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Website:www.unfpaprocurement.org/prequalification-programme

To: Nulatex Sdn Bhd, Malaysia

Date: January 10, 2020

Ref: **Notice of Concern on the male latex condoms manufactured by Nulatex Sdn Bhd under the WHO/UNFPA Prequalification Programme**

Dear Tharampal Singh

During the inspection carried out for the WHO/UNFPA prequalification re-assessment of Nulatex Sdn bhd in November 2018, there were major findings made. The manufacturer was requested to submit a response detailing the corrective and preventive actions to be implemented to address these findings. The documentation submitted in response to the findings has been reviewed and found inadequate. We regret to inform you that UNFPA is issuing a Notice of Concern against Nulatex Sdn Bhd in light of the inadequacy of the response submitted, as shown in the summary table below. The Notice of Concern (NOC) will be published on the UNFPA website, until the manufacturer submits acceptable corrective and preventive action, and will remain in effect until implementation of all the CAPA has been verified onsite, through a full prequalification inspection.

In the interest of public health, Nulatex Sdn Bhd will be removed from the list of WHO/UNFPA prequalified manufacturers with effect from **10 January, 2020.**

Table 1: *Summary of outstanding observations and evaluation of documentation*

Observation	**Evaluation of response**	**Status (Accepted/ Not Accepted)**
The organization had not implemented the committed CAPA in relation to handling and disposal of scrap and rejected condoms as given in the CAPA plan (Ref: Minutes of the meeting held on 5 May, 2016) submitted by them. The actions on identification of approved scrap contractor, implementation of shredding of rejected condoms, timely disposal of rejected condoms, orderly storage of scrap condoms and documentation of scrap condoms from departments to the warehouse and its verification – had not been implemented. Still there are huge piles of rejected and scrap	The reasons for not implementing the committed CAPAs have not been explained in the CAPA, although the actions to be taken since the inspection have been submitted. a) The reasons for sending the condoms in un-shredded condition and the inconsistencies in the labelling and documentation of materials have not been clarified. b) The letter from the agent, who was not authorised, is general in nature and does not give details of quantities of scrap used for the said purposes and does not confirm that	**Not Accepted**

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Observation	Evaluation of response	Status (Accepted/ Not Accepted)
condoms, in unrolled, rolled, foiled and consumer packed conditions. The rejected finished goods of SABS were stored in the proposed expansion area without adequate control. 25,000 Kgs of "Rejected condoms" had been sent to a service provider outside Malaysia/in India in 2018. The shipping advice had the description as "Reject condoms", while the other documentation such as packing list, invoice, bill of Lading had the description documented as "Rubber condoms untested" in loose bulk bags. The shipping documents stated that they had been packed in 1,262 gunny sacks. This is classified as critical nonconformity because a) the committed CAPA had not been implemented and b) the rejected condoms had been sent to unauthorised agency in un-shredded condition, which poses a threat of potential misuse.	they were shredded before using for the said products. This still poses the risk of 'Rejected' condoms being exposed to potential misuse. The shredding of condoms is reported to have been implemented only from October 1, 2019, which is almost a year since the inspection. No details have been submitted regarding the huge pile of rejected products observed at the time of inspection and subsequent accumulation of rejected condoms. The schedule to shred them and dispose them has not been submitted.	
The composition of lots was not homogenous, as some of the batches (sub lots) of products were not processed in sequence, giving gaps in processing flow of dates. E.g. Lot No: S1811/02 had bins; 18K13DLNS -1 and 18K13DRNS -7; the Lot 1809/08 had discontinuous dipped products of 18F04BRNR -1 and 18F05BRNR-1,2,3,4,6,7,8,9; Lot 1811/23 had dipped products of discontinuous bins from 26 and 29 June, and 1,9,10 and 11 of Aug.	**The SOP**//06/002D has been reviewed. It does not define the composition of lots and does not require that the lots be made up of homogeneous sublots.	**Not Accepted**
Large quantities of rejected and non-moving foils were stored in different parts of warehouse without control on the storage condition, identification and status	The identification on the foil rolls has been reviewed and accepted. No definite schedule of disposal of rejected foils has been submitted	**Not Accepted**

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Observation	Evaluation of response	Status (Accepted/ Not Accepted)
labelling and were contaminated heavily due to accumulated dust. Some of the foils had been procured on 19.11.2012. The residues of rolls of foils returned from production area were not properly identified and labelled.		
Stability studies and shelf life estimation: For the first series, which is complete, the detailed data for the last 3 years of the trial were lost. The summaries are available, but the results are erratic, suggestive on inhomogeneous product. Two new series have been started, natural smooth in 2017 and pink smooth in 2018 . The 2017 accelerated data appear fine. The samples have not been selected and treated in accordance with the company's limits for storage of product prior to foiling. The 2017 series should continue, but the 2018 series should be assessed to see whether the time from dipping to foiling is adequate for the study.	No Definite schedule has been committed to conduct/ restart stability studies in accordance with ISO 4074: 2015. Supporting data have not been provided. Explanation for not complying with the requirement of storage prior to foiling has not been provided.	**Not Accepted**
The process parameters defined in the SOP for dipping were not in line with the conditions in which the dipping line had been validated. The process parameters in the SOP were wider than those with which validation had been done. The dipping machine speed had been specified as 80 to 140 pcs/minute, while the validation had been done only in the range of 90 to 94 pcs/minute.	The results of the products dipped at different speeds have not been submitted	**Not Accepted**

Right to make an appeal

An NOC contains the factual information based on product testing and/or observations made during an inspection. Results from testing will have been shared with the manufacture and observations will have been discussed during the inspection and listed in the inspection report. Generally, the results or facts that form the basis of the observation(s) are not in dispute. However, the manufacturer, testing laboratory or agencies may disagree that a risk exists or with the level of risk identified by UNFPA and that has resulted in the issuing of the NOC.

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If the manufacturer disagrees with any aspect of the inspection report and subsequent NOC, it should send information to UNFPA that gives the basis for its disagreement by email (psb.prequalification@unfpa.org). The matter will then be investigated and a response provided within 15 working days. Should the site not be satisfied with the response, a one to one discussion, via teleconference may be arranged.

Please do not hesitate to contact us at psb.prequalification@unfpa.org for any clarifications.

Thank you,

Seloi Mogatle
Technical Specialist
UNFPA, Procurement Services Branch