DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MUTUAL CONFIDENTIALITY ARRANGEMENT AND COMMITMENT NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY AND BETWEEN THE U. S. FOOD AND DRUG ADMINISTRATION WITHIN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE QUALITY ASSURANCE AND SAFETY: MEDICINES UNIT OF THE WORLD HEALTH ORGANIZATION

Whereas as part and in the course of the discussions between the United States Food and Drug Administration within the Department of Health and Human Services (HHS/FDA) and the Quality Assurance and Safety: Medicines Unit of the World Health Organization (WHO/QSM), aimed at coordinating and facilitating the HHS/FDA's regulatory activities and WHO/QSM's activities to assess the acceptability in principle of certain health related products for procurement by United Nations (UN) Agencies (hereinafter also referred to as WHO/QSM's "pre-qualification activities"), each party may (as "the Disclosing Party") disclose to the other party (as "the Receiving Party") certain information relating to its aforesaid activities that it considers non-public, confidential or proprietary to it or parties collaborating with it.

Whereas the aforesaid information may include confidential product and/or commercial information; trade secret information; personal privacy information; law enforcement information; and/or internal, pre-decisional information.

Whereas the Disclosing Party will advise the Receiving Party of the non-public, proprietary or confidential nature of the information it intends to disclose, at the time of disclosure. In addition, the Disclosing Party will mark the information in question as confidential, or in the case of oral disclosure, will confirm the non-public, proprietary or confidential nature of the information to the Receiving Party in writing within 15 (fifteen) calendar days after oral disclosure. Any information of the type described in the previous paragraph and designated by HHS/FDA or WHO/QSM, as the case may be, as non-public, proprietary or confidential as aforesaid is hereinafter referred to as "Information".

Whereas HHS/FDA and WHO/QSM are willing to disclose Information to each other for the sole purpose of undertaking discussions aimed at coordinating and facilitating HHS/FDA's regulatory activities and WHO/QSM's pre-qualification activities (hereinafter referred to as "the Purpose").

Whereas HHS/FDA and WHO/QSM each affirm that they have the authority to protect Information from public disclosure.

Therefore, HHS/FDA and WHO/QSM each agree that in accepting Information as Receiving Party from the other as Disclosing Party, they shall abide by the following:

(a) The Information disclosed by one Party ("the Disclosing Party") shall be treated by the Party receiving such Information ("the Receiving Party") as strictly confidential. The Receiving Party shall use such Information only for the Purpose and shall make no other use thereof unless and until a further agreement is executed with the Disclosing Party and/or, where appropriate, the owner of the Information in question permits such other use thereof. In connection with the foregoing, the Receiving Party shall restrict access to Information received from the Disclosing Party hereunder strictly to those persons within its organization (i.e., HHS/FDA or WHO/QSM, as the case may be) who have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement. For the avoidance of doubt and for purposes of this Arrangement "persons within its organization" shall, for WHO/QSM, include WHO/QSM experts and temporary advisers (provided always, of course, that such experts and temporary advisers have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement).

(b) The Receiving Party will not publicly disclose Information from the Disclosing Party without the written authorization of the owner of such Information, the written authorization from the individual who is the subject of the personal privacy Information, or a written statement from the Disclosing Party that the Information is no longer subject to the obligations contained herein.

(c) Nothing in this Arrangement shall prevent the Disclosing Party from disclosing its own Information to any third party.

(d) Nothing in this Arrangement shall be construed as a grant to the Receiving Party of any rights to the Information.

(e) The Receiving Party undertakes to maintain the Information received from the Disclosing Party in confidence. In this regard, the Receiving Party shall take all reasonable measures to ensure that the Information shall not be used for any purpose other than the Purpose, and shall only be disclosed to persons within its organization who have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained in this Arrangement.

(f) The obligations of confidentiality and restrictions on use referred to above shall not apply to any part of the Information which the Receiving Party is clearly able to, and does, demonstrate to the Disclosing Party:

(i) was lawfully in its possession and known to it (without any obligation of confidentiality) prior to disclosure by the Disclosing Party (as evidenced by written records or other competent proof); or
(ii) was in the public domain or the subject of public knowledge at the time of disclosure by the Disclosing Party; or
(iii) becomes part of the public domain or the subject of public knowledge through no fault of the Receiving Party; or
(iv) becomes available to the Receiving Party from a third party not in breach of a legal obligation of confidentiality; or
(v) was subsequently and independently developed by or on behalf of the Receiving Party without access to the Information of the Disclosing Party.

(g) In addition, the Receiving Party shall be permitted to disclose Information received hereunder as may be strictly required by order of competent legislative or judicial authorities to which is it directly subject, provided that the Receiving Party shall:
(i) immediately notify the Disclosing Party in writing of any effort made to obtain Information of the Disclosing Party by such order, and provide adequate opportunity to the Disclosing Party to object to, or restrict, such disclosure or request confidential treatment thereof; and
(ii) take all reasonable measures in an effort to ensure that the Information in question will be disclosed to such competent legislative or judicial authorities in a manner that protects such Information from public disclosure.

Upon completion of the Purpose, each Party shall, upon written request from the other Party, promptly return to the other Party, or destroy, all of the Information received from the other Party, except that each Party may retain one copy of the Information in its confidential files for archival purposes only.

(h) Any notice to be given under this Arrangement shall be deemed to be sufficiently given for all purposes if successfully transmitted by facsimile and confirmed by mail, or if sent by registered mail or recorded delivery post (postage prepaid) addressed to the Party to be notified at the following address:

If to WHO/QSM: Department of Medicines Policy and Standards
Attn: Coordinator, Quality Assurance and Safety: Medicines (QSM)
20, avenue Appia
1211 Geneva 27
Switzerland
Tel.nr: + 41 22 791 44 20
Fax. nr: + 41 22 791 15 98

If to HHS/FDA:

Office of International Programs
Attn: Beverly Corey, D.V.M.
5600 Fishers Lane (HFG-1)
Rockville, MD 20841
United States of America
Tel. nr: +1 301 827 4480
Fax. nr: +1 301 827 0003

(i) This Arrangement constitutes the entire understanding of the Parties hereto with respect to the subject matter hereof and shall not be modified except by mutual agreement in writing.

(j) The Receiving Party will promptly inform the Disclosing Party of any circumstances or changes that would affect its ability to honor the commitments in this Arrangement.

(k) Nothing in or relating to this Arrangement shall imply an obligation on the part of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO under any national or international law, convention or agreement.

(l) In the unlikely event that any difference shall arise in the interpretation or application of this Arrangement, the matter shall be submitted to the Director of the Office of Global Health Affairs within the U.S. Department of Health and Human Services and to the Director, Office of the General-Director of the World Health Organization, who will settle the question personally and jointly or through their duly authorized representatives.

Agreed and accepted
on behalf of HHS/FDA:

Signature: _____

Name: Lester M. Crawford, D.V.M., Ph.D.
Title: Commissioner of Food and Drugs

Date: August 11, 2005

Agreed and accepted
on behalf of WHO/QSM:

Signature: _____

Name: Dr. V. Lepakhin
Title: Assistant Director-General,
Health Technology and
Pharmaceuticals

Date: August 11, 20