F. No. 12-01/24-DC(Pt-104)

Government of India

Directorate General of Health Services

Central Drugs Standard Control Organization

(New Drugs Division)

FDA Bhawan, Kotla Road
New Delhi
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CIRCULAR

The requirement for toxicity studies for New Drugs, Subsequent New Drugs (SNDs), Fixed Dose Combinations (FDCs) excluding biological products and Investigational New Drugs (INDs) were reviewed and the following points are reiterated from NDCT Rules, 2019.

1) A repeated dose toxicity study is required for new drugs as per clause 2, 1.1 of the NDCT Rules, 2019. However, this requirement may not be mandatory in certain cases as outlined below:
   a. Second schedule, Table 1, 4(note) specifies that "Where the data on animal toxicity as per the specifications of clause 2 has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing."
   b. Second schedule, clause 2 (1.8, Note(1)) of NDCT Rules state that "Animal toxicity data generated in other countries may be accepted and may not be asked to be repeated or duplicated in India on a case to case basis depending upon the quality of data and the credentials of the laboratory where such data has been generated."

In view of the above, it has been decided to accept already generated preclinical toxicity data for review in the case of Drug Substance and Drug Product, based on the quality of data and the credentials of the laboratory where such data has been generated.

However, the animal toxicity data needed in certain cases such as new claims namely, indications, dosage, dosage form or route of administration etc. should be determined on case by case basis depending on the nature of new claims as well as the mechanism of action etc. and non-clinical data already generated with the drug in the approved claim. Use of unapproved excipient in the formulation will require relevant safety data.

Furthermore, as per the NDCT Rules, 2019, "sub-acute animal toxicity studies for intravenous infusions and injectables" data is still required to be submitted by an applicant for grant of permission to import or manufacture such new drug as mentioned in Second schedule, Table 2, 4.2.

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Drugs Controller General (India)

To

1. All the concerned applicants

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1. JS(R) Ministry of Health and Family welfare
2. All the JDCs(I) and DDCs(I)
3. O/o the DCG(I)
4. CDSCO Website