F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 13/3/2020

NOTICE

Subject: Guideline for approval of synthetically manufactured drug which has been previously approved as r-DNA derived drug – reg.

Under the New Drugs and Clinical Trials Rules, 2019, CDSCO grants permission for import/manufacture of new drugs for sale and distribution.

Regulatory pathway regarding approval of synthetically manufactured drug that refers to a previously approved drug of r-DNA origin has been under discussion for quite some times now.

In this regard, it is clarified that for approval of such synthetically manufactured drug which has been previously approved as r-DNA derived drug, the applicant is required to submit application as a subsequent new drug (synthetic peptide and other than biological product) and such application will be processed considering all aspects of safety, efficacy as per the New Drugs and Clinical Trials Rules, 2019. Further, first time synthetically manufactured peptide will also be treated in similar manner.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

All Stakeholders.