi. As agent of **M/s Turkuaz Saglik Himetleri Medikal Temizlik Kimyasal Urunler San.ve Tic. Ltd. Sti.** Yakuplu Mah. Beysan San. Sitesi Birlik Cad. No: 34 Beylikduzu / **ISTANBUL**.
3. **M/s Bismillah Traders**, Quanchi More, Lahore Road, Sargodha. As agent of **M/s PT. Univetama Dinamika**, Jl. Balap Sepeda No. 61 GH Rawamangun Jakarta 13220, **INDONESIA**.
4. **M/s Bismillah Traders**, Quanchi More, Lahore Road, Sargodha. As agent of **M/s Shijiazhuang ZDHF Stock-Raising Co. Ltd**, No.260-1, Heping East Road, Shijiazhuang, Hebei province, **CHINA**.
5. **M/s Otsuka Pakistan Limited**, 30-B, S.M.C.H. Society, Near Masjid Maulana Roomi, Karachi. As agent of **M/s PT. Otsuka Indonesia**, Jl. Sumber Waras No. 25, Lawang, Malang 65216, **INDONESIA**.
6. **M/s Rana Shaukat Ali**, P-130/6, Street # 06, Fatehabad-East Satyana Road, Faisalabad. As agent of **M/s Guangdong Yanling Sheng Life Technology Co., Ltd.**, 1 She Town, Guangzhou (Meizhou) Industrial Transfer Park Area B Meizhou city, **CHINA**.
7. **M/s Mind Fire Media**, 1<sup>st</sup> Floor, P/130, Kohinoor City, Jarranwala Road, Faisalabad. As agent of **M/s Lysi hf**, Fiskisloo 5-9, 101 Reykjavik, **ICELAND**.
8. **M/s A.S.M Pharma**, 47-Basement, Al-Miraj Arcade, Chouburji, Lahore. As agent of **M/s Saudi Pharmaceutical Industries**, P.O. Box-355127, Riyadh-11383, **Kingdom of Saudi Arabia**.

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9. **M/s Care Marketing**, 173 (2) Block G, Model Town, Lahore. As agent of **M/s Chung Yu Biotechnology Co., Ltd**, No.18, Lane 852, Tucheng Road, Dali District, Taichung City, 41275, **TAIWAN**.
10. **M/s Novartis Pharma (Pakistan) Limited**, 15 West Wharf, Karachi. As agent of **M/s Probiotics International Limited**, Lopen Head South Petherton Somerest TA13 5JH, **United Kingdom**.
11. **M/s ATCO Healthcare (Pvt.) Ltd.**, B-18, S.I.T.E., Karachi. As agent of **M/s Rohto-Mentholatum Australasia Pty Ltd.**, 12-16 Janine Street, Scoresby, Victoria 3179, **AUSTRALIA**.
12. **M/s Dr. Salim Ahmed & Co (Homoeopathic)**. 310 Hashoo Centre, Abdullah Haroon Road, Karachi. As agent of **M/s Tegor Laboratories, S.L.**, Poligono Industrial Ugaldeuren, 1, Zamudio, 48170, Vizcaya, **SPAIN**.
13. **M/s Dr. Salim Ahmed & Co (Homoeopathic)**. 310 Hashoo Centre, Abdullah Haroon Road, Karachi. As agent of **M/s Dr. Reckeweg & Co. GmbH**, Berliner Ring 32, 64625 Bensheim, **GERMANY**.
14. **M/s Route2Health (Pvt.), Ltd.**, 229-Sundar Industrial Estate, Raiwind Road, Lahore. As agent of **M/s Engelhard Arzneimittel GmbH & Co. KG**, Herzbergstr. 3. 61138 Niederdorfelden. **GERMANY**.
15. **M/s Orient Traders International**, CM-10, Block A, Kazimabad, Model Colony, Karachi. As agent of **M/s Olmix SA**, Z.A. du Haut du Bois 56580 Brehan- **FRANCE**.
16. **M/s Vet Line International**, 55/5, First Floor, Main Shadman Market, Lahore. As agent of **M/s Miavit GmbH**, Robert Bosch Str. 349632 Essen (Oldb.), **GERMANY**.

### **Decision**

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6. It was also decided that product specific free sale certificates shall be required for the Importers who want to import from the principal having multiple agreements with the Pakistani Importers. Only one similar formulation could be enlisted into Pakistan for a particular product by any of the agent.

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### **B. Application For Enlistment As Agent Of Abroad Principal Manufacturer Meeting The Prescribed Criteria**

1. **M/s Kaap Pharmaceuticals (Pvt.) Ltd.**, 18-KM, Ferozepur Road, Lahore.  
(Agent of **M/s SIRIO Pharma. Co. Ltd.**, No. 83, Taishan Road. Shantou, Guangdong, CHINA 515041)

#### **Back ground:**

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm and decided to defer the application for further evaluation because firm has applied for the product VitaminD3 200000IU which does not come under the definition of Food Supplements.

Now the firm has submitted that they withdraw from the product containing Vitamin D3 200,000IU. They have requested to enlist the firm as importer for the remaining products.

#### **Decision:**

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6. It was also decided that product specific free sale certificates shall be required for the Importers who want to import from the principal having multiple agreements with the Pakistani Importers. Only one similar formulation could be enlisted into Pakistan for a particular product by any of the agent.

2. **M/s Atco Healthcare (Pvt.) Ltd.**, B-18, S.I.T.E., Karachi.  
(Agent of **M/s Rohto Mentholatum Co., Ltd.**, No. 16 VSIP, Street 5, Vietnam Singapore Industrial Park, Thuan an Town, Binh Duong Province, VIETNAM)

#### **Decision of 8<sup>th</sup> Meeting of EEC:**

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm and required verifications from the drug control organization in the country of origin because investments certificates must be verified by the regulators in the country of origin.

Now the Ministry of Health have certified that Rohto-Mentholatum (Vietnam) Company Ltd., No. 16 VSIP, Street 5, Vietnam Singapore Industrial Park, Thuan an Town, Binh Duong Province, VIETNAM is in the field of practice of finished medicine not containing antibiotic b-Lactam in the dosage form: eye drops cream and ointment. This certification is valid upto 21-07-2015.

#### **Decision:**

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6, subject to validation of certification from the Ministry of Health Vietnam. The earlier certification has expired.

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### **C-1. Applications having certain deficiencies.**

1. **M/s Prism Health Pakistan**, 705-706 Anum Blessings, Block 7/8 KCHSU, Karachi. As agent of **M/s Probiotics International Limited (PIL)**, Lopen Head Somerest, TA13 5JH, **United Kingdom**. (Firm registration and partnership deed or Form-29).
2. **M/s Filix Pharmaceuticals (Pvt.) Ltd.**, Plot No. 4-B, Main Road RCCI, Rawat, Rawalpindi. As agent of **M/s Biotron Laboratories, Inc.** 750 North 1250 West Centerville, UT 84014, **USA**. (FDA registration required).
3. **M/s A.S.M Pharma**, 47-Basement, Al-Miraj Arcade, Chouburji, Lahore. As agent of **M/s Tav Veterinaria S.L. C/ Industria 51-53 Sant Marti de Centelles, BARCELONA**. (Site Master File is not available).
4. **M/s Nature's Edge**, Plot No. 17, Street No. E-3, RCCI, Industrial Estate, Rawat, Rawalpindi. As agent of **M/s Minh Dung Veterinary – Aquaculture Medicine Company Ltd.**, 47/4B Khanh Hoi, Tan Phuoc Khanh, Tan Uyen, Binh Duong, **VIETNAM**. (Drug Sale License and certified copy of inspection report or inspection based GMP certificate)
5. **M/s Himont Laboratories (Pvt.) Ltd.**, 17 – Km, Ferozpur Road, Lahore. As agent of **M/s Matxin Laboratories Pvt. Ltd.**, Plot No. M-11, 7<sup>th</sup> Cross, 1<sup>st</sup> Stage, Peenya Industrial Area, Bangalore-560058, **INDIA**. (Attested Agency Agreement (original), Drug Sale License and Form-29)
6. **M/s Genetics Healthcare**, 537-A, Sunder Industrial Estate, Lahore. As agent of **M/s Gnosis Bioresearch S.A.** Via Lischedi 6592 S. Antonino (CH), **SWITZERLAND**. (M/s Gnosis Bioresearch S.A. is API manufacturer while Vitaquest is manufacturer of tablet. So either Free sale certificate of the product or agency agreement with the principal manufacturer is required).
7. **M/s Biotron Altair Pakistan**, Plot No. 80, First Floor, Street No. 24, Korangi Industrial Area, Karachi. As agent of **M/s Pharmcross. Co., Ltd.**, 50, Geodudanji 2-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Republic of **KOREA**. (Firm Registration and NTN certificate).

### **Decision:**

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and deferred the cases for completion to be placed in the forthcoming Meeting of EEC.

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### (C-2)

1. **M/s MPC Health & Food**, SF-13, 5<sup>th</sup> Floor, Shahnaz Arcade, Block-3, Behind Naheed Super Market, Main Shaheed-e-Millat Road, Karachi. As agent of **M/s Insto Cosmetics Pvt. Ltd.**, C11/19, 47 to 50, NICE, Satpur, Nashik, Maharashtra, **INDIA- 422 007**.

(i. Agency Agreement not attested. ii. There are observations in the inspection report of Principal Manufacturer like broken glasses, regarding expired control sample disposals, medical checkup of the work personnel and dust & wire gauze. Its reflects that the unit GMP compliance is compromised).

### Decision:

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and rejected the case on the basis of observations in the inspection report which reflect that the GMP compliance of the Principal Manufacturer is compromised.

- D. **M/s. Graton Pharma**, Suit#102, 1<sup>st</sup> Floor, Plaza, Block-09, Clifton 2-Talwar, Karachi, Pakistan, (Agent of **M/s. ESSENTIAL PHARMACEUTICAL, CORP.** 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA)

### Background of the Case

**M/s Graton Pharma** and **M/s Nutralake Healthcare**, filed applications from the same principal manufacturer however import documents like Site Master File, Manufacturing License etc have variable contents in these documents. Site Master File of **M/s. Graton Pharma** and **M/s. Nutralake Healthcare** have same document number QA 205, revision no. 01, same effective date and review date but differing in number of pages and name of principal manufacturer. In the document of **M/s. Nutralake Healthcare Life Saver Solutions, Inc.** has been included as prefix to the **M/s. ESSENTIAL PHARMACEUTICAL, CORP.** in the Site Master File as principal manufacturer same is included as suffixed and prefixed in the Free Sale Certificate and Department of Public Health Food and Drug Branch Registration Certificate.

2. Both the firms have filed these documents as legalized by the Notary Public and attested by the Consulate General of Pakistan at Los Angeles and Embassy of Pakistan at Washington DC. The Site Master File of **M/s. Graton Pharma**, contains signatures purported to be made by the qualified technical personnel as a confidential document. Whereas the Site Master File of the **M/s. Nutralake Healthcare**, does not bear such signature. Agency Agreement of the **M/s. Nutralake Healthcare** has been signed by Mr. Justin Dam on behalf of Life Saver Solutions, Inc. while distribution agreement for USA Health Supply, Inc. has been signed by Dr. Bruce Y Lin as CEO of **M/s. ESSENTIAL PHARMACEUTICAL, CORP.**



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### 3. Decision of 5<sup>th</sup> Meeting of EEC:-

“The Committee after going through the variability in the import documents of one principal manufacturer i.e. M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA presented by the two different agents i.e. (I). M/s. Graton Pharma, Suit#102, 1<sup>st</sup> Floor, The Plaza, Block-09, Clifton 2-Talwar, Karachi, Pakistan and (II). M/s. Nutralake Healthcare, Plot # C-105, KDA Scheme # 01, Off Karsaz Road, Karachi-Pakistan. Both have presented as attested by the Notary Public and Counter Signed by the Embassy or Consulate of Pakistan. It is concluded that after such verification there exist gray areas which are being manipulated and miss used because one manufacturer registered with same registration No could not have two different particulars. This tantamount that misrepresentation could exist even after present mechanism of attestations. The committee made following decisions.”

- (i). Counter verification mechanism by any means and mechanism should be evolved for validation of attested documents.
- (ii). Both the firms who presented documents shall be asked to explain their position and their reply shall be placed before the committee for examination and if required firms shall be called upon in the forthcoming meeting of the EEC.
- (iii). Cases of importer included in the agenda item III are deferred for further evaluation.

4. Accordingly both the firms **M/s Nutralake Healthcare** and **M/s Graton Pharma** were asked to explain their positions and submit the certified documents. The Principal manufacturers were also contacted through email provided by the both firms. The manufacturers endorsed that both the firms are our clients. It was clarified that principal manufactures Essential Pharmaceutical Corporation is principal manufacture of the products of Life Saver Solutions with health wise logo and we confirm that Nutralake Healthcare of Plot # C-105, KDA Scheme # 01, Off Karsaz Road, Karachi-Pakistan is our exclusive/ sold distribution for dietary supplements for the Territory of Pakistan and Afghanistan.

We are in contract manufacturing agreement with USA Health Supply, Inc. of 3065 S. Jones Blvd Suite # 100, Las Vegas, NV 89164 U.S.A for their products under Private Label with U.S Health Supply logo for their worldwide distribution. USA Health Supply Inc. has appointed **Graton Pharma** with an office at Suite # 102, 1<sup>st</sup> Floor, The Plaza, Block=09, Clifton 2-Talwar, Karachi Pakistan as an exclusive distributor for US Healthy supply dietary supplements.

We **Essential Pharmaceutical Corp**, are pleased to inform that they are Registered manufacturer with the State of California (Business License # C56119 City of Pomona Account # 00095335) and are also registered with U.S FDA (FDA Registration # 17683297144).

Our operations are fully in accordance with California State laws, FDA regulations, “Public Health Security and Bioterrorism Preparedness and Response Act of 2002” for dietary

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supplements. There is no such regulation in our knowledge that would prohibit a certified manufacturer like us from any sort of contract manufacturing / Private label.

5. Mr. Mac Choudhary attended the office of the Director (Health & OTC Division) and he verified his signatures as well as signatures of the Dr. Bruce Lin, CEO, **M/s Essential Pharma**. He also countersigned the documents in the presence of Director and DDC (Health & OTC Division) on 10<sup>th</sup> February, 2016.

6. **M/s Graton Pharma**, submitted that they are also distributor of **M/s Essential Pharmaceutical Corp**, who is legal manufacturer. USA Health Supply Inc. is supplier/ importer and **M/s Graton Pharma**, Karachi has been declared exclusive distributor in Pakistan for their products. They have also undertaken to submit free sale certificate dully issued by the FDA for their products.

### **Decision of 8<sup>th</sup> Meeting of EEC:**

The Enlistment Evaluation Committee considered the applications/ record and previous proceeding of the Committee and decided:

- i) To grant enlistment certificates to M/s Nutralake Healthcare on Form-6 based on verification by the Principal Manufacturer.
- ii) Application of M/s Graton Pharma was deferred because overseas as well as local contract manufacturing has not been started. Moreover applicant is required to submit exclusive product specific agreement with the Principal Manufacturer along-with free sale certificates for the applied products.

Now the firm has submitted free sale dully legalized and attested by the Embassy of Pakistan, Washington, DC for 32 products being manufactured by the **M/s Essential Pharmaceutical Corporation**.

### **Decision:**

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6. This approval shall be valid for the products whose Free Sale Certificate has been submitted by the applicant. Only one similar formulation could be enlisted into Pakistan for a particular product by any of the agent.

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### ITEM NO. 4: - MISCELLANEOUS CASES:-

(i) Product Applications for the Grant of Enlistment.

Enlistment Evaluation Committee has already constituted sub-committee for evaluation of products applications. Product Enlistment applications are placed as **Annex-A**.

**Decision:-**

The Enlistment Evaluation Committee referred the applications to the Sub-Committee for the evaluation.

(ii) CHANGE IN FORMULATION

1. **a) M/s. Abbott Laboratories (Pakistan) Limited**, located at the address **Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi-Pakistan** products are manufactured by **M/s. Abbott Laboratories B.V. Rietweg 21, city 8041 AJ Zwolle province 8000 AP Zowlle, Netherlands**, was issued Enlistment Certificate. Now they have identified some mistakes which were originated in their own application. They have filed application on Form-5 for necessary corrections.

Enlistment No.	Brand Name	Incorrect composition	Correct composition
007.0001	Ensure Powder (Chocolate Flavor)	<b>Per 100gm:</b> Energy INT: 431Kcal, Protein: 15.90g, Fat:14g, Linoleic Acid: 2.7g, Carbohydrate: 58.50g, FOS: 3.60g, Moisture (water): 5g, Vitamin A: 1170IU, Vitamin D3: 95IU, Vitamin E: 11IU, Vitamin K1: 18mcg, Vitamin C: 68mg, Folic Acid: 200mcg, Vitamin B1: 0.72mg, Vitamin B2: 0.80mg, Vitamin B6: 1mg, Vitamin B12: 3.1mcg, Niacin: 10mg, Pantothenic acid: 5mg, Biotin: 150mcg, Choline: 136mcg, Sodium: 360mg, Potassium: 670mg, Chloride: 610mg, Calcium: 280mg, Phosphorus: 230mg, Magnesium: 90mg,	<b>Per 100gm:</b> Energy INT: 431Kcal, Protein: 15.90g, Fat:14g, Linoleic Acid: 2.7g, Carbohydrate: 58.50g, FOS: 3.60g, Moisture (water): 5g, Vitamin A: 1170IU, Vitamin D3: 95IU, Vitamin E: 11IU, Vitamin K1: 18mcg, Vitamin C: 68mg, Folic Acid: 200mcg, Vitamin B1: 0.72mg, Vitamin B2: 0.80mg, Vitamin B6: 1mg, Vitamin B12: 3.1mcg, Niacin: 10mg, Pantothenic acid: 5mg, Biotin: 150mcg, Choline: 136mg, Sodium: 360mg, Potassium: 860mg, Chloride: 610mg, Calcium: 280mg, Phosphorus: 230mg, Magnesium: 105mg,

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		Iron: 4.4mg, Zinc: 5.4mg, Manganese: 1.2mg, Copper: 0.52mg, Iodine: 34mcg, Selenium: 19mcg, Chromium:20mcg, Molybdenum: 38mcg	Iron: 4.4mg, Zinc: 5.4mg, Manganese: 1.2mg, Copper: 0.52mg, Iodine: 34mcg, Selenium: 19mcg, Chromium:20mcg, Molybdenum: 38mcg
007.0002	<b>Ensure Powder (Strawberry Flavor)</b>	<b>Per 100gm:</b> Energy INT: 431Kcal, Protein: 15.90g, Fat:14g, Linoleic Acid: 2.7g, Carbohydrate: 58.50g, FOS: 3.60g, Moisture (water): 5g, Vitamin A: 1170IU, Vitamin D3: 95IU, Vitamin E: 11IU, Vitamin K1: 18mcg, Vitamin C: 68mg, Folic Acid: 200mcg, Vitamin B1: 0.72mg, Vitamin B2: 0.80mg, Vitamin B6: 1mg, Vitamin B12: 3.1mcg, Niacin: 10mg, Pantothenic acid: 5mg, Biotin: 150mcg, <b>Choline: 136mcg,</b> Sodium: 360mg, Potassium: 670mg, Chloride: 610mg, Calcium: 280mg, Phosphorus: 230mg, Magnesium: 90mg, Iron: 4.4mg, Zinc: 5.4mg, Manganese: 1.2mg, Copper: 0.52mg, Iodine: 34mcg, Selenium: 19mcg, Chromium:20mcg, Molybdenum: 38mcg	<b>Per 100gm:</b> Energy INT: 431Kcal, Protein: 15.90g, Fat:14g, Linoleic Acid: 2.7g, Carbohydrate: 58.50g, FOS: 3.60g, Moisture (water): 5g, Vitamin A: 1170IU, Vitamin D3: 95IU, Vitamin E: 11IU, Vitamin K1: 18mcg, Vitamin C: 68mg, Folic Acid: 200mcg, Vitamin B1: 0.72mg, Vitamin B2: 0.80mg, Vitamin B6: 1mg, Vitamin B12: 3.1mcg, Niacin: 10mg, Pantothenic acid: 5mg, Biotin: 150mcg, <b>Choline: 136mg,</b> Sodium: 360mg, Potassium: 670mg, Chloride: 610mg, Calcium: 280mg, Phosphorus: 230mg, Magnesium: 90mg, Iron: 4.4mg, Zinc: 5.4mg, Manganese: 1.2mg, Copper: 0.52mg, Iodine: 34mcg, Selenium: 19mcg, Chromium:20mcg, Molybdenum: 38mcg
007.0003	<b>Ensure Powder (Vanilla Flavor)</b>	<b>Per 100gm:</b> Energy INT: 431Kcal, Protein: 15.90g, Fat:14g, Linoleic Acid: 2.7g, Carbohydrate: 58.50g, FOS: 3.60g, Moisture (water): 5g, Vitamin A: 1170IU,	<b>Per 100gm:</b> Energy INT: 431Kcal, Protein: 15.90g, Fat:14g, Linoleic Acid: 2.7g, Carbohydrate: 58.50g, FOS: 3.60g, Moisture (water): 5g, Vitamin A: 1170IU,

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		<p>Vitamin D3: 95IU,  Vitamin E: 11IU,  Vitamin K1: 18mcg,  Vitamin C: 68mg,  Folic Acid: 200mcg,  Vitamin B1: 0.72mg,  Vitamin B2: 0.80mg,  Vitamin B6: 1mg,  Vitamin B12: 3.1mcg,  Niacin: 10mg,  Pantothenic acid: 5mg,  Biotin: 150mcg,  <b>Choline: 136mcg,</b>  Sodium: 360mg,  Potassium: 670mg,  Chloride: 610mg,  Calcium: 280mg,  Phosphorus: 230mg,  Magnesium: 90mg,  Iron: 4.4mg,  Zinc: 5.4mg,  Manganese: 1.2mg,  Copper: 0.52mg,  Iodine: 34mcg,  Selenium: 19mcg,  Chromium:20mcg,  Molybdenum: 38mcg</p>	<p>Vitamin D3: 95IU,  Vitamin E: 11IU,  Vitamin K1: 18mcg,  Vitamin C: 68mg,  Folic Acid: 200mcg,  Vitamin B1: 0.72mg,  Vitamin B2: 0.80mg,  Vitamin B6: 1mg,  Vitamin B12: 3.1mcg,  Niacin: 10mg,  Pantothenic acid: 5mg,  Biotin: 150mcg,  <b>Choline: 136mg,</b>  Sodium: 360mg,  Potassium: 670mg,  Chloride: 610mg,  Calcium: 280mg,  Phosphorus: 230mg,  Magnesium: 90mg,  Iron: 4.4mg,  Zinc: 5.4mg,  Manganese: 1.2mg,  Copper: 0.52mg,  Iodine: 34mcg,  Selenium: 19mcg,  Chromium:20mcg,  Molybdenum: 38mcg</p>
007.0006	<b>Glucerna RTF</b>	<p><b>Per 250ml:</b>  Energy: 248kcal  Osmolality: 354mOsm/kgH<sub>2</sub>O  Protein (16.9%): 10g/250ml,  Fat (49.3%): 14g,  Carbohydrate (33.8%): 20g,  Dietary fibers: 3.6g,  Water: 212g,  Taurine: 28g,  Carnitine: 20g  Inositol:210g  Vitamin A: 1365g  Vitamin D3: 70g  Vitamin E: 8g  Vitamin K1: 14g  Vitamin C: 28g  Folic Acid: 105g  Vitamin B1: 0.4g  Vitamin B2: 0.45g  Vitamin B6: 0.53g  Vitamin B12: 0.75g  Niacin 4.3g  Pantothenic Acid: 1g  Biotin: 10mg  Choline: 105g  Sodium: 233g  Potassium: 325g  Chloride: 313g  Calcium 175g  Phosphorus: 163g</p>	<p><b>Per 250ml:</b>  Energy: 248kcal  Osmolality: 354mOsm/kgH<sub>2</sub>O  Protein (16.9%): 10g/250ml,  Fat (49.3%): 14g,  Carbohydrate (33.8%): 20g,  Dietary fibers: 3.6g,  Water: 212g,  Taurine:28mg  Carnitine: 20mg  Inositol:210mg  Vitamin A: 1365IU  Vitamin D3: 70IU  Vitamin E: 8IU  Vitamin K1: 14mcg  Vitamin C: 28mg  Folic Acid: 105mcg  Vitamin B1: 0.4mg  Vitamin B2: 0.45mg  Vitamin B6: 0.53mg  Vitamin B12: 0.75mcg  Niacin 4.3mg NE  Pantothenic Acid: 1.9mg  Biotin: 10mcg  Choline: 105mg  Sodium: 233mg  Potassium: 325mg  Chloride: 313mg  Calcium 175mg  Phosphorus: 163mg</p>

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		Magnesium: 50g Iron: 3.3g Zinc: 3.0g Manganese: 0.88g Copper: 350g Iodine: 28g Selenium: 12g Chromium: 18g Molybdenum: 25g	Magnesium: 50mg Iron: 3.3mg Zinc: 3.0mg Manganese: 0.88mg Copper: 350mcg Iodine: 28mcg Selenium: 12mcg Chromium: 18mcg Molybdenum: 25mcg
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- b) **M/s Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi, Pakistan** products are manufactured by **M/s. Abbott Manufacturing Singapore Private Limited** situated at **26 Tuas South Avenue 10, Singapore** was issued Enlistment Certificate. Now they have identified some mistakes which were originated in their own application. They have filed application on Form-5 for necessary corrections.

Enlistment No.	Brand Name	Incorrect composition	Correct composition
009.0001	<b>Pedia Sure (Chocolate Flavor)</b>	Energy: 442 Protein: 13.27g, Fat: 17.41g, Linoleic acid: 3.98g, Linolenic acid: 0.40g, DHA: 19.6g, AA: 6.5g, Carbohydrate: 58.6g, FOS: 1.96g, Taurine: 31.9g Carnitine: 7.52g Inositol: 35.4g Vitamin A: 885g Vitamin D3: 354g Vitamin E: 10.2g Vitamin K1: 26.1g Vitamin C: 44.2g Folic Acid: 111g Vitamin B1: 1.37g Vitamin B2: 0.93g Vitamin B6: 1.15g Vitamin B12: 1.33g Niacin: 6.64g Pantothenic Acid: 3.1g Biotin: 8.8g Choline: 133g Sodium: 168g Potassium: 769g Chloride: 448g Calcium: 425g Phosphorus: 384g Magnesium: 107.1g Iron: 6.99g Zinc: 3.10g Manganese: 0.84g Copper: 0.44g	Energy: 442 k cal Protein: 13.27g, Fat: 17.41g, Linoleic acid: 3.98g, Linolenic acid: 0.40g, DHA: 19.6mg AA: 6.5mg Carbohydrate: 58.6g, FOS: 1.96g, Taurine: 31.9mg Carnitine: 7.52mg Inositol: 35.4mg Vitamin A: 885IU Vitamin D3: 354IU Vitamin E: 10.2IU Vitamin K1: 26.1mcg Vitamin C: 44.2mg Folic Acid: 111mcg Vitamin B1: 1.37mg Vitamin B2: 0.93mg Vitamin B6: 1.15mg Vitamin B12: 1.33mcg Niacin: 6.64mg NE Pantothenic Acid: 3.1mg Biotin: 8.8mcg Choline: 133mg Sodium: 168mg Potassium: 769mg Chloride: 448mg Calcium: 425mg Phosphorus: 384mg Magnesium: 107.1mg Iron: 6.99mg Zinc: 3.10mg Manganese: 0.84mg Copper: 0.44mg

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		Iodine: 42.9g Selenium: 14.2g Chromium: 20.8g Molybdenum: 17.7g	Iodine: 42.9mcg Selenium: 14.2mcg Chromium: 20.8mcg Molybdenum: 17.7mcg
009.0002	<b>Pedia Sure (Vanilla Flavor)</b>	<b>Energy: 463</b> Protein: 13.87g, Fat: 18.19g, Linoleic acid: 4.17g, Linolenic acid: 0.42g, DHA: 20.6g, AA: 6.81g, Carbohydrate: 61.3g, FOS: 2.06g, DHA: 20.6g AA: 6.81g Taurine: 33.3g Carnitine: 7.87g Inositol: 37g Vitamin A: 926g Vitamin D3: 370g Vitamin E: 10.7g Vitamin K1: 27.3g Vitamin C: 46.3g Folic Acid: 116g Vitamin B1: 1.43g Vitamin B2: 0.98g Vitamin B6: 1.21g Vitamin B12: 1.39g Niacin: 6.94g Pantothenic Acid: 3.24g Biotin: 9.3g Choline: 139g Sodium: 176g Potassium: 606g Chloride: 469g Calcium: 444g Phosphorus: 386g Magnesium: 91.7g Iron: 6.48g Zinc: 3.10g Manganese: 0.69g Copper: 0.30g Iodine: 44.9g Selenium: 14.8g Chromium: 13.9g Molybdenum: 18.5g	<b>Energy: 463 kcal</b> Protein: 13.87g, Fat: 18.19g, Linoleic acid: 4.17g, Linolenic acid: 0.42g, DHA: 20.6mg, AA: 6.81mg, Carbohydrate: 61.3g, FOS: 2.06g, DHA: 20.6mg AA: 6.81mg Taurine: 33.3mg Carnitine: 7.87mg Inositol: 37mg Vitamin A: 926IU Vitamin D3: 370IU Vitamin E: 10.7IU Vitamin K1: 27.3mcg Vitamin C: 46.3mg Folic Acid: 116mcg Vitamin B1: 1.43mg Vitamin B2: 0.98mg Vitamin B6: 1.21mg Vitamin B12: 1.39mcg Niacin: 6.94mg NE Pantothenic Acid: 3.24mg Biotin: 9.3mcg Choline: 139mg Sodium: 176mg Potassium: 606mg Chloride: 469mg Calcium: 444mg Phosphorus: 386mg Magnesium: 91.7mg Iron: 6.48mg Zinc: 3.10mg Manganese: 0.69mg Copper: 0.30mg Iodine: 44.9mcg Selenium: 14.8mcg Chromium: 13.9mcg Molybdenum: 18.5mcg
009.0003	<b>Pedia Sure (Strawberry Flavor)</b>	<b>Energy: 463</b> Protein: 13.87g, Fat: 18.19g, Linoleic acid: 4.17g, Linolenic acid: 0.42g, DHA: 20.6g, AA: 6.81g, Carbohydrate: 61.3g, FOS: 2.06g, DHA: 20.6g AA: 6.81g	<b>Energy: 463 kcal</b> Protein: 13.87g, Fat: 18.19g, Linoleic acid: 4.17g, Linolenic acid: 0.42g, DHA: 20.6mg, AA: 6.81mg, Carbohydrate: 61.3g, FOS: 2.06g, DHA: 20.6mg AA: 6.81mg

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		Taurine: 33.3g Carnitine: 7.87g Inositol: 37g Vitamin A: 926g Vitamin D3: 370g Vitamin E: 10.7g Vitamin K1: 27.3g Vitamin C: 46.3g Folic Acid: 116g Vitamin B1: 1.43g Vitamin B2: 0.98g Vitamin B6: 1.21g Vitamin B12: 1.39g Niacin: 6.94g Pantothenic Acid: 3.24g Biotin: 9.3g Choline: 139g Sodium: 176g Potassium: 606g Chloride: 469g Calcium: 444g Phosphorus: 386g Magnesium: 91.7g Iron: 6.48g Zinc: 3.10g Manganese: 0.69g Copper: 0.30g Iodine: 44.9g Selenium: 14.8g Chromium: 13.9g Molybdenum: 18.5g	Taurine: 33.3mg Carnitine: 7.87mg Inositol: 37mg Vitamin A: 926IU Vitamin D3: 370IU Vitamin E: 10.7IU Vitamin K1: 27.3mcg Vitamin C: 46.3mg Folic Acid: 116mcg Vitamin B1: 1.43mg Vitamin B2: 0.98mg Vitamin B6: 1.21mg Vitamin B12: 1.39mcg Niacin: 6.94mg NE Pantothenic Acid: 3.24mg Biotin: 9.3mcg Choline: 139mg Sodium: 176mg Potassium: 606mg Chloride: 469mg Calcium: 444mg Phosphorus: 386mg Magnesium: 91.7mg Iron: 6.48mg Zinc: 3.10mg Manganese: 0.69mg Copper: 0.30mg Iodine: 44.9mcg Selenium: 14.8mcg Chromium: 13.9mcg Molybdenum: 18.5mcg
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### 2. Glorious Laboratories, Islamabad.

Enlistment No.	Brand Name	Typographic Mistake in existing formulation according to Form-7	Correction in Formulation
002.0012	<b>Uniflex Tablet</b>	<b>Each Tablet contains:</b> Glucosamine sulphate (USP)..1000mg Chondroitin sulphate (USP).....200mg MSM (USP).....800mg	<b>Each Tablet contains:</b> Glucosamine sulphate (USP)...500mg Chondroitin sulphate (USP)....150mg Methylsulfonylmethane (MSM) (USP) .....100mg Magnesium Oxide (USP).....125mg Zinc (as zinc sulphate) (USP)...10mg Copper Sulphate (USP).....1mg Hyaluronic acid.....15mg Vitamin D3 (as Cholecalciferol) (USP).....400IU Sodium selenite (USP).....0.12mg USP specification / specification monograph
002.0022	<b>Uth Tablet</b>	<b>Each Tablet Contain:</b> Vitamin A (USP)..... 3500IU Vitamin E (USP).....45IU VitaminD3 (USP).....400IU Vitamin C (USP).....500mg Vitamin K (USP).....10mcg Niacin (USP)..... 20mg	<b>Each Tablet Contain:</b> Vitamin A (USP)..... 3500IU Vitamin E (USP).....45IU VitaminD3 (USP).....400IU Vitamin C (USP).....500mg Vitamin K (USP).....10mcg Niacin (USP)..... 20mg



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		<p>Thiamin (USP).....1.5mg  Riboflavin (USP).....1.7mg  Vitamin B6 (USP).....3mg  Biotin (USP).....30mcg  Pantothenic acid Vit B5(USP).10mg  Calcium Carbonate (USP).....220mg  Phosphorus (as dicalcium phosphate) (USP).....48mg  Iodine(as potassium iodide) (USP).....150mcg  Magnesium Oxide(USP).....100mg  Zinc (as zinc sulphate) (USP)...15mg  Selenium (USP).....20mcg  Copper (as copper sulphate) (USP).....2mg  Manganese Sulphate (USP).....2mg  Potassium Chloride (USP)....100 mg  Boron (USP).....150mcg  Silicon (USP).....2mg  Nickel.....5mcg  Vanadium.....10mcg  Lycopoene.....300mcg</p>	<p>Thiamin (USP).....1.5mg  Riboflavin (USP).....1.7mg  Vitamin B6 (USP).....3mg  Biotin (USP).....30mcg  Pantothenic acid Vit B5(USP).10mg  Calcium Carbonate (USP).....220mg  Phosphorus (as dicalcium phosphate) (USP).....48mg  Iodine(as potassium iodide) (USP).....166mcg  Magnesium Oxide(USP).....100mg  Zinc (as zinc sulphate) (USP)...15mg  Selenium (USP).....20mcg  Copper (as copper sulphate) (USP).....2mg  Manganese Sulphate (USP).....2mg  Potassium Chloride (USP)....100 mg  Boron (USP).....150mcg  Silicon (USP).....2mg</p> <p>USP specification / specification monograph</p>
002.0023	<b>Silinor Tablet</b>	<p>Each Tablet Contain:  Zinc (as zinc sulphate) (USP). ...10mg  Selenium (USP).....25mcg</p>	<p>Each Tablet Contain:  Powdered Milk thistle extract (USP).....300mg  Traxacum officinale (Eur. Ph)..55mg  Betacarotene (USP).....50IU  Vitamin C (USP).....60mg  Zinc (as zinc sulphate) (USP).. 10mg  Selenium (USP).....25mcg</p> <p>USP specification / specification monograph</p>
002.0024	<b>Mom-C Tablet</b>	<p>Each Tablet Contain:  Vitamin E (USP).....30mg  Vitamin C (USP).....90mg  VitaminD3 (USP).....15mcg  Thiamin (USP).....8mg  Riboflavin (USP).....5mg  Zinc (USP).....15mcg  Selenium (USP).....50mcg  Copper (USP).....1000mcg  Magnesium (USP).....60mg</p>	<p>Each Tablet Contain:  Alfalfa extract (API).....150mg  Vitamin A (USP).....20mg  Vitamin E Acetate (50%)(USP).30mg  Vitamin C (USP).....90mg  VitaminD3 (USP).....1200IU  Vitamin B1 (USP).....8mg  Vitamin B6 (USP).....10mg  Vitamin B3 (USP).....20mg  Vitamin B5 (USP).....6mg  Folic Acid (USP).....400mcg  Biotin (USP).....3mcg  Riboflavin (USP).....5mg  Zinc (USP).....10mg  Sodium selenite (USP).....50mcg  Copper sulphate (USP)....1000mcg  Vitamin B12 (USP).....20mcg  Iron (USP).....14mg  Magnesium oxide (USP).....30mg  L-Arginine (USP).....50mg  Myo-Inositol (USP).....50mg  Spirulina (dried) (USP).....90mg</p> <p>USP specification / specification monograph</p>

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002.0025	<b>ALCAREEZE Tablets</b>	Each Tablet Contain: L-carnitine (USP).....750mg Vitamin E (USP).....400IU Zinc (USP).....7.5mg	Each Tablet Contain: L-carnitine (USP).....750mg Vitamin E (USP).....50mg Coenzyme Q-10 (USP).....50mg Zinc (USP).....7.5mg USP specification / specification monograph
002.0028	<b>Fertimax Capsule</b>	Each Capsule Contains: Tribulus Extract (USP).....300mg Ginseng Extract (USP).....200mg Ginko Biloba Extract (USP).....50mg Vitamin C (USP).....15mg Vitamin E (USP).....20mg L-arginine (USP).....10mg Zinc (USP).....15mg Sodium selenite (USP).....0.8mg Emblica extract (IP)..... 1mg	Each Capsule Contains: Tribulus Extract (USP).....100mg Pycnogenol (USP).....40mg Co Enzyme Q10 (USP).....25mg Vitamin C (USP).....15mg Vitamin E (USP).....20mg L-arginine (USP).....200mg Zinc (USP).....15mg Sodium selenite (USP).....0.8mg USP specification / specification monograph
002.0124	<b>Multiday –M Syrup</b>	<b>Each 5 ml contains:</b> Alfalfa extract .....100mg Vitamin A(USP).....2500IU Vitamin E acetate (USP).....25mg Vitamin D(USP).....400IU Vitamin C(USP).....125mg Folic acid(USP).....150mcg Thiamine mononitrate vitB(USP)....15mg Riboflavin (vitB2)(USP).....15mg Pyridoxine HCL(vit B6)(USP).....20mg Nicotinamide (vit B3)(USP).....20mg Cyanocobalamine (vit B12)(USP).....14mcg Zinc(USP).....15mg Selenium (USP).....70mcg	<b>Each 5 ml contains:</b> Vitamin A (USP).....1666iu Vitamin D3 (USP).....400iu Vitamin E (USP).....1mg Vitamin B12 (USP).....3mcg Vitamin C (USP).....50mg Vitamin B1 (USP).....1mg Vitamin B2 (USP).....1mg Vitamin B3 (USP).....5mg Vitamin B6 (USP).....2mg Calcium pantothenate (USP)...5mg Inositol (USP).....5mg Zinc(USP).....5mg Folic Acid (USP).....400mcg Biotin (USP).....1mg Magnesium sulphate (USP)...150mg L-Lysine (USP).....5mg USP specification / specification monograph

### **Decision:**

Changes in formulations for the above mentioned products were approved by the EEC.

3. **M/s Brooklyn Pharmaceuticals**, located at the address **687, Ground Floor, New Abadi Ali Abad, Alla Abad Road, Westridge-III, Rawalpindi - Pakistan** products are manufactured by **M/s. Omana Group LLC, Garden Grove, California, USA**

Enlistment No.	Brand Name & Composition (List of ingredients with strength)	Common Name of ingredients	Recommended use	Pack size	Decision by EEC
1	<b>IMFIT Tablet</b> Each tablet contains: Vitamin A (USP).....5000 IU	Retinyl acetate Ascorbic acid	A complete multivitamin / multi mineral supplement contains key	30 Tab/ bottle	Approved for standard recommend ed use.

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	<p>Vitamin C (USP).....90mg  Vitamin D (USP).....400 IU  Vitamin E (USP).....30 IU  Vitamin K (USP).....25mcg  Thiamin (USP).....2.25mg  Riboflavin (USP).....2.6mg  Niacin (USP).....20mg  Vitamin B6 (USP)... .....3mg  Folic Acid(USP).....400 mcg  Vitamin B12 (USP).....9mcg  Biotin.....45mcg  Pantothenic Acid (USP)....10mg  Calcium (USP).....162mg  Iron (USP).....27mg  Phosphrous (USP).....125mg  Iodine (USP).....150mcg  Magnesium (USP).....100mg  Zinc (USP).....15mg  Selenium (USP).....25mcg  Copper (USP).....2mg  Manganese (USP).....5mg  Chromium (USP).....25mcg  Molybdenum (USP).....25mcg  Chloride (USP).....27.2mg  Potassium (USP).....30mg</p> <p>USP Specifications</p>	<p>cholecalciferol  dl-alpha tecopheryl  Phytonadione  Thiamin  Riboflavin  Niacin  Pyridoxine hydro  Folic Acid  Cyanocobalamin  Biotin  Pantothenic Acid  Calcium  Iron  Phosphate  Potassium iodide  Magnesium  Zinc sulfate  Sodium selenate  Cupric oxide  Manganese sulfate  Chromium  Molybdenum  Chloride  Potassium</p>	<p>nutrients to help  protect heart,  immune system,  eyes, hair &amp; bones.</p>		
2	<p><b>ADJOINT Tablet</b>  <b>2 tablet provide:</b>  Glucosamine HCl (USP)..750mg  Chondroitin sulfate (USP)..50mg  Vitamin C (USP).....30mg  Vitamin E (USP).....60IU  Boron (USP).....1.5mg  Manganese (USP).....2mg  Special blend (USP).....690mg  <b>Which contains</b>  Methyl Sulfonyl Methane (MSM)  (USP).....240mg  Bovine Collagen Hydrolysate  (USP).....100mg  Nettle leaf extract(USP)..80mg  Turmeric extract(USP)....80mg  Boswellia extract (USP)....80mg  Bromelain (USP).....70mg  Noni extract (USP).....20mg  Shark Cartilage(USP).....20mg</p> <p>USP specification</p>	<p>Glucosamine HCl  Chondroitin sulfate  Vitamin C  Vitamin E  Boron  Manganese</p> <p>Methyl Sulfonyl  Methane (MSM)  Collagen  Boswellia extract  Nettle leaf extract  Turmeric</p> <p>Bormelain  Noni extract  Shark cartilage</p>	<p>An alternative to  drugs for arthritis, for  relief of joint pain &amp;  stiffness, also  enhances flexibility  and motility.</p>	30 Tab/ bottle	<b>-do-</b>

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3	<p><b>Energ Tablet</b>  <b>Each tablet contains:</b>  Vitamin A (USP) .....5000 IU  Vitamin C (USP)..... 90mg  Vitamin D (USP).....400 IU  Vitamin E (USP).....30 IU  Vitamin K (USP).....25mcg  Thiamin (USP).....3mg  Riboflavin(USP).....5mg  Niacin (USP).....30mg  Vitamin B6 (USP).....5mg  Folic Acid (USP).....400 mcg  Vitamin B12 (USP).....12mcg  Biotin (USP).....45 mcg  Pantothenic Acid (USP).....15mg  Calcium (USP).....162mg  Iron (USP).....27mg  Phosphorous (USP).....125mg  Iodine (USP).....150mcg  Magnesium (USP).....100mg  Zinc (USP).....15mg  Selenium (USP).....25mcg  Copper (USP).....2mg  Manganese (USP).....5mg  Chromium (USP).....25mcg  Molybdenum (USP).....25mcg  Chloride (USP).....27.2mg  Potassium (USP).....30mg</p> <p>USP Specifications</p>	Retinyl acetate Ascorbic Acid Cholecalciferol dl-alpha tocopheryl Phytonadione Thiamin Riboflavin Niacin Vitamin B6 Folic Acid Vitamin B12 Biotin Pantothenic Acid Calcium Iron Phosphorous Potassium iodide Magnesium Oxide Zinc sulfate Sodium selenate Cupric oxide Manganese sulfate Chromium Molybdenum Chloride Potassium	Energ contains extra strength of B1, B2, B3, B5, B6, & B12 to enhance human's body overall healthy by helping cells, tissues and organs function properly.	30 Tab/ bottle	<b>-do-</b>
4	<p><b>Digestion Plus Capsule</b>  <b>Each Capsule Contain:</b>  Thiamin(USP).....1.5mg  Riboflavin(USP).....1.7mg  Niacin USP).....10mg  Pyridoxine USP).....2mg  Special USP Grade Blend.<b>510mg</b>  <b>Which Contains:</b>  Pancreatic Enzymes (USP).100mg  Bromelain (USP).....80mg  Ginger extract (USP).....75mg  Papain (USP).....50mg  Fructooligosacchrides (USP)50mg  Fennel(USP).....50mg  Peppermint Extract (USP).50mg  Artichoke extract (USP)....30mg  Chamomile extract (USP)..20mg  Noni Extract (USP).....5mg</p> <p>USP Specifications for dietary supplements</p>	Thiamin Riboflavin Niacin Pyridoxine  Pancreatic enzymes Bromelain Ginger Papain Fructooligosacchrides Fennel Peppermint Artichoke Chamomile Noni	Potent extracts of peppermint & artichoke with a blend of other world renowned natural herbs, pancreatic enzymes, plant enzymes & vitamins to support a healthy digestive system. Relieves nausea, vomiting, indigestion, heartburn, gas, constipation, diarrhea & helps cleansing digestive tract	30 Cap/ bottle	<b>-do-</b>

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5	<p><b>Formens Capsule</b>  <b>Three capsules contain:</b>  Maca Extract(USP).....600mg  Hornygoat weed(USP).....180mg  <b>Special Blend 1485mg Which contain:</b>  L-Arginine HCl(USP).....450mg  Rhodiola extract (USP)....300mg  Muiru Puama Extract(USP)180mg  Ashwaghanda Extract (USP).150mg  Powdered Ginseng Extract (USP).....150mg  Oat Straw Extract (UPS)....120mg  Ginkgo Biloba Extract(USP).90mg  Saw Palmetto Extract(USP).30mg  Zinc Oioxide (USP).....15mg</p> <p>USP Specifications</p>	<p>Maca Extract  Horny goat weed</p> <p>L-Arginine HCl  Rhodiola  Muiru Puama  Ashwaghanda  Ginseng</p> <p>Oat Straw  Ginkgo Biloba  Saw Palmetto  Zinc</p>	<p>A Natural Virility &amp; Healthy Libido Product. To be used as a dietary supplement in sexual dysfunction</p>	30 Cap/ bottle	-do-
6. 0039.0003	<p><b>CMZ-3 Plus Tablet</b>  <b>Three Tablets provide:</b>  Calcium(USP).....1100mg  Magnesium(USP).....400mg  Zinc(USP).....15mg  Vitamin D (USP).....1000IU  Copper(USP).....2mg  Manganese(USP).....2mg  Boron(USP).....250mcg  Vitamin C(USP).....6mg  Vitamin E(USP).....10IU</p> <p>Finished product shall conform to USP Specifications</p>	<p>Calcium  Magnesium  Zinc  Vitamin D  Copper  Manganese  Boron  Vitamin C  Vitamin E</p>			-do-

4. a) **M/S Ferozsans Laboratories Limited**, Amangarh Nowshera, Khyber Pakhtunkhwa products are manufactured by **M/s Farmasierra Manufacturing S.L.** Country of origin, Spain under License Holder **M/s BioGaia AB**, P.O. Box 3242, 103 64 Stockholm, **Sweden**.

Enlistment No.	Brand Name & Composition (List of ingredients with strength)	Common Name	Recommended Use	Pack Size	Decision by EEC
1	<p><b>BioGaia ProTectis chewable Tablets</b>  <b>Active:</b> Lactobacillus reuteri DSM 17938 (Protectis)  <b>In-active:</b> Isomal, Xylitol, palm oil, Lemon flavor and Citric acid</p>	<p>Lactobacillus reuteri</p> <p>Isomal</p>	<p>Probiotics are dietary supplement. WHO defines probiotics as live microorganisms which, when administered in adequate amount confer health benefit on the host.</p>	1x10's	Approved for standard recommended use.

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b) **M/s. Ferozsons Laboratories Limited**, Amangarh Nowshera, Khyber Pakhtunkhwa products are manufactured by **M/s TwoPac AB, Vindelvagen 3, SE 241 38 Eslov, SWEDEN** under License Holder **M/s BioGaia AB, P.O. Box 3242, 103 64 Stockholm, Sweden.**

Enlistment No.	Brand Name & Composition (List of ingredients with strength)	Common Name	Recommended Use	Pack Size	Decision by EEC
2	<b>BioGaia ProTectis Drops Shelf-stable plus</b> <b>Active:</b> Lactobacillus reuteri DSM 17938 (Protectis) <b>In-active:</b> Sunflower oil, medium chain triglyceride, and anti-caking agent (Silicon dioxide)	Lactobacillus reuteri  Sunflower oil	Probiotics are dietary supplement. WHO defines probiotics as live microorganisms which, when administered in adequate amount confer health benefit on the host.	5ml	Approved for standard recommended use.

### ii) TEST REPORT

A sample of Blood Rich Lot No.BR-1505 manufactured by M/s SHMZ International (Nutraceutical & Herbal Division), Lahore was picked and sent to Central Drugs Laboratory Karachi by Drug Inspector Gilgit for test/ analysis of ingredients Vitamin-E & Iron as the manufacturer was claimed that the product is both Herbal and allopathic simultaneously by stating; the composition of Vitamin-A 0.750mg and Vitamin-E 2.500mg, outer packing of the drug is attached as ready reference.

The Analyst (CDL Karachi) vide his Report No. R.NAS.187/2015 dated 26-02-2016 has also detected the Vitamin-E during the process of analysis but the calculation 1.0435mg per 5ml observed, below the respective limits. The Vitamin-E is being used in food items and allopathic medicines as such the clarity of position of product is dire need. Further there shown the matter and before fixing the offence of gravity. The analyst has thrown the ball under the code of Director Registration for his technical opinion and guidance.

**Description:** Red coloured syrup in ambered glass bottle.

**Identification:** Vitamins A, E and Iron identified.

**Assay for Vitamin E:**  
**Determined / 5ml** 1.0435mg

**Remarks of the Analyst: -** 1) The other ingredients (Vitamin A & Iron) could not be quantified because of the interference in the method.

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2) The label claims "Nutraceutical Product for Balanced Haematinic Anti-Oxidant" Best for Prevention & Treatment of all kind of Iron deficiency anemia.

3) The assay result for Vitamin E has been calculated as 1.0435mg per 5ml. The RDA (adults) for Vitamin E range is 15.0mg; hence the assay result of Vitamin E is below the limits of the respective RDA.

4) Furthermore, Vitamin E is used in food supplements as per Pharmacopoeia and also by the allopathic manufacturer's as a registered product, therefore, the fate of sample may kindly be decided under the guidance of Directorate of Registration DRAP, Islamabad.

### Claim of the Manufacturer:

1. **Composition:**

Vitamin A 2500 IU.....0.750mg  
Vitamin E.....2.500mg  
Zinc sulphate.....4.167mg  
Ferrous Bisglycinate.....32.50mg

2. **Recommended use:**

Balanced Haematinic Anti-Oxidant,  
Best for Prevention & Treatment of all kind of Iron deficiency  
Anemia

3. **Disclaimer:**

As per Drugs Act, 1976. This is not an Allopathic Drug.

Drug Inspector, Gilgit-Baltistan, Drug Control Administration, Health Department has stated that the position of said medicine may please be clarified that the whether the same may be treated as Herbal product or ingredient of allopathic medicines, as this product falls 100% under the definition of allopathic drug, according to his opinion.

### Decision:

The Committee decided that the Drug Testing Laboratories shall conduct qualitative and quantitative testing and analysis of products as per pharmacopieal specifications and issue test analysis report as per prescribed format without undergoing the classification of products. It was also decided that the claim of product on the label states as under:

**Recommended use:**

Balanced Haematinic Anti-Oxidant, Best for Prevention & Treatment of all kind of Iron deficiency Anemia.

The said claim is not permissible for food supplement and makes the products therapeutic drug. QC Division is advised to process accordingly.

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### **iii. Limits of Vitamins and Minerals in the Food Supplements:**

Recommended Dietary Allowances (RDAs) have sometimes been used by national regulatory authorities as the basis for setting safe upper levels for vitamins and minerals. However, it is important to note that the RDA and the UL are determined by two completely different conceptual approaches. There is now increasing scientific consensus that upper safe levels should be established by scientific risk assessment based on generally accepted scientific data, and that safe upper levels based on arbitrary multiples of RDAs have no scientific validity. For example, at its 2003 meeting the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) dropped any further consideration of RDA-based limits.

RDA values are set on a very similar basis from one country to another—that basis is the consensus of scientific opinion on the quantities of these nutrients needed to confidently assure the performance of recognized physiological functions related to their essentiality.

Thus, the RDA values are related to avoidance of classical nutrient deficiency signs and symptoms. Although this basis for the RDA may be appropriate for undernourished populations, the needs are different for well-nourished and over-nourished populations.

A significant fraction, such as 15 percent, of the RDA can be used appropriately to set lower limits for vitamins and minerals in supplements.

RDA-based values are not valid for judging safety because:

1. The RDA is not defined or identified to describe safety or represent a safety limit for total or supplemental intake.
2. RDA-based limits are not possible for nutrients without established RDA values. For example, no RDA has been set for lutein, lycopene, boron, and many other important substances with nutritive value. These substances have beneficial effects, but the available evidence has not been judged sufficient to identify RDAs, although that may occur in the future. Risk assessment can be used to identify appropriate safety limits for these important nutrients, whether or not an RDA has been set.
3. Arbitrary limits at or near the RDA may preclude certain benefits of some nutrients. For example, well-documented benefits of nutrient quantities above the RDA include:
  - a. Folic acid, vitamin B6 and vitamin B12 which help control plasma homocysteine concentrations. Homocysteine is not yet accepted as a recognized risk factor for heart disease, but there is an ever-increasing body of scientific evidence to support this finding. Supplementation with these three vitamins definitely helps control plasma concentrations of homocysteine, and is likely to be proven to reduce risk of heart disease.
  - b. Supplementation with 200 micrograms of selenium to diets containing about 100 micrograms has been shown in a long-term, well-conducted clinical trial to reduce the incidence of three important types of cancer. A confirmatory clinical trial is underway that, if positive, would justify a widespread public health policy to increase selenium intake in many populations. In the meantime, there is no reason to deny accurate information about the state of the current evidence and to restrict selenium supplements to the RDA.
  - c. Supplementation of diets containing less than 40 micrograms of chromium with additional 200 to 400 micrograms helps maintain normal blood glucose levels and minimize the signs and symptoms of type II diabetes. Clinical trials confirm the safety of up to 1,000 micrograms of supplemental chromium.
4. The imposition of RDA-based upper limits is a disproportionate restriction on supplement products, compared with conventional foods. Certain conventional foods contain many multiples of the RDA of some nutrients. For example, the natural amounts of vitamin B12 in conventional foods such as liver and some shellfish can approach 100 micrograms per 100 gram serving. The adult RDA for this vitamin is commonly set at approximately 1.4 to 2.5 micrograms. Thus, these ordinary conventional foods may contain upwards of 40 to 70 multiples of the RDA of vitamin B12. There is no known toxicity of oral vitamin B12 in humans. Thus, RDA-based upper limits are not rational, serve no useful purpose, and are a disproportionate response to any hypothetical safety concern about this vitamin.



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5. Labeling, not limits, can address proper usage. Labeling can provide information on contents, benefits related to RDA or other measures of benefit, and draw attention to limits imposed on a safety basis, as identified by risk assessment.

Food and Nutrition Board, Institute of Medicine National Academies USA has defined tolerable upper intake levels of vitamins and minerals which could be used safely in the dietary supplements or food supplements. Attachment of the Board, Institute of medicine and National academies defined limits is attached herewith to be opted as reference documents for the food supplements enlistment. (Annex-\_)

### Decision:

The matter was discussed and deferred for further deliberation and evaluation in the forthcoming Meeting of EEC.

iv. **M/s Bio Roots Laboratories (Pvt.) Ltd., Rawalpindi.** The case of M/s Bio Roots Laboratories, Rawat was considered by the EEC in its 9<sup>th</sup> Meeting held on 04-04-2016. Following decision was made on the recommendation of panel that the facility is residential and congested.

1.	<b>M/s Bio Roots Laboratories (Pvt.) Ltd.,</b> Opposite NIZ Chamber Mor GT Road, Rawat, Rawalpindi.	10-03-2016 & 29-03-2016	01. Dr. Abdur Rashid, DDG (E&M), DRAP, Islamabad.  02. Mr. Khalid Mahmood, FID-II, DRAP, Islamabad.	Not Good	Committee rejected the application due to the reasons given in the Inspection Report by the panel.
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2. Rejection letter was served to the applicant but he has undertaken that the facility is commercial. He has also furnished Notarized undertaking that his electricity bill is commercial as A2-C (TOD) which as per his statement is commercial. He has requested to reconsider his case in the next Meeting of EEC to fulfill demand of justice.

### Decision:

The Committee considered the view point of the applicant and decided to verify from the relevant TMA about the status of building whether it is residential or commercial. If it is verified that the building is not residential the sections of the firm recommended by the Panel shall stand approved for enlistment as manufacturer. Otherwise the pervious decision shall prevail.

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### **ITEM:-5** CONFIRMATION OF RECCOMEN'DATIONS OF SUB-COMMITTEE FOR PRODUCTS ENLISTMENT MEETING HELD ON 28-12-2015.

- A) Products recommended by Sub-committee .Sub-committee considered the products referred during the 4<sup>th</sup> meeting of EEC and committee recommended approval subject fulfillment of requirements as per checklists devised by EEC for products enlistment as per respective forms .However it was also recommended that products which does not come under the upper tolerable limits of respective ingredients due to safety criteria may be defined by EEC to avoid mistakes. As a principle only one brand of a product formulation shall be issued to the applicants. If the applicants do not possess manufacturing facility for a particular product, the products may not be enlisted for those sections. It was also recommended that ingredients described in specified publications shall comply with the monograph of referred publications. If the ingredients or preparations are not included in the specified publications, they shall comply with the specifications as per specification monograph as per pharmacopoeial procedures. Homeopathic products shall conform to the homeopathic pharmacopoeias as prescribed in the rules and dosage forms shall comply to pharmacopoeias as recognized in the homeopathic Pharmacopoeias or specification monograph approved by EEC. Applicants for product enlistment shall submit evidence that the applied product is generic otherwise they have to submit application on form 5 in schedule A. Locally manufactured generic formulations are exempted from stability data requirements but shelf life will be within 2 years period and storage conditions will be as per original products. Recommended conditions for use shall be as per evidence as under.
- i) Regulatory approval by the SRA countries recognized by the Authority as reference countries by the Authority.
  - ii) Authoritative Books of particular system of treatment recognized by the Authority.
  - iii) Published literature about particular formulation published in the peer reviewed journals.
  - iv) Clinical trials data duly reviewed by the regulatory Authority.
  - v) Clinical trial data duly evaluated and recognized by the Authority itself or by experts of relevant specialty.
  - vi) Expert's reports from the area of relevant specialty recommending the recommended condition for use based on the experience for usage of particular medicine for at least ten years.
  - vii) Recommended conditions for use for food supplement same as permissible in USA, UK, and EU countries, Health Canada, Australia and Japan.
  - viii) Recommended conditions for Baby Milks and Foods shall be as prescribed by Codex Alimentarius of FAO & WHO.
  - ix) Recommended conditions for use for disinfectants and antiseptic shall be same as prescribed in USA, UK, and EU countries, Health Canada, Australia and Japan.
  - x) Recommended conditions for use for medicated cosmetics shall be same as per USA, UK, and EU countries, Health Canada, Australia and Japan
  - xi) Sub-committee considered the products referred by EEC in its 4<sup>th</sup> meeting. Products for the following firms/ companies were considered.
    - a. Herbion Site 1 (34 products).
    - b. Herbion Site 2(8 products lozenges).
    - c. Global Laboratories (capsules 21, creams 21, oral liquid 22, tablets 13, external liquids 7, (oral powders 1 & sachets 19 products).
    - d. BM Homeopathy (Pvt.) Ltd Lahore. Mother Tinctures (120), Potencies (120), Tablets and granules (46), Drops (55), general items (14), Homeopathic trituration's and tablets (22), biochemic tablets (12) and homeopathic syrups (14).
- B) **Products recommended in 28<sup>th</sup> December 2015 meeting of sub-committee.**
- i. Evergreen Pharmaceuticals (19 products).
  - ii. Hit Natural Pharma Lahore (27products).
  - iii. Kamal Laboratories(Mother Tinctures 100), mother tinctures preparations(60), ,veterinary products(5)
  - iv. Natural products(30)
  - v. Nugen Lahore (135 products).
  - vi. Hinucan (16 products).
  - vii. Item 3. Imported products.

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- viii. Dara-ul-Adviyat imported products ((100).
- ix. GSK from SmithKline Becham Srilanka (1 PRODUCT).
- x. ICI Pakistan
- xi. Vida Laboratories from Wehai, Baihe Biology Technological China (26 products.
- xii. Vida Laboratories from Bio growing China (4 products).
- xiii. Vida Laboratories from CHR Hansen (5).
- xiv. Tarobina (7 products) from Shangdong BAOLALI-LEELAI China (4 products), from Feed Up Korea (1product), Vitfos Denmark, (1product) and Insect Biotech Korea (1product).
- xv. Omana International from Omana Group California USA (5products).
- xvi. Nutra zone Healthcare Karachi from Patheion Newzeland through Health Aid UK (25 products).

**C) Withheld Products.** Following types of products will be withheld and their enlistment certificates will not be issued. Applicants shall be required to submit justifications/evidence for relevant requisite parameters. In case of failure to justify the formulations, the matter will be placed before the EEC in its forthcoming meeting.

- i. Non-submission of Evidence that the product is generic.
- ii. Failure to prove that the food supplemental ingredients are within the upper limits approved by the EEC.
- iii. Absence of Pharmacopoeial reference for the product raw materials and products is submitted.
- iv. Absence of Recommended conditions for the products as prescribed above.
- v. Sections are not approved for the products being applied to be enlisted.
- vi. Products have already been approved and enlisted or deferred for further evaluation.
- vii. Products having safety concerns or withdrawn locally or internationally.
- viii. Absence of Import documents like GMP Compliance Certificate, product marketing authorization or free sale certificates for the OTC Products or COPP for the herbal medicinal products duly attested from the Embassy or consulate of Pakistan in the country of Origin are not submitted. If the documents have already been submitted to the Authority for firm/company enlistment, photocopies could be acceptable.

**D) BRAND NAME / CHANGE IN BRAND NAME:**

Application for change in brand name will be entertained subject to the following conditions only.

- i. Application on prescribed form for enlistment with fee.
- ii. Application is submitted within sixty days after the issuance of certificate.
- iii. The brand name resembles with the already registered or enlisted brand names.
- iv. Undertaking on stamp paper that the product will not be marketed with the old brand name and if proved otherwise, the product shall be liable to revocation of enlistment. It will also be undertaken that the proposed brand name does not resemble with the already registered or enlisted products brand name. It shall also undertake that if name resembles with the already registered brand name, the applicant will add company name as prefix with proposed name.
- v. Product brand names will not be changed after sixty days of product enlistment unless it resembles with the already registered or enlisted products.

**E) DELEGATION OF POWERS TO THE CHAIRMAN EEC.**

It is submitted that some of the issues are delayed for placement in forthcoming meetings of EEC and Division becomes handicapped for addressing the issues on urgent basis. So it is proposed that for disposal of day to day business on behalf of EEC following powers may be delegated to the chairman EEC for timely disposal.

- i. **Change of brand name**
- ii. **Change of formulations or corrections in the already enlisted products.**
- iii. **Extension in sealing periods requested by Federal Inspectors of Drugs.**
- iv. **Permission to retain for seized articles.**
- v. **Grant of product enlistment certificate for export purpose subject to submission of product application and purchase order from the overseas countries.**

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- vi. Grant of GMP Certificate and free sale certificates on the basis of inspections conducted for grant of enlistment certificates as manufacturers from the date of inspection for one year.

### **Decision:**

The Committee confirmed the recommendations of the sub-committee for product enlistment. The guidelines framed by the Committee were approved as Standard Operating Procedure for product enlistment. SOP of brand name change was also approved by the EEC. Proposed authorization to the Chairman EEC was also approved.

### **Disclaimer:**

Errors / omissions / mistakes may be reported to the Director (Health & OTC Division) for corrections.

**Pakistan Zindabad**