



Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority Of Pakistan
Health & OTC Products Division (Non-Drugs)

Islamabad, the 26th August, 2022


“SAY NO TO CORRUPTION”

SUBJECT: SUBMISSION OF DEFICIENT INFORMATION / DOCUMENTS

The applications of following applicants were placed before the Enlistment Evaluation Committee (EEC) in its 109th meeting held on 05th July, 2022 and the same have been deferred being deficient of the information / documents as specified in column (3) of the Table below which may be furnished within 20 days of uploading of this letter on official website of DRAP along with soft data as per **Annexed Format** at the end of this letter/document. Replies received after given time will not be entertained:-

S.No (1)	Brand name (2)	Decision (3)
M/s Prospect Group (Pvt.) Ltd, 125-Upper Mall, Lahore agent of M/s Nutra Manufacturing, 1050 Woodruff Road, Greenville, SC 29607. Subsidiary of General Nutrition Corporation (GNC), USA		
1.	GNC Isomer E Capsule	Deferred with final opportunity
2.	GNC Kids Eye Health Chewable Tablet	Deferred with final opportunity for the provision of following documents: <ul style="list-style-type: none"> • Brand Name mentioned on Form 5 is GNC Kids Eye Health Chewable Tablet • Capsule and brand name given on Exhibit A attached copy of Certificate of Free Sale is Kids Eye Health Chewable Tablet, needs clarification. • Accelerated and long term stabilities data of three (03) batches is required according to requirement of Zone IV A • Manufacturing license of principal manufacturer issued by regulatory body in country of origin duly notarized and counter signed by Embassy of Pakistan, is required.
3.	GNC Brighten Capsule	Deferred with final opportunity for the provision of following documents: <ul style="list-style-type: none"> • Brand Name mentioned on Form 5 is GNC Brighten Capsule and brand name given on COA is Skin lightening Pil Vegetable Hard-shell capsule, needs clarification. • Accelerated and long term stabilities data of three (03) batches is required according to requirement of Zone IV A. • Valid and Notarized fee sale certificate attested by the regulatory body in the country of origin and countersigned by the Embassy of Pakistan in the country of origin • Manufacturing license of principal manufacturer issued by regulatory body in country of origin duly notarized and counter signed by Embassy of Pakistan, is required.
4.	GNC PN Stress Support Caplets	Deferred with final opportunity for the provision of following documents: <ul style="list-style-type: none"> • Brand Name mentioned on Form 5 is GNC PN Stress Support Caplets and brand name given on Exhibit A attached copy of Certificate of Free Sale is PN Stress Support Caplets, needs clarification. • Monograph of Magnolia Bark Extract and Phellodendron Bark Extract are required. • Accelerated and long term stabilities data of three (03) batches is required according to requirement of Zone IV A. • Manufacturing license of principal manufacturer issued by regulatory body in country of origin duly notarized and counter signed by Embassy of Pakistan, is required.
5.	GNC Inositol 500 Tablet	Deferred meeting with the final opportunity for the provision of following documents: <ul style="list-style-type: none"> • Brand Name mentioned on Form 5 is GNC Inositol 500 Tablet

S.No (1)	Brand name (2)	Decision (3)
		<ul style="list-style-type: none"> and brand name given on Exhibit A attached copy of Certificate of Free Sale is Inositol 500 Tablet, needs clarification. Accelerated and long term stabilities data of three (03) batches is required according to requirement of Zone IV A. Manufacturing license of principal manufacturer issued by regulatory body in country of origin duly notarized and counter signed by Embassy of Pakistan, is required.
6.	GNC (INTL) AMP GOLD Thermo Tablet	Deferred with final opportunity for the provision of following documents: <ul style="list-style-type: none"> Brand Name mentioned on Form 5 is GNC (INTL) AMP GOLD Thermo Tablet and brand name given on Exhibit A attached copy of Certificate of Free Sale is INTL AMP GOLD Thermo Tablet, needs clarification. Accelerated and long term stabilities data of three (03) batches is required according to requirement of Zone IV A. Manufacturing license of principal manufacturer issued by regulatory body in country of origin duly notarized and counter signed by Embassy of Pakistan, is required.
M/s Multicare International Compnay (SMC PRIVATE) LIMITED located at the address A-99 Ittefaq Town Road, Near Bohistaan Masjid Sector G-12 Islamabad agent of M/s Shijiazhuang ZDHF Stock Raising Co., Ltd. office No. 260-1 Heping East Road, Shijiazhuang City Hebei Province China. Factory address No 1 yinhai road weixian county industry district Xingtai city Hebei China		
7.	Multi ND Saver Oral Solution	Deferred for clarification of use B-cyloalamine in formulation.
M/s ANB International Pvt Ltd., Suite No. D-01, 1ST Floor, Plot No. 48-D, Commercial Street 21, Phase – II Ext., DHA, Karachi, agent of M/s FeriCare Swiss AG, Seepark 6, CH-9422 Staad, Switzerland (Principal Manufacturer: M/s Alpex Pharma, Via Cantonale 6805, Mezzovico, Switzerland)		
8.	Swiss Energy Collagen Effervescent Tablet	Deferred for following reasons: <ul style="list-style-type: none"> Original Free sale certificate not provided. The document provided as Free sale certificate does not depict that the product is freely available in the country of origin. Clarificatiion regarding the use of name Swill Energy as a brand name required as Swiss energy is neither exporter nor manufacturer.
9.	Swiss Energy Active Tablet	Deferred for following reasons: <ul style="list-style-type: none"> Original Free sale certificate not provided. The document provided as Free sale certificate does not depict that the product is freely available in the country of origin. Clarificatiion regarding the use of name Swill Energy as a brand name required as Swiss energy is neither exporter nor manufacturer.
10.	Swiss Energy Multivitamins + Biotin Tablet	Deferred for following reasons: <ul style="list-style-type: none"> Original Free sale certificate not provided. The document provided as Free sale certificate does not depict that the product is freely available in the country of origin. Clarificatiion regarding the use of name Swill Energy as a brand name required as Swiss energy is neither exporter nor manufacturer.
11.	Swiss Energy Vitamin C 1000mg Tablet	Deferred for following reasons: <ul style="list-style-type: none"> Original Free sale certificate not provided. The document provided as Free sale certificate does not depict that the product is freely available in the country of origin. Clarificatiion regarding the use of name Swill Energy as a brand name required as Swiss energy is neither exporter nor manufacturer.
12.	Swiss Energy Antiage Tablet	Deferred for following reasons: <ul style="list-style-type: none"> Original Free sale certificate not provided. The document provided as Free sale certificate does not depict that the product is freely available in the country of origin. Clarificatiion regarding the use of name Swill Energy as a brand name required as Swiss energy is neither exporter nor manufacturer.
M/s Mcpharm International, 721, J-II, Johar Town Lahore-Pakistan is an agent of M/s Aniva International S.A., 3 Kifissias Av., 15123 Maroussi Athens, Greece (Principal Manufacturer M/s Lifeplan Products Ltd., Elizabethan Way, Lutterworth, Leicestershire LE17 4ND, United Kingdom)		
13.	Lifeplan – Eye C	Deferred for change of brand name.


 (Ayyaz Ahmad)

Secretary, Enlistment Evaluation Committee

ANNEXURE

The firm is directed to submit soft data in both MS Excel & MS Word on following formats in **USB ONLY**.

MS Excel Format

Sr. No.	Company name	Product Name	Dosage Form	Composition	Common name	Recommended use	Pack Size	Date of R&I submission
1.	(Company name, City) Without address	XYZ	Tablet	Each tablet contains: Abc (USP)...50mg	XXX	XXX	10's 20's	DD.MM.YYYY
2.								

MS Word Format

Sr. No.	Company name	Product Name and composition	Common name	Recommended use	Pack Size
1.	(Company name, City) Without address	XYZ Tablet Each tablet contains: Abc (USP)...50mg	XXX	XXX	10's 20's
2.					