SMS Lifesciences India Limited
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To,

Date: 04.11.2019

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

Security Code: 540679

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.

Symbol: SMSLIFE

Dear Sir/Madam,

Subject: Update on Ranitidine HCL.

In Continuation to our earlier communication dated 10th October, 2019, we would like to inform you that the USFDA has issued a Press release on November 01st, 2019 and it states that consuming up to 0.096 micrograms or 0.32 parts per million (ppm) of NDMA per day is considered reasonably safe for human ingestion based on lifetime exposure. Through their testing so far, they have found levels of NDMA in Ranitidine HCL that are similar to the levels you would expect in common foods like grilled or smoked meats.

In this connection, we would like to inform you that we are confident of manufacturing Ranitidine HCL well within the limits as mentioned in the said press release issued by the USFDA i.e. lower than 0.096 micrograms or 0.32 parts per million (ppm)

The press release from the USFDA is been enclosed for your reference.

Kindly take the same into your records.

Thanking you

Yours Faithfully

For SMS Lifesciences India Limited

Pavan Pise
Company Secretary

For Immediate Release : November 01, 2019.
Statement from : Director - Center for Drug Evaluation and Research Janet Woodcock M.D.

Statement on new testing results, including low levels of impurities in ranitidine drugs

Summary

- The agency has tested numerous ranitidine products on the market over the past few months, and today we're releasing a summary of the results we have to date. Through our testing so far, we have found levels of NDMA in ranitidine that are similar to the levels you would expect to be exposed to if you ate common foods like grilled or smoked meats.
- Not all ranitidine brands had NDMA above permissible limits. We also conducted tests that simulate what happens to ranitidine after it has been exposed to acid in the stomach with a normal diet and results of these tests indicate that NDMA is not formed through this process. Similarly, if ranitidine is exposed to a simulated small intestine environment, NDMA is not formed.
- FDA also developed a simulated gastric fluid (SGF) model to be used with the LC-MS testing method to estimate the biological significance of in vitro findings. The SGF and simulated intestinal fluid (SIF) models are intended to detect the formation of NDMA in systems that approximate the stomach and intestinal fluids, respectively. The results of these tests showed no additional NDMA generated in the stomach. Although many of these levels of NDMA observed through FDA testing are much lower than the levels some third-party scientists first claimed
- For reference, consuming up to 0.096 micrograms or 0.32 parts per million (ppm) of NDMA per day is considered reasonably safe for human ingestion based on lifetime exposure. (which means, if a person consumes 0.32ppm/0.096mg of NDMA for entire life of 70 years)
- FDA has set the acceptable daily intake limit for NDMA at 0.096 micrograms or 0.32 ppm for ranitidine. The calculated acceptable intake for NDMA in drugs is based on methods described in the 2018 ICH Guidance M7(R1) *Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*. If ONLY NDMA levels above the acceptable limits (96 nanograms per day or 0.32 ppm), we are asking companies to voluntarily recall ranitidine. If within permissible limit, needs no recall and its safe.

https://www.fda.gov/drugs/drug-safety-and-availability / https://www.fda.gov/news-events/press-announcements