World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 3717
Fax direct: +41 22 791 4730
E-mail : prequalassessment@who.int

In reply please
refer to the WHO product Ref N°: HA456

Your reference:

Mr Kameshwar Bhardwaj
General Manager - Regulatory Affairs
Matrix Laboratories Ltd
1-1-151/1, 5th Floor, Sairam Towers
Alexander Road
500 003 Secunderabad
Andhra Pradesh
Inde

11 November 2009

Dear Mr Bhardwaj,

WHO Prequalification of Medicines Programme

This is in reference to your letter expressing Matrix Laboratories Limited's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and amended subsequently in the Forty-first report, as published in the WHO Technical Report Series N° 943 in 2007.

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

- Abacavir (as sulfate)/Lamivudine 60 mg/30 mg Tablets - HA456

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO, and is acceptable in principle for procurement by UN agencies.

This conclusion is based on information available to WHO at this time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us.

Thus, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

Please note that inclusion in 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 listed. 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 details to WHO of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

ENCL: (2)

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Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, please:

- consult the "Guidance on variations to a prequalified product dossier", as adopted in 2006 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 6 of the WHO Technical Report Series N° 943 in 2007, and
- submit the respective information about the intended variations and the required additional data by email to – "prequalassessment@who.int", and in hard copy, clearly marked as indicated below, to the following address:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification of Medicines Programme

  UNICEF Supply Division
  UNICEF Plads – Freeport
  2100 Copenhagen
  Denmark

Finally, we should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. In this regard 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 and manufacturing sites will be removed from the list. Failure of an applicant or a manufacturer to participate in the reassessment procedure (as set forth in the above-mentioned Guiding Principles) will also lead to removal from the list.

WHO welcomes your company's voluntary participation in this programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Matrix Laboratories Limited and the WHO Prequalification of Medicines Programme, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*), and return these, signed by a duly authorized representative of Matrix Laboratories Limited, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification of Medicines Programme
HSS/PSM/QSM
20 Avenue Appia
1211 Geneva 27
Switzerland.

We look forward to receiving this information from you by 25 November 2009 at the latest. For further information please use the e-mail address – prequalassessment@who.int – and kindly ensure that any correspondence mentions the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Head of Assessments
Prequalification Programme
Quality Assurance and Safety: Medicines