



Pharmaceuticals Limited

Registered & Corporate Office :

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CIN : L24239TG1987PLC008066

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Date: 9th April, 2020

To,

The Manager,
Corporate Filings Department,
BSE Limited,
Phiroze Jeejeebhoy Towers,
Dalal Street,
Mumbai- 400 001

The Manager,
Listing Compliance Department,
National Stock Exchange of India
Ltd. Exchange Plaza, Plot no. C/1,
G Block, Bandra-Kurla Complex,
Bandra (E), Mumbai - 400 051.

Security Code: 532815

Symbol: SMSPHARMA

Dear Sir,

Sub: "SMS Pharmaceuticals Limited (SMS Pharma) provides updates against USFDA statement in connection with Ranitidine"

In September 2019, The USFDA has observed that, some ranitidine medicines contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. We are one of the manufacturer of Ranitidine HCl Active Pharmaceuticals Ingredient (API).

We understand that through the FDA news release, The US Food and Drug Administration (USFDA or the Agency) has requesting Ranitidine formulation manufacturers to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. This is the latest step taken by FDA in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications. FDA also made a statement as **"We didn't observe unacceptable levels of NDMA in many of the samples that we tested. However, since we don't know how or for how long the product might have been stored, we decided that it should not be available to consumers and patients unless its quality can be assured"**.

As a Ranitidine HCl drug substance manufacturer, we have performed the detailed risk assessment study for the formation of NDMA impurity in the Ranitidine HCl drug substance. It is observed that, the NDMA impurity is increasing in the storage of the drug substance. Also, we have identified the root cause for the same. Based on the risk assessment study, we have modified the process of Ranitidine HCl drug substance to control the NDMA impurity during the storage and the modified process details has been submitted to the FDA. The modified process material is more stable and the NDMA impurity is well controlled in our modified process of the Ranitidine HCl drug substance.



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FDA has also requested all the formulators of Ranitidine HCl to provide the stability data of the drug product at the elevated long term stability conditions to confirm the stability data of the drug product w.r.to NDMA content. Some of our customers has initiated the FDA recommended stability studies.

We have already submitted the available stability of Ranitidine HCl drug substance to the USFDA authority recently (March 2020). As per the normal process of GMP guidelines, the USFDA has conducted CGMP inspection in our API manufacturing facility during January 2020 and subsequently we have received the EIR report. The validation batches of modified process have been already initiated for the required stability studies and the stability data shall be updated to the Authority as required. We anticipate this activity would take about 9 to 10 months period.

We further inform you that, till date we have not sold any Ranitidine API for the commercial distribution in the US. Whatever the quantities sold are for the purpose of drug product development and the product has not entered into commercials till date in the US Market.

The share of SMS Pharmaceuticals Ltd's revenue contributed from Ranitidine product during the last couple of year is below 1% of the total revenues. Hence, there is no material impact on the company's current and future revenues as well as margins.

In view of the above, our commercial supplies of the Ranitidine HCl drug substance to our customers for US market from us is currently delayed by 9-10 months and expected to start by end the current calendar year. In the mean time we will utilize these capacities to other existing products, hence, no impact on our operations as well as revenues during the current financial year as well as future years.

This is for your information and records.

Thanking you,

Yours faithfully,

Sd/-

V.S.Venkatish
Company Secretary