World Health Organization

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In reply please refer to: V2-447-3/ML/DS/1

Your reference: 008-007, NP2019-009

Bayer S.A.S
Mr Jean-Christophe Thomas
Rue Jean-Marie Leclair
CS 90106
69266 Lyon
France

28 October 2020

Dear Mr Thomas,

WHO Prequalification Unit (PQT) – Vector Control Product Assessment Team (VCP)
Letter of Prequalification

Product number: 008-007

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

- Fludora Co-Max – PQ Reference Number 008-007

has been completed and it has been found to meet the norms and standards recommended by the World Health Organization (WHO) for indoor and outdoor space spraying and is acceptable, in principle, for procurement by the United Nations (UN) and other international agencies and countries.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of ISO 9001 Certification at the facilities used for the manufacture of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, the product will now be included on the list of vector control products, which are considered to be acceptable, in principle, for procurement by UN and other international agencies and countries. This list is published by WHO at http://www.who.int/pq-vector-control/prequalified-lists/en/.

Please note that inclusion on the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products will be removed from the list. The failure of an applicant or a manufacturer to participate in the reassessment procedure will also lead to removal from the list.

Yours sincerely,

Mr Deus Mubangizi
Unit Head
Prequalification Unit
Regulation and Prequalification Department