Minutes of the 12th Meeting of Enlistment Evaluation Committee held on 27th June, 2016

No. F. 10-06/2016-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
DRUG REGULATORY AUTHORITY OF PAKISTAN

Islandabad, the 27th June, 2016

MINUTES OF THE 12TH MEETING OF ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

12th 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 27th June, 2016. Meeting of Committee was attended by the following:-

<table>
<thead>
<tr>
<th>S. #.</th>
<th>Name &amp; Designation</th>
<th>Position in the Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Abdul Samad Khan,</td>
<td>Ex-Officio Chairman</td>
</tr>
<tr>
<td></td>
<td>Director Health &amp; OTC</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Abdul Sattar Sohrani,</td>
<td>Ex-Officio Member / Secretary</td>
</tr>
<tr>
<td></td>
<td>Deputy Drug Controller Health &amp; OTC</td>
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<tr>
<td>3.</td>
<td>Homeopathic Dr. Muhammad Tariq Khan,</td>
<td>Expert Member</td>
</tr>
<tr>
<td></td>
<td>Assistant Professor,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Department College of Pharmacy,</td>
<td></td>
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<tr>
<td></td>
<td>Margalla Institute of Health Sciences, Rawalpindi.</td>
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</tr>
<tr>
<td>4.</td>
<td>Hafiz Muhammad Asif,</td>
<td>Expert Member</td>
</tr>
<tr>
<td></td>
<td>Assistant Professor Faculty of Health and medical Sciences Department of Eastern Medicines and Surgery, University of Poonch (Rawala Kot), AJ&amp;K.</td>
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<tr>
<td>5.</td>
<td>Dr. Lajbar Khan,</td>
<td>Expert Member</td>
</tr>
<tr>
<td></td>
<td>Ex-Chief Scientific Officer, Medicinal Botanic Centre, PCSIR Laboratories Complex, Peshawar.</td>
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</tr>
<tr>
<td>6.</td>
<td>Chief, DC &amp; TMD, NIH</td>
<td>Ex-Officio Member -Not Present-</td>
</tr>
<tr>
<td>7.</td>
<td>Dr. Amjad Ali,</td>
<td>Ex-Officio Member</td>
</tr>
<tr>
<td></td>
<td>Chief, Nutrition Division, NIH</td>
<td></td>
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<tr>
<td>8.</td>
<td>Mr. Akhtar Abbass,</td>
<td>Observer</td>
</tr>
<tr>
<td></td>
<td>Deputy Director (PER Division)</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Mr. Adnan Faisal Saim,</td>
<td>Observer (Not Present)</td>
</tr>
</tbody>
</table>
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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.

Deferred Agenda of 11th Meeting of EEC

A. CORRECTION IN THE MINUETS OF THE 10TH MEETING OF EEC.


Decision of 8th 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 of 10th Meeting of EEC:

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.

“The certification of Ministry of Health about 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 was produced by the applicant. This certification was valid from 21-07-2015, but due to misunderstanding it was written as valid upto 21-07-2015. The documents of the importer are complete.”

Case is submitted for consideration of the Enlistment Evaluation Committee.

2. M/s RAX Laboratories (Homoeopathic), was inspected and following sections were approved in 10th Meeting of EEC held on 29-04-2016. Supportive documents like layout plan and invoices were
Minutes of the 12th Meeting of Enlistment Evaluation Committee
held on 27th June, 2016

attached at 22-KM, Ferozpur Road, Gujju Mata, Lahore which created confusion and issuance of enlistment certificate on Form-6 was with held.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name and address of the Manufacturer</th>
<th>Name of approved Sections</th>
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</thead>
</table>

But it was revealed that the firm submitted application at 14 Allama Iqbal Road, Lahore. It was verified from Mr. Adnan Faisal Saim, DDC (QC-1 & II), who stated vide his letter dated 11-05-2016 & Diary No. 254 dated 12/05/2016 as under:

“In compliance to letter No.F.1-628/2016-DDC (Health & OTC) the panel visited the manufacturing site situated at 21 KM Ferozpur Road, Lahore. The firm has also submitted the request in this regard (copy enclosed).”

Decision:-

Enlistment Evaluation Committee allowed to correct the minutes of the 10th Meeting of EEC and granted approval of Enlistment Certificate on Form-6 to 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). The Committee also granted approval of Enlistment Certificate on Form-6 to M/s Rax Laboratories (Homoeopathic), 21 KM Ferozepur Road, Lahore for the approved sections.

3. M/s. Z-JANS Pharmaceuticals (Pvt.) Ltd., Following sections of M/s Z-Jans were approved.

<table>
<thead>
<tr>
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<th>Name of approved Sections</th>
</tr>
</thead>
</table>

The enlistment certificate on Form-6 was issued but ointment and cream section was with held as the same was not available in the layout plan submitted by the firm.

Decision:-

EEC allowed to correct the minutes and withdraw ointment / cream section which was with held by the Division.
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B. DRUG MANUFACTURING LICENSE INSTEAD OF DIETARY SUPPLEMENT MANUFACTURER REGISTRATION.


Decision

Agenda item No. 5 (1 & 2) is deferred for further evaluation on the basis of Principal decision given below.

Basic Decision:-

1. Exclusive Sole Agency Agreement shall be provided from the Principal Manufacturer for the products/ formulations which are on Free Sale and authorized to be marketed in the local market.
2. Countries like USA where Nutraceutical products or Dietary Supplements or Health Supplements are categories separate from the Allopathic Drugs, Drug Manufacturing License will not be acceptable as manufacturing authorization. Relevant manufacturing authorization from the regulatory authority shall be submitted by the applicant.
3. Manufacturing Authorization as drug shall be submitted by the applicants from the regulatory authorities where the Herbal products are categorized as drugs like EU Countries.
4. Manufacturing units having both type of facilities shall be required to submit both authorizations, otherwise only the products of the facility whose manufacturing authorization have been submitted will be entrained for enlistment.
5. Only applicants having Sole Agency Agreement for the product with Principal Manufacturer / Legal Owner abroad will be entrained.
6. Valid GMP Certificate issued by the regulatory authority based on inspection report shall be sufficient to replace inspection report. Otherwise inspection report by the regulatory authority shall be required to be submitted for enlistment.
7. This decision will be applicable on all the applicants, in item 4, item 5 sub item 1 & 2 and already enlisted firms.

The firm has provided FDA registration, products specific Agency Agreement and free sale certificates as per decision of the EEC.

Decision:-

EEC after verification of records granted approval for issuance of Form-6 to the applicant.

C. IMPORTED PRODUCTS WITH HELD AT PORT DUE TO NON CLEARANCE:-

1. M/s Merck Specialties (Private) Limited, Head office: 4th Floor, D-7, Shaheed-e-Millat Road, P.O. Box 13021, Karachi (As agent of M/s Hovid Berhad, 121, Jalan Tunku, Abdul REhman, 30010 IPOH, Perak, MALAYSIA) Enlistment No. 0069

<table>
<thead>
<tr>
<th>S.</th>
<th>Brand Name &amp; composition</th>
<th>Common name</th>
<th>Recommended</th>
<th>Pack size</th>
<th>MRP</th>
<th>Decision by EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
Minutes of the 12\textsuperscript{th} Meeting of Enlistment Evaluation Committee held on 27\textsuperscript{th} June, 2016

<table>
<thead>
<tr>
<th>No.</th>
<th>(List of ingredients with strength) of ingredients</th>
<th>conditions for use</th>
<th>Pack size</th>
<th>MRP</th>
<th>Decision by EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Seven Seas Cod Liver Oil Gold</td>
<td></td>
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<tr>
<td></td>
<td>Cod Liver Oil (BP)……..264mg</td>
<td>1. Supplement</td>
<td></td>
<td></td>
<td>Approved for</td>
</tr>
<tr>
<td></td>
<td></td>
<td>containing Vitamin</td>
<td></td>
<td></td>
<td>standard</td>
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<td></td>
<td></td>
<td>A, D, and Omega 3</td>
<td></td>
<td></td>
<td>recommended</td>
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<tr>
<td></td>
<td></td>
<td>Fatty acids.</td>
<td></td>
<td></td>
<td>use as per</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Maintenance of</td>
<td></td>
<td></td>
<td>Pharmacopoeial</td>
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<tr>
<td></td>
<td></td>
<td>good health.</td>
<td></td>
<td></td>
<td>specification.</td>
</tr>
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<tr>
<td>2.</td>
<td>Seven Seas Ginkgo Max</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ginkgo Biloba extract (USP)………………40mg</td>
<td>i. Helps to</td>
<td>90 Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>enhance cognitive</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>function in</td>
<td></td>
<td>Rs.1400/-</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>adults.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>ii. Helps to</td>
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<tr>
<td></td>
<td></td>
<td>enhance memory in</td>
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<tr>
<td></td>
<td></td>
<td>adults.</td>
<td></td>
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<td></td>
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<td>iii. Helps to</td>
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<td></td>
<td>support peripheral</td>
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<tr>
<td></td>
<td></td>
<td>circulation.</td>
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</tbody>
</table>

2. **M/s Matrix Pharma (Pvt.) Limited**, Plot No. 12, Sector-15, Korangi Industrial Area, Karachi-74900 is Agent of **M/s ANA Bio Research and Development JSC**, Head Office: No. 22, Lot 7, Van Khe Urban, La Khe Ward, Ha Dong district, Hanoi City, VIETNAM. **Enlistment No. 0015**

<table>
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<th>Decision by EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Matrix Ospor Oral Suspension (Drinkable Ampoule)</td>
<td>Bacillus Clausii</td>
<td>Probiotics for oral use</td>
<td>5ml</td>
<td></td>
<td>Approved for</td>
</tr>
<tr>
<td></td>
<td>Each 5ml contain:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>standard</td>
</tr>
<tr>
<td></td>
<td>Bacillus Clausii….2 billion CFU per 5ml (sterilized water)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>recommended</td>
</tr>
<tr>
<td></td>
<td>USP / specification monograph</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>use as per</td>
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<td></td>
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<td></td>
<td></td>
<td>Pharmacopoeial</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>specification.</td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Deep Heat Regular Rub</td>
<td>Methyl salicylate Menthol</td>
<td>For temporary relief of minor</td>
<td>50g</td>
<td></td>
<td>Approved for</td>
</tr>
<tr>
<td></td>
<td>Each Tube contain:</td>
<td>Turpentine oil Eucalyptus</td>
<td>aches and pains of muscles</td>
<td>100g</td>
<td></td>
<td>standard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>oil Lanolin Chloroxylenol</td>
<td>and joints.</td>
<td>140g</td>
<td></td>
<td>recommended</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Glyceryl stearate Water</td>
<td></td>
<td></td>
<td></td>
<td>use as per</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pharmacopoeial</td>
</tr>
</tbody>
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<th>MRP</th>
<th>Decision by EEC</th>
</tr>
</thead>
</table>
| 1.     | REDOXON DOUBLE ACTION Each tablet contain:                   | Ascorbic acid               | 1. Vitamin C and zinc supplements.  
                  Vitamin C (USP)..........1000mg   | zinc citrate                | 2. Antioxidant for maintenance of good health.  
                  Zinc (USP)......................10mg |                             |                               |           |     | Approved for standard recommended use as per Pharmacopoeial specification, subject to approval of recommended guidelines for upper limits of vitamins and minerals by the Authority. |

Case is submitted for consideration of the Enlistment Evaluation Committee.

D. 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 (CCNFSU) 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:
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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.

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 of 10th Meeting of EEC:**

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

**International Comparisons:**
Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN), US Institute of Medicine (IOM), European Commission on Safety of Food (ECSCF) or European Food Safety Authority (EFSA), and UK Expert group on Vitamins Minerals (EVM).

<table>
<thead>
<tr>
<th>Nutrient Vitamins and Minerals</th>
<th>CRN UL (amount/ day)</th>
<th>US IOM UL (amount/ day)</th>
<th>EC SCF/EFSA UL (amount/ day)</th>
<th>UK SVM SUL or GL (amount/ day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>10,000 IU (3,000 µg RAE)</td>
<td>10,000 IU</td>
<td>10,000 IU</td>
<td>5,000 IU</td>
</tr>
<tr>
<td>Beta Carotene</td>
<td>25mg non-smokers, smokers should not use.</td>
<td>Not determined</td>
<td>Not determined</td>
<td>7 mg supplements, smokers should not use.</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>250 µg (10,000 IU)</td>
<td>100 µg (4,000 IU)</td>
<td>100 µg (4,000 IU)</td>
<td>250 µg (1,000 IU)</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>1000mg (1600IU)</td>
<td>1000mg (1600IU)</td>
<td>300mg</td>
<td>540mg</td>
</tr>
<tr>
<td>Vitamin k</td>
<td>10mg</td>
<td>Not determined</td>
<td>Not determined</td>
<td>1mg</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>2000mg</td>
<td>2000 mg</td>
<td>Not determined</td>
<td>1000mg</td>
</tr>
<tr>
<td>Vitamin B1 (Thiamine)</td>
<td>100mg</td>
<td>Not determined</td>
<td>Not determined</td>
<td>100mg</td>
</tr>
<tr>
<td>Vitamin B2 (Riboflavin)</td>
<td>200mg</td>
<td>Not determined</td>
<td>Not determined</td>
<td>40mg supplement 43 mg total (GL)</td>
</tr>
<tr>
<td>Nicotinic acid</td>
<td>500mg</td>
<td>35mg</td>
<td>10mg</td>
<td>17mg</td>
</tr>
<tr>
<td>Nicotinamide</td>
<td>1500mg</td>
<td>35mg</td>
<td>900mg</td>
<td>500mg supplement 560 mg total (GL)</td>
</tr>
<tr>
<td>Pyridoxine</td>
<td>100mg</td>
<td>100mg</td>
<td>25mg</td>
<td>10mg</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>1000µg</td>
<td>1000µg</td>
<td>1000 µg</td>
<td>1000 µg</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>3000 µg</td>
<td>Not determined</td>
<td>Not determined</td>
<td>2000 µg</td>
</tr>
<tr>
<td>Biotin</td>
<td>2500 µg</td>
<td>Not determined</td>
<td>Not determined</td>
<td>900 µg</td>
</tr>
<tr>
<td>Pantothenic Acid</td>
<td>1000mg</td>
<td>Not determined</td>
<td>Not determined</td>
<td>200mg supplement 210mg total (GL)</td>
</tr>
</tbody>
</table>

Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN), European Food Authority (EFSA), UK Expert group on Vitamins and Minerals (EVM), European Commission on Safety of Food (ECSCF) and US Institute of Medicine (IOM).

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<th>CRN UL (amount/ day)</th>
<th>US IOM UL (amount/ day)</th>
<th>EC SCF/EFSA UL (amount/ day)</th>
<th>UK SVM SUL or GL (amount/ day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>1500mg</td>
<td>2500mg</td>
<td>2500mg</td>
<td>1500mg</td>
</tr>
<tr>
<td>Phosphorous</td>
<td>1500mg</td>
<td>4000mg</td>
<td>Not determined</td>
<td>250 mg supplement 2400 mg total (GL)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>400mg</td>
<td>350mg</td>
<td>250mg</td>
<td>400mg supplement (GL)</td>
</tr>
<tr>
<td>Potassium</td>
<td>1500mg (500mg thrice)</td>
<td>Not determined</td>
<td>Not determined</td>
<td>3700 mg supplement (GL)</td>
</tr>
<tr>
<td>Boron</td>
<td>6mg</td>
<td>20mg</td>
<td>10mg</td>
<td>9.6 mg (SUL)</td>
</tr>
<tr>
<td>Chromium</td>
<td>1000mcg</td>
<td>1000mcg</td>
<td>Not determined</td>
<td>10 mg (10,000 µg) total (GL)</td>
</tr>
<tr>
<td>Copper</td>
<td>9mg</td>
<td>10mg</td>
<td>5mg</td>
<td>10 mg total (SUL)</td>
</tr>
<tr>
<td>Fluoride</td>
<td>No ULS (UL=6 mg)</td>
<td>10</td>
<td>7mg</td>
<td>Not determined</td>
</tr>
<tr>
<td>Iodine</td>
<td>500µg</td>
<td>1100µg</td>
<td>600µg</td>
<td>500 µg supplement 930µg total (GL)</td>
</tr>
<tr>
<td>Iron</td>
<td>60mg (full stomach)</td>
<td>45mg (empty stomach)</td>
<td>Not determined</td>
<td>17mg supplement (GL)</td>
</tr>
<tr>
<td>Manganese</td>
<td>10mg</td>
<td>11mg</td>
<td>Not determined</td>
<td>4 mg supplement 12.2mg total (GL)</td>
</tr>
<tr>
<td>Molybdenum</td>
<td>350µg</td>
<td>2000µg</td>
<td>600µg</td>
<td>230µg food (GL)</td>
</tr>
<tr>
<td>Selenium</td>
<td>200 µg</td>
<td>400 µg</td>
<td>300 µg</td>
<td>350 µg supplement</td>
</tr>
</tbody>
</table>
CRN: Council for Responsible Nutrition  
US IOM: United States Institute of Medicine  
ECSCF: European Commission on Safety of Food  
EFSA UL: European Food Authority (EFSA)  
GL: Guidance Level (may apply to total or supplemental intake)  
UK EVM: UK Expert group on Vitamins and Minerals (EVM)  
SUL: Safe Upper Tolerable Limit  
UL: Tolerable upper intake level

Decision:-

EEC recommended that upper limits of vitamins and minerals declared tolerable and safe in the food supplements as OTC Products by the Council for Responsible Nutrition, United States Institute of Medicine, European Commission on Safety of Food, European Food Authority (EFSA) and UK Expert group on Vitamins and Minerals (EVM) may be declared as reference to be permitted in the food supplements. As the matter is linked with the Health & OTC Division as well as Pharmaceutical Evaluation and Registration, final approval of the Authority is required. So the recommendations shall be forwarded to the Authority for final approval.

<table>
<thead>
<tr>
<th>Enlistment No.</th>
<th>List of ingredients with strength</th>
<th>Common Name of Ingredients</th>
<th>Recommended use</th>
<th>Pack Size</th>
<th>Maximum Retail Price</th>
</tr>
</thead>
</table>
| 1. Vegan Tablet  | Vitamin A, 4000 IU  
Vitamin C, 5mg  
Vitamin D, 400 IU  
Thiamin, 3mg  
Riboflavin, 2mg  
Niacin, 10mg  
Vitamin B6, 1mg  
Folic Acid, 800mcg  
Vitamin B12, 2mcg  
Calcium, 250mg  
Iron, 27mg  
Iodine, 0.01mg  
Magnesium, 0.15mg  
Zinc, 0.085mg  
Copper, 0.15mg  
Manganese, 0.05mg  
Potassium, 0.835mg |  
Vitamin A  
Vitamin C  
Vitamin D  
Thiamin  
Riboflavin  
Niacin  
Vitamin B6  
Folic Acid  
Vitamin B12  
Calcium  
Iron  
Iodine  
Magnesium  
Zinc  
Copper  
Manganese  
Potassium | Nutritional Supplement | 30 Tablets | 795/- |
| 2. Joints Life Capsule | Vitamin C, 20mg  
Vitamin E, 20mg  
Manganese, 0.7mg  
Boron, 0.5mg  
Chicken Collagen |  
Vitamin C  
Vitamin E  
Manganese  
Boron  
Chicken Collagen | It protects joints, Keep people active, Useful for | 30 Capsules | 1050/- |
Hydrolysate..............300mg  
Shark Cartilage..........150mg  
Boswellia Extract........60mg  
Stinging Nettle Leaf Extract.60mg  
Bromelain................50mg  
Turmeric Extract.........30mg

| 3. Vegan Plus AZ Tablet | Vitamin A,........5000 IU  
|                       | Vitamin C,.........90mg  
|                       | Vitamin D,.........400 IU  
|                       | Vitamin E,.........30 IU  
|                       | Vitamin K,.........25mcg  
|                       | Thiamin,...........2.25mg  
|                       | Riboflavin.........2.6mg  
|                       | Niacin,............20mg  
|                       | Vitamin B6.........3mg  
|                       | Folic Acid.........400mcg  
|                       | Vitamin B12.........9mcg  
|                       | Calcium,..........162mg  
|                       | Iron,..............27mg  
|                       | Iodine,...........150mcg  
|                       | Magnesium.........100mg  
|                       | Zinc,..............15mg  
|                       | Copper,...........2mg  
|                       | Manganese.........5mg  
|                       | Potassium.........30mg  
|                       | Biotin,...........45mcg  
|                       | Pantothenic Acid...10mg  
|                       | Phosphorous.......125mg  
|                       | Chromium..........25mcg  
|                       | Molybdenum........25mcg  
|                       | Chloride..........27.2mg  

| 4. Formula for Joints Tablet | Vitamin C.........15mg  
|                            | Vitamin E.........30mg  
|                            | Manganese.........1mg  
|                            | Boron...............0.75mg  
|                            | Glucosamine Sulphate...375mg  
|                            | Chondroitin Sulfate...25mg  
|                            | Boswellia Extract...40mg  
|                            | Stinging Nettle Leaf Extract.40mg  
|                            | Bromelain..........35mg  
|                            | Turmeric Extract...40mg  
|                            | Shark Cartilage...10mg  
|                            | Noni...............10mg  
|                            | Methyl Sulfonyl Methane..120mg

| 5. Fisol | Natural Fish Oil..............100mg  
|          | Omega 3 Fatty Acids........300mg  
|          | DHA.........................120mg  
|          | EPA.........................180mg  

| 6. Res. 30 | Vitamin B1........1.5mg  
|            | Vitamin B2........1.7mg
## Minutes of the 12th Meeting of Enlistment Evaluation Committee held on 27th June, 2016

<table>
<thead>
<tr>
<th>Vitamin B6</th>
<th>Calcium Carbonate</th>
<th>Niacine</th>
<th>Magnesium</th>
<th>It promotes restful sleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin B6</td>
<td>Calcium Carbonate</td>
<td>Niacine</td>
<td>Magnesium</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vitamin B6</th>
<th>Calcium Carbonate</th>
<th>Niacine</th>
<th>Magnesium</th>
<th>For Healthy bones</th>
<th>30 Tablets</th>
<th>1790/-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin B6</td>
<td>Calcium Carbonate</td>
<td>Niacine</td>
<td>Magnesium</td>
<td>Vitamin D</td>
<td>Vitamin E</td>
<td>Vitamin E</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>Vitamin D</td>
<td>Vitamin E</td>
<td>Calcium</td>
<td>Magnesium</td>
<td>Zinc</td>
<td>Copper</td>
</tr>
<tr>
<td>For Healthy bones</td>
<td>30 Tablets</td>
<td>1790/-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Bone Health Booster
- Ascorbic Acid: 6mg
- Cholicalciferol: 1200 IU
- Vitamin E: 10 IU
- Calcium: 1200mg
- Magnesium: 400mg
- Zinc: 15mg
- Copper: 2mg
- Manganese: 2mg
- Vanadium: 50mg
- Boron: 250mg
- Silicon: 25mg

### Nervix
- Vitamin B1: 37.50mg
- Vitamin B2: 2.55mg
- Vitamin B6: 2mg
- Vitamin B12: 3mcg
- Alpha Lipoic Acid: 225mg
- Acetyle L Carnitine: 235mg
- Turmeric Extract: 45mg

### Fisol
- Lepidium meyenii: 200mg
- Epimedium sagattaum: 60mg
- Proprietary blend: 490mg
- L-arginine HCl, Cnidium extract, Muira pauma extract (Ptychopetalum olacoids)
- Ashwaganda extracts (Withania somnifera), ginseng extract (Panax ginseng), Oat straw extract (Avena sativa), Saw palmetto extract (Serenoa repens) Berry, ginkgo biloba.

### Bone Health Plus
- Ascorbic Acid: 6mg
- Cholicalciferol: 800 IU
- Vitamin E: 10 IU
- Calcium: 1000mg
- Magnesium: 400mg
- Zinc: 15mg
- Copper: 2mg
- Manganese: 2mg
- Boron: 250mg

### Bone Health Tablet
- Cholicalciferol: 400 IU
- Calcium: 1000mg
- Magnesium: 400mg
- Zinc: 15mg

Already Form-7 issued to **M/s. Brooklyn Pharmaceuticals**, located at the address **687, Ground Floor, New Abadi Ali Abad, Alla Abad Road, Westridge-III, Rawalpindi - Pakistan** to be manufactured by **M/s. Omana Group LLC, 11562 Knott Avenue, Suite 5, Garden Grove, California 92841 U.S.A.** same overseas Principal and 5 products were approved by EEC in its 10th Meeting.
<table>
<thead>
<tr>
<th>Enlistment No.</th>
<th>Brand Name &amp; Composition (List of ingredients with strength)</th>
<th>Common Name of ingredients</th>
<th>Recommended use</th>
<th>Pack size</th>
<th>Decision by EEC</th>
</tr>
</thead>
</table>
| 0039.0001     | **Ecolin Tablet**  
Each Tablet Contain:  
Vitamin C(USP) ……………………6mg  
Cranberry Extracts(Eur.Ph)...250mg | Ascorbic acid  
Vaccinium macrocarpon | 1. (Traditionally) used as Herbal Medicine to help prevent (recurrent) urinary tract infections (UTIs)  
2. (Used as Herbal Medicine to) help(s) prevent recurrent urinary tract infections (UTIs) in women  
3. Provides antioxidants for the maintenance of good health. | 30 Tab/ bottle | -do- |
| 0039.0002     | **CMZ-3 Tablet**  
Amount as per three tablets serving:  
Calcium(USP)…………………1000mg  
Magnesium(USP)………………400mg  
Zinc(USP)……………………15mg  
VitaminD3(USP),………………..400 IU | Calcium  
Magnesium Oxide  
Zinc sulfate  
Cholecalciferol | 1. Vitamin D3, calcium, magnesium and zinc supplement.  
2. Maintenance of good health. | 30 Tab/ bottle | -do- |
| 0039.0003     | **CMZ-3 Plus Tablet**  
Three Tablets provide:  
Calcium(USP)…………………1000mg  
Magnesium(USP)………………400mg  
Zinc(USP)……………………15mg  
Vitamin D (USP),………………1000IU  
Copper(USP),………………….2mg  
Manganese(USP),………………2mg  
Boron(USP)………………….250mg  
Vitamin C(USP)………………6mg  
Vitamin E(USP)………………10IU | Calcium  
Magnesium  
Zinc  
Vitamin D  
Copper  
Manganese  
Boron  
Vitamin C  
Vitamin E | 1. Multivitamin – multi-mineral Supplement  
2. Maintenance of good health. | 30 Tab/ bottle | -do- |
| 0039.0004     | **BCIP Plus Tablet**  
Amount as per three tablets serving:  
Calcium (USP)…………………1100mg  
Magnesium(USP)………………400mg  
Zinc (USP)………………….15mg  
Vitamin D(USP),………………1000 IU  
Vitamin C(USP)………………6mg  
Vitamin E(USP)………………10 IU  
Copper (USP)…………………2mg  
Manganese (USP)………………2mg  
Boron(USP)………………….250mcg  
Fish Oil concentrate (DHA/EPA) | Calcium carbonate  
Magnesium Oxide  
Zinc gluconate  
Cholecalciferol  
Ascorbic acid  
dl-alpha tocopherol  
Copper sulfate  
Manganese sulfate  
Boroncitrate  
Fish Oil (DHA/EPA) | 1. Multivitamin – multi-mineral Supplement  
2. Maintenance of good health. | 30 Tab/ bottle | -do- |
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(USP)..............................150mg
Finished product shall conform to
USP Specifications

Decision:-
As the M/s. Omana Group has filed variation in the applications, so the matter is
forwarded to products enlistment sub-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.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name and address of the Manufacturer</th>
<th>Name of approved Sections/ Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>M/s. BIONS (Bio Natural Solution)</td>
<td>Sections:-</td>
</tr>
<tr>
<td></td>
<td>Plot No. 15, 1 Km Bhangree Road, T-Chowk, Rawat, Islamabad.</td>
<td>1. Oral liquid (Veterinary)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Oral powder (Veterinary).</td>
</tr>
<tr>
<td>2.</td>
<td>M/s. PCP Health Care,</td>
<td>Following Sections as approved subject to rectification of deficiencies identified by the panel in the inspection report.</td>
</tr>
<tr>
<td></td>
<td>98-KM, Multan road, Akhtarabad, Okara</td>
<td>Sections :-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Capsule</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Oral Liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Ointment/ Cream</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Sachet</td>
</tr>
<tr>
<td>3.</td>
<td>M/s. Nutris Laboratories</td>
<td>Section:-</td>
</tr>
<tr>
<td></td>
<td>46(B)-M Block, Quaid-e-Azam Industrial Estate, Lahore.</td>
<td>1. Capsule</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Oral Liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Sachet</td>
</tr>
<tr>
<td>4.</td>
<td>M/s Genbiotch Nutraceuticals,</td>
<td>Section: -</td>
</tr>
<tr>
<td></td>
<td>Plot No. 24, Street No. NS-2, NIz RCCI, Rawat, Rawalpindi.</td>
<td>1. Topical Semisolid (Cream / ointment, shampoo &amp; gels)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Oral liquid (Syrup)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Capsule</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Powder (Sachet)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Tablet</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>No.</th>
<th>Company Name</th>
<th>Address</th>
<th>Section</th>
</tr>
</thead>
</table>
| 5   | M/s. Concept Pharma, | 46/M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore | 1. Mouthwash  
2. Tooth Paste |
| 6   | M/s. Cibex (Pvt) Ltd, | F-405, SITE Area, karachi | 1. Liquid (Solution, Syrup, Suspension, Drop)  
2. Tablet  
3. Capsule  
4. Sachet  
5. Cream |
| 7   | M/s Crystolite Pharmaceuticals | Plot #72, S-2, NIZ Rawat. | 1. Tablet  
2. Capsule  
3. Cream/ Lotion  
4. Oral liquid (Syrup)  
5. Sachet  
6. Medicated Soap |
2. Oral Liquid (Syrup)  
3. Capsule  
4. Sachet |
| 9   | M/s Zainb Nutraceutical Industries | 11Km Sahiwal Road, Arifwala | 1. Oral Liquid (Veterinary)  
2. Dry powder (Veterinary) |
| 10  | M/s. Amarant Health Care, | Plot No. 168, Sector 23, Korangi Industrial Area, Karachi. | 1. Tablet  
2. Hard gel Capsule  
3. Soft gel Capsule  
4. Oral Liquid (syrup)  
5. Ointment/ cream  
6. Sachet |
| 11  | M/s. Islamabad Pharmacy, | Behind Qadir Gas Way 1, G.T. Road Wah District, Rawalpindi | 1. Tablet  
2. Capsule  
3. Mother Tincture  
4. Potency  
5. Syrup  
6. Herbal Capsule |
| 12  | M/s. Opal Laboratories (Pvt) Ltd | Plot LC 42, Lite Landhi, Karachi | 1. Tablet |
3. **INSPECTION REPORT NOT RECOMMENDED BY THE PANEL:**

<table>
<thead>
<tr>
<th>S. #.</th>
<th>Name of the Firm</th>
<th>Date of Inspection</th>
<th>Inspection Panel Members</th>
<th>Ranking / Evaluation</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M/s. Angel Human Health, P-1278, St # 1, Fatahabad East Canal Road, Faisalabad</td>
<td>02.05.2016</td>
<td>01.Dr. Mian Kamran Sharif, Member Advisory Committee</td>
<td>Not Recommended</td>
<td>Committee rejected the application due to the reasons given in the Inspection Report</td>
</tr>
</tbody>
</table>
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| 2. | M/s. K.M Homeo Pharma, Chak No.118, Tehsil Jahanian, District Khanewal | 31.05.2016 | 1.Dr. Tariq Khan Member EEC 2. Aisha Irfan, FID, DRAP, Lahore | Not Recommended | Committee rejected the application due to the reasons given in the Inspection Report by the panel.
 |
| Table: | 
| Section: | 
| 1. Tablet | 
| 2. Oral Liquid | 
| 3. Sachet Section | 

**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.

**ITEM IV. PRODUCT ENLISTMENT**

Product Enlistment applications of the following firms/companies for Import / Local Manufacturing are as under:-

1. M/s. Graton Pharma, Karachi from the Principal Manufacturer M/s. Essential Pharmaceutical, Inc. USA
2. M/s. Focus & Rulz, Rawat, Islamabad
3. M/s. Wilshire Laboratories, Lahore
4. M/s. Wilson's Health Care, Islamabad
5. M/s. Global Laboratories, Islamabad
7. M/s. Rafay Laboratories, Karachi
8. M/s. Mac & Rain Health Care, Lahore
9. M/s. Herbion Karachi
10. M/s. Reign Nutraceuticals, Karachi
11. M/s. Dr. Masood Homeopathic Pharmaceuticals, Lahore
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12. M/s. Vida Corporations, Karachi
13. And other applicants whose applications are complete as per checklist

Decision:- The EEC decided to refer the applications to the subcommittee of EEC for product enlistment for evaluation and presentation before the committee for final decision.

Disclaimer:

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

Pakistan Zindabad