



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

Most Immediate
Through UMS

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. Convell Laboratories,
Saidu Sharif,
Sawat.

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:

2. That the Additional Director, DRAP, Peshawar, forwarded the Inspection report of M/s Convell Laboratories, Saidu Sharif Swat, holding Drug Manufacturing License (DML) No. 000509 and Provisional Enlistment (Form-6) No. 00121, vide letter No. No. F. 11-58/2005-Convell-DRAP (P), dated 18-05-2022, which is reproduced as under;

“Please refer to the subject cited above and to say that it was learnt from media and reliable sources that building of M/s. Convell Laboratories, Saidu Sharif Swat, having Drug Manufacturing License (DML) No. 000509, granted under the Drugs (Licensing, Registering and Advertising Rules, 1976), has collapsed on 14.05.2022 afternoon. Under the said rules, it is the responsibility of the manufacturer to maintain/ensure/comply with all the conditions required for DML.

In order to assess the factual position, the firm was visited on 17.05.2022. The firm's production manager Mr. Fazal Mabood was available at the firm's premises who informed about the collapse of the building. During the site visit, it was observed that;

i. Major building part of the firm including tablet general, capsule general, liquid syrup general, dry suspension general, tablet psychotropic, ware house, finished goods and section of H&OTC vide E.No.00121 (Tablet, Capsule, Oral Liquid syrup, Sachet) have been totally collapsed.

ii. Some remaining tilted walls/ major slabs are also being demolished by the firm.

iii. Small portion of the building having Ceph section and QC is intact, however, due to major collapse, dirt/ dust, building scrap, this area is also totally nonoperational.

iv. The approved management of the firm was involved in legal matters as informed by technical person and not available at the site. Inspection book was also not available at the time of visit.

In the light of above-mentioned position, it is submitted that the conditions under which DML No. 000509 was granted in accordance with the Drugs (L.R.&A), Rules 1976 of the Drugs Act 1976/ DRAP Act, 2012 no more exist. Hence, the DML No. 000509 of M/s. Convell Laboratories, Saidu Sharif, Swat may be cancelled as per laid down procedure under the DRAP, Act, 2012.”

3. The said case was considered by the EEC, in its 107th meeting, held on 23rd May, 2022 and the Committee decided as under;

“The EEC perused the inspection report of M/s Convell Laboratories, Saidu Sharif Swat (E. No. 00121) and after detailed deliberation on the matter, reached to the conclusion that the firm has failed to fulfill the requirements and responsibilities defined under the DRAP Act, 2012 and rules framed thereunder, regarding quality and safety related to the manufacturing of therapeutic goods. Establishing and maintaining a proper building structure for manufacturing of therapeutic goods, is the prime responsibility of the manufacturer whereas in the instant case a severe negligence has

been observed at the end of the management of the firm which has resulted in the collapse of the building structure and endangered the lives of the staff performing their duties at the manufacturing site. Since the major part of the manufacturing unit has collapsed, there is no reason to allow the firm to continue the provisional enlistment granted earlier under the Alternative Medicines and Health Products (Enlistment) Rules, 2014. Keeping in view the said facts, the EEC decided to revoke the provisional enlistment as manufacturer (Form-6) issued vide No. 00121, dated 01-02-2016 and all the provisional product enlistments (Form-7) granted to the firm at the said manufacturing site."

4. In compliance to the above decision of the EEC, a show cause notice was issued to the firm vide No.F.10-6/2022-DD-(H&OTC)-(M-107), dated 09th June, 2022, but 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 that the major part of the building of manufacturing facility has collapsed. Show cause notice and Personal hearing notices were issued and are not returned back undelivered.

Proceedings and Decision of the EEC:-

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 deliberation 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 (Form-6) No. 00121 of Manufacturer M/s Convell Laboratories, Saidu Sharif Swat, 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 Convell Laboratories) to the Authority within 7 days of issuance of this decision.

5. Therefore, Provisional Enlistment No.00121 dated 01.02.20216 issued in the name of M/s. Convell Laboratories, located at Saidu Sharif, Sawat stands revoked with immediate effect. You are therefore ordered to surrender Certificates of enlistment including Form-6 and all Form-7 issued in favor of M/s. Convell Laboratories, located at Saidu Sharif, Sawat to the Authority within 7 days of issuance of this decision.

6. You are therefore directed to comply with the decision of Enlistment Evaluation Committee (EEC) in its letter and spirit.

7. 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.


26/12/2022

(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.
- iii. The Director, MIS, DRAP, Islamabad – for uploading this letter on official website of DRAP in larger public interest.
- iv. The Additional Director, DRAP, Peshawar – for information and necessary action, Please.
- v. The Chief Drug Controller, Punjab/Sindh/KPK/Baluchistan/AJK/GB/Sr. Inspector of Drugs, ICT – for information and necessary action.
- vi. Area Federal Inspector of Drugs, DRAP, Peshawar – for information and necessary action, please.
- vii. Office Copy.
- viii. Company file.