

No.F.10-11/2022-DD (Health & OTC) (112-M)

Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
DRUG REGULATORY AUTHORITY OF PAKISTAN

TF Complex, Sector G-9/4, Islamabad

"SAY NO TO CORRUPTION"

Islamabad, the 26th December, 2022

 M/s Uuama International Group, Office No. 8, 1st Floor Safdar Mention, Fazal-e-Haq Road, Blue Area, Islamabad.

as agent of

M/s Zhengzhou Biocaro Pharmaceutical & Healthcare Products Co. Ltd., No.5, Hehuan Street, High Tech Development Area, Zhengzhou, Henan, **CHINA**.

- Zaheer Ud Deen Butt S/o Zahoor Ahamed Butt,
 R/o H#14-A, Lalzar Colony, Tehsil & District <u>JEHLUM</u>.
- 3. Kiani Saeed Iqbal S/o Muhammad Iqbal Kiani R/o H#216, St#15, Sector F, Scheme III, RAWALPINDI CANTT.

Subject:

REVOCATION / CANCELLATION OF FORM-6 (PROVISIONAL CERTIFICATE FOR ENLISTMENT AS MANUFACTURER/IMPORTER) & FORM-7 (PROVISIONAL CERTIFICATE FOR ENLISTMENT OF PRODUCTS).

I am directed to refer the subject cited above and to communicate the decision of Enlistment Evaluation Committee (EEC) taken in its 112th Meeting held on 03rd November, 2022:

02. That the Inspector of Drugs, Islamabad, forwarded the report of M/s Uuma International Group, Ist Floor, Safdar Mention, Blue Area, Islamabad, which is reproduced as under;

"It is submitted that a complaint was posted on twitter wherein the complainant mentioned about alleged fake Neutro Vita Jelly Vites, a nutraceutical by M/s Shaheen Chemist, F-6, Islamabad. The complainant (later in his written complaint submitted on 12-08-2022) further mentioned that on 07th August 2022 (Sunday) at around 9:00pm, he visited M/s Shaheen Chemist, F-6 Markaz Islamabad for the purchase of imported multivitamin supplement "Neutro Vita Jelly Vites" purported to be manufactured by "Biocaro Pharmaceutical & Health Care PROC", China and imported by UUAMA International Group Islamabad. He mentioned/informed that after opining the Bottle (Jar) at home it presented with obnoxious smell and tasted unusual resulting which he looked for the manufacturer website and after

initial probe it was revealed that the product is neither manufactured nor supplied by the said manufacturer in Pakistan.

In pursuance of the said complaint, the undersigned inspected the premises of M/S Shaheen Pharmacy & Chemist F-6 Markaz, Super Market Islamabad on 12.8.2022 in exercise of the powers conferred u/s 18 of the Drugs Act, 1976. During inspection, two bottles (Jars) of the said multivitamins were found in premises, which after fulfilment of necessary legal formalities, were seized and the invoice/warranty issued by M/s Fatima Distributor & Drug Sources, Rawalpindi was taken in custody. Copy of Form-7, purported to be issued by DRAP for enlistment of said product was also obtained.

In order to determine the veracity of said Form-7 and to also ascertain the importer duly approved by the DRAP, the undersigned visited the HoTC Division of Drug Regulatory Authority of Pakistan (DRAP) on the same day. After due verification, it was found that the Form 6 is issued by DRAP to Uuma International Group, Ist Floor, Safdar Mention, Blue Area, Islamabad for import of this product and the same firm has been issued Form-7 for this particular product (Form-6 & Form-7 Annexed-I).

After verification of Form 6 and 7, the undersigned visited the importer address which was mentioned on the Form-6 and Form-7 to further investigate the case and to verify the imported consignment, however, it was noticed with concern that the said importer is not operating at said address.

A notice was also issued to the local distributor (warrantor) i.e M/S Fatima Distributor, & Drug Sources Rawalpindi (who supplied the product to M/s Shaheen Chemist, purportedly after purchasing it form Uuma International) for further inquiry. The said distributor/warrantor submitted the bill invoice on the name of same importer i.e Uuma International Group while giving his address as DHA Phase-I, Islamabad. The undersigned again visited the said address for further investigations, however, shockingly, it was revealed that the said importer (which is approved by DRAP) is not even operating at this address too.

By the investigation conducted so far, it has come to fore that the importer i.e Uuma International Group, which is duly approved by the DRAP and has been issued Form-6 for import of nutraceuticals is not operating from a proper premises and the fact that the consignment of said product is actually imported by him or is packed locally, cannot be commented upon as the importer is operating as street vendor without having any proper premises/address and it is suspected that the supplement in question is being packed locally.

Recommendations:

Based on the above investigation it is recommended that;

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- i. The DRAP may be approached/recommended for the cancellation of Form 6 and Form 7 issued in favor of M/S Uuma International and take legal action against the firm after fulfillment of all legal/codal formalities in this regard;
- ii. DRAP may also be asked to share data of importers of Health & OTC products located in Islamabad with the Health Department ICT, Islamabad for their regular monitoring;
- iii. It is also recommended that DRAP must ensure release of Health & OTC products import consignments while adopting the procedure similar to adopted for drugs and share the imported consignment data to the extent importers operating in Islamabad with Health Department Islamabad for further monitoring at sale level;
- iv. DRAP may take Drug Control Section of the Health Department, Islamabad in loop during the issuance of FORM-6 in the Islamabad Territory and make them part of the inspection teams.

The report is submitted for perusal and further action, please."

03. That the said case was considered by the Enlistment Evaluation Committee (EEC), in its 111th meeting, held on 30th August, 2022 and the Committee decided as under;

The EEC considered the report forwarded by the Inspector of Drugs, Islamabad, wherein it has been revealed that the importer firm M/s UUAMA International Group, located at Office No. 8, 1st Floor Safdar Mention, Fazal-e-Haq Road, Blue Area, Islamabad (agent of M/s Zhengzhou Biocaro Pharmaceutical & Healthcare Products Co. Ltd., No.5, Hehuan Street, High Tech Development Area, Zhengzhou, Henan, China) holding Provisional Enlistment (Form-6) No. 00163, does not exist at the provided address and possibly operating form an unknown place. Therefore, it can not be ascertained that whether the firm is actually importing its products in finished form from the country of origin or they are being produced/packed locally at any unknown place, which is serious cause of concern with respect to public health safety and violates the provisions of DRAP, Act, 2012 and rules framed thereunder. Keeping in view the said facts, the EEC decided to direct the firm to show in writing within 07 days of communication of this decision, that why not provisional enlistment of the firm and its products be revoked. The EEC also decided to call the firm for personal hearing in its next meeting."

O4. That in compliance to the above decision of the Enlistment Evaluation Committee (EEC), a show cause notice was issued to the firm vide No.F.10-10/2022-DD-(H&OTC)-(M-111), dated 02-09-2022. However the firm has not submitted any response. In this regard, the firm has been called for personal hearing to defend their case that why not the provisional enlistment of the firm be revoked/cancelled, on the account of the violations of DRAP Act, 2012. Show cause notice and Personal hearing notices were issued.

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05. Keeping in view of the above the Enlistment Evaluation Committee (EEC), in its 112th meeting, held on 03rd November, 2022 decided as under:

"Decision: As the firm has not submitted any response to show cause and did not appear before the EEC on stipulated date and time, the EEC after threadbare delibration and consideration of the case in detail unanimously is of the opinion that the firm has nothing to present in his defence. Accordingly the EEC decided to revoke the Provisional Enlistment of M/s Uuma International Group, Ist Floor, Safdar Mention, Blue Area, Islamabad, (E. No.00163), with immediate effect in the best interest of public health and safety. The firm is further directed to surrender Certificates of enlistment (Form-6 and all Form-7 issued in favor of M/s Uuma International Group) to the Authority within 7 days of issuance of this decision."

- 06. Therefore, Provisional Enlistment No.00163 dated 07.03.2016 issued in the name of M/s Uuma International Group, Office No. 08, 1st Floor, Safdar Mention, Blue Area, Islamabad stands revoked with immediate effect. You are therefore ordered to surrender Certificates of enlistment (Form-6 and all Form-7 issued in favor of M/s Uuma International Group as agent of M/s Zhengzhou Biocaro Pharmaceutical & Healthcare Products Co. Ltd., China) to the Authority within 7 days of issuance of this decision
- 07. You are therefore directed to comply with the decision of Enlistment Evaluation Committee (EEC) in its letter and spirit.
- 08. If you are aggrieved with the decision of EEC, you may prefer an appeal before the Appellate Board under prescribed rules and procedure within stipulated time.
- 09. This issues with the approval of Chairman EEC.

(Farman Ali Bozdar)

Deputy Director/Designated Officer,
Division of Health and OTC,
Drug Regulatory Authority of Pakistan,
Islamabad.

Copy to:-

- i. Chairman EEC/Director (H&OTC), DRAP, Islamabad.
- ii. The Director, QA<, DRAP, Islamabad for information and necessary action, Please.
- The Director, MIS, DRAP, Islamabad for uploading this letter on official website of DRAP in larger public interest.
 - iv. The Chief Drug Controller, Punjab/Sindh/KPK/Baluchistan/AJK/GB/Sr. Inspector of Drugs, ICT for information and necessary action.
 - v. Office Copy.
- vi. Meeting File.