ANX 6

13. Subject: Manufacture/ import of APIs in contravention with the legal provisions- regardin g

Sir,

Recently CDSCO has conducted raids across the country in the premises of various firms who are dealing with Active Pharmaceutical ingredients (APIs) to verify compliance to the provisions under Drugs and Cosmetics Act and Rules made thereunder.

The raids were conducted at M/s. Kawarlal & Co. and M/s Nutranol ingrdients at Chennai and further Continued the investigation at other places based on the information obtained during the raids at Chennai.

During the raid at M/s. kawarlal & Co., the drugs namely, Erythromycin Stearate, Veraoamil Hydrochloride, Megestrol Acetate, Trimetazidine Dihydrochloride, Silymarin 70 %, FOLIC Acid and Calcium D Pantothenate have been seized for contravening various provisions of the Act and Rules.

From the raids it is revealed that drug Sulphamethoxazole labeled to be manufactured by M/s Andhra Organics Ltd., India and Emtricitabine labeled to be manufactured by M/s. SMS Pharmaceuticals Ltd. , India supplied by M/s.Nutranol Ingredients, Chennai were deemed to be spurious as the manufacturers mentioned on the label denied manufacturing the said drug.

It was found that many drugs, whose source could not be established, were distributed by the aforesaid firms, M/s. Kawarlal & Co., Chennai and M/s. Nutranol Ingredients, Chennai to various manufacturers in the country. In certain cases these firms have sold certain APIs in quantities excess to their purchase. Many of the APIs supplied by these firms claim to have been purchase. Many of the APIs supplied by these firms claim to have been manufactured in china which are not found registered with CDSCO.

In view of the above, it is requested to verify the availability of aforesaid drugs supplied by aforesaid firms, with the manufacturers under your control. In case any of the aforesaid drugs are found unutilized with any of the formulation manufactures/ traders, you are requested to issue suitable directions to them to stop use of the APIs and take appropriate steps such as seizure, etc.

You are also requested to carry out further investigation on all the other APIs supplied by the aforesaid firms to ensure that the APIs have been manufactured / imported in compliance with the provision of the Act and Rules. Further, all the manufacturers under your jurisdiction, whoever have procured APIs from the aforesaid firms, may be directed to verify the certificate of Analysis (COAs) as well as source of manufacture or samples of the APIs/ formulations may be

got tested at laboratory and appropriate action should be taken under the provisions of the Act and Rules.

The matter may be accorded top priority and the action taken may please be intimated to this office.

14. MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

Notification

New Delhi, the 24th June, 2019

Subject: issue draft notification 447 copy of notification is attached.

G.S.R. 447(E).- The following draft certain rules further to amend the drugs and Cosmetics Rules, 1945. Which the Central Government proposes to make in exercise of the powers conferred by sub- section (1) of section 12 and sub- section (1) of section 33 of the drugs and cosmetics Act, 1940 (23 of 1940), in consultation with the drugs Technical Advisory board is hereby Published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of thirty days from the date on which copies of the Gazette of india containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any , may be addressed to the under Secretary (Drugs), Ministry of health and Family Welfare, Government of india, Room No. 414A, D Wing, Nirman Bhavan, New Delhi – 110011 or emailed at drugsdiv-mohfw@gov.in

DRAFT RULES

1. (1) These rules may be called the drugs and cosmetics (…….Amendment ) Rules, 2019.

(2) They shall come into force on the date of their final publication in the official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (here in after to be referred as said rules) in rule 2,-

2. In the Drugs and Cosmetics Rules, 1945 (here in after to be referred as said rules) in rule 2,-

(1) after clause (e), the following clause shall be inserted, namely:-

"(ea) ' Marker' means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution."

(ii) after clause (ea) the following existing clauses (ea) and (eb) shall be renumbered as (eb) and (ec), respectively.

3. In the said rules, after rule 84D , the following rule shall be inserted, namely:-\
" 84E. Responsibility of marketer of the drugs: any marker who sells or distributes any drug shall be responsible for quality of that drug as well as other requlatory compliances along with the manufacturer under these rules."

4. In the said rules, in rule 96, after sub clause (xii) of clause (i), the following sub- clause shall be interested, namely:-

"(xiii) (a) the name of the marketer of the drug and its address, in case the drug is marketed by a marketer:

Provided that if the drug is contained in an ampoule or a similar Container, it shall be enough if only the name of the marketer is shown,".