No. F. 7-3/2011-I&E (Pt)
GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
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Islamabad, the 15th January, 2014

Subject: **GUIDELINES FOR AUTHORIZED OFFICERS UNDER SPECIAL SROs FOR ISSUANCE OF NOC OR APPROVAL FOR IMPORT OF DRUGS UNDER THE DRUGS ACT, 1976 AND RULES FRAMED THEREUNDER.**

1. Under SRO 28 (I)/2013 dated 22nd January, 2013, all applications under special SRO shall be addressed to Authorized Officer.
2. Application shall be accompanied with following documents.
   i. Proof of free sale in country of export shall be substantiated with Free Sale Certificate or Certificate of Pharmaceutical Product or any other document which authorized officer shall deem to fulfill the purpose.
   ii. Certificate of Analysis or conformance.
   iii. An affidavit on stamp paper containing following conditions:-
      a. the imports shall be made with the prior approval of the licensing authority under rule 9 of the Drugs (Import and Export) Rules, 1976;
      b. the drug shall not be sold or distributed in the market;
      c. the drug is on free sale in the country of origin;
      d. the drug shall be used for therapeutic purpose in the hospital or institutions only and not for the purpose of clinical trial, examination, test or analysis;
      e. clearance certificate shall be obtained from Assistant Drug Controller concerned, at the time of arrival of shipment, before customs clearance. Consumption or utilization record must be maintained by the importer, under the supervision of qualified person; and
      f. the drug (generic) is not registered or available in Pakistan.
3. Applications under SRO 28 (I)/2013 dated 22nd January, 2013 through commercial importers shall be discouraged.
4. Under SRO 334 (I)/2010 dated 18th May, 2010, all applications under special SRO shall be addressed to Authorized Officer.
5. Application shall be accompanied with following documents.

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i. Proof of free sale in country of export shall be substantiated with Free sale certificate or Certificate of Pharmaceutical Product or any other document which authorized officer shall deem to fulfill the purpose.

ii. Certificate of Analysis or conformance.

iii. Certificate of donation from donor.

iv. Copy of packing list

v. Copy of invoice.

vi. An affidavit of stamp paper containing following conditions:-

   a. the drug does not contain any narcotic or psychotropic ingredient;
   b. the drug is allowed to be sold freely in the country of its origin;
   c. the drug has minimum of six months expiry; and
   d. the drug shall not be sold, in any form in the market in Pakistan

6. The Authorized Officer shall dispose off the case with in five (05) working days.

7. He shall give five (05) more working days to the applicant to complete formalities, if application so submitted is incomplete. The Authorized Officer shall dispose off the application, if applicant fails to comply. Aggregate of not more than 10 working days shall be taken for disposal of cases under all circumstances.

8. If Authorized Officer is unable to decide the case, due to any reason of difficulty, within five (05) days as mentioned above, he shall refer the case to Licensing Authority through Director (QA), Drug Regulatory Authority of Pakistan, Head Quarters, Islamabad without delay with justified reasons of inability to dispose off the case. He shall have to provide explanation, whiling referring the case, for unnecessary delay, if occurred, in disposal of case or referring the case to Licensing Authority.

9. The decision communicated from Drug Regulatory Authority of Pakistan, Head Quarters shall be final for implementation by the Authorized Officer with out delay.

10. The Authorized Officer shall submit by 5th of each month detailed activity report (hard copy by courier and soft copy by mail) to Director (QA), Drug Regulatory Authority of Pakistan, Head Quarters, Islamabad for perusal of Licensing Authority. The Deputy Director General (E&M) shall be responsible for data submission at Head Quarters.

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