DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

CONFIDENTIALITY COMMITMENT

The FOOD AND DRUG ADMINISTRATION

Introduction:

The Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) and the Food and Drug Administration (FDA) of the United States of America (US) are the regulatory authorities with responsibility in their respective countries for the authorization, granting, renewal, variation, suspension, and revocation of licenses, certificates, or other regulatory mechanisms relating to those medicinal products and medical devices for human use which are clinically investigated, marketed, supplied, manufactured, or assembled in the UK and US respectively.

The FDA, an operating division of the United States Department of Health and Human Services, affirms that it is authorized under its regulations at 21 C.F.R. § 20.89 ("Communications with Foreign Government Officials") to disclose otherwise non-public information to the MHRA regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

Both regulatory authorities consider that from time to time circumstances will arise in which sight and/or knowledge of information held by one authority will assist the other in conducting its regulatory functions in relation to medical devices or of ensuring the safety, quality, and efficacy of medicinal products for human use under clinical investigation, authorized for marketing, or under review for marketing authorization in both the UK and the UK.

Therefore, the FDA is pleased to co-operate with the MHRA to facilitate the sharing of otherwise non-public documents and information for these purposes and by this document sets out a framework understanding of the information which they may share with each other and the basis upon which they may share it. This co-operation and framework understanding shall not create any kind of legal obligation on the part of the MHRA or the FDA.

In this context the term "medicinal products for human use" excludes all medicinal products subject to evaluation or authorized by the European Medicines Agency (EMEA) under the centralized procedure as well as medicinal products authorized at national level by EU Member States that are subject to official European Community arbitration and referrals.

Types of Information that May Be Shared between the two Regulatory Authorities:

The types of information that may be shared include, but are not limited to:

1. Post – authorization pharmacovigilance data held by an authority which raises safety concerns about a product manufactured or distributed in the territory of the other.

2. Information on quality defect or product recalls held by an authority in relation to medicinal products and medical devices which are distributed or have been manufactured in the other.

3. Information contained in marketing authorization applications and applications to vary the same which are of significant public health interest to the authority to which they are disclosed.

The regulatory authorities, their officials or representatives, may limit the scope of the above information, particularly if its dissemination or exchange may harm the commercial interests of a third party, breach a duty of confidence or privacy attaching to the information, disclose a trade secret, or be contrary to the public interest or the interests of the authority. In some cases, exchange of information under this understanding may be subject to prior agreement from the companies or individuals concerned.

The Bases Upon Which this Information Is Shared between the two Regulatory Authorities:

Both authorities recognize that it is an essential element of this understanding that confidential information emanating from one party to the other will be treated as such, and agree, to the extent permitted by their respective laws, to keep the information exchanged confidential.

Some of the information the MHRA may share with the FDA may include non-public information exempt from public disclosure under the laws and regulations of the US, such as confidential commercial information (including information referenced in the US Freedom of Information Act, 5 U.S.C. s. 552(b)(4)), trade secret information, personal privacy information, law enforcement information, or internal pre-decisional information. This non-public information is shared in confidence with the FDA, and the MHRA considers it critical that the FDA maintain the confidentiality of this information. The MHRA will advise the FDA of the non-public status of the information at the time that the information is shared.

The FDA affirms that it has the authority to protect such non-public information provided to it (including its officials and representatives) by the MHRA, and will protect such information as information not to be disclosed under the US Freedom of Information Act. The FDA understands that the MHRA considers it crucial that such non-public information should not be disclosed without the consent of the MHRA and that disclosure made without such consent could endanger the international relations between the parties.

MHRA is of the view that the disclosure by the FDA of any non public information provided to it (including its officials and representatives) by the MHRA could seriously jeopardize any further scientific and regulatory interactions between the FDA and the MHRA and would prejudice the international relations between the MHRA and the FDA. The MHRA considers that it is crucial that this non–public information is protected from disclosure and that the condition of sharing this non-public information with the FDA is that it be held in strict confidence by the FDA.

The FDA affirms that it has the authority on this basis to protect non-public information, including confidential commercial information, provided to its officials or representatives by the MHRA as exempt information under 5 U.S.C. Section 552 et seq., and will take all legal steps to protect the information unless the owner of the information provides written authorization to make the information public or unless, in relation to the information requested, the MHRA informs the FDA that it no longer considers the information non-public or that it no longer consider that disclosure of the information will harm international relations between the MHRA and the FDA.

Therefore, because decisions as to disclosure under UK law have to be made within 20 days of receipt of the third party request, the FDA agrees that within 5 working days of receiving a request to do so from the MHRA, the FDA will inform the MHRA as to whether it remains of the view that disclosure should not be made and that if made will endanger international relations between the parties.

On each occasion on which there is a request for disclosure to third parties of non-public information received from the FDA, the FDA understands that the MHRA has agreed to consult with the FDA, and FDA will respond as agreed in the previous paragraph. Likewise, when the FDA has received a request for disclosure to third parties of non-public information received from the MHRA, the FDA agrees to consult with the MHRA, and the FDA understands that the MHRA agrees to provide the FDA with its opinion on the releasability of the non-public information within 5 working days

Both authorities recognize that in some cases the authority to whom confidential information is given may as a result of receiving that information need to take steps or measures to protect public health which may necessitate sharing of some or all of the information with certain third parties. In those circumstances the parties agree that any decision as to whether to share the information shall be taken only upon agreement by the other authority.

Both the MHRA and the FDA recognize that if requests for information in their possession (including otherwise non-public information received from the other party) are demanded by judicial, parliamentary/congressional order or other order issued under statute, the regulatory authority will have to surrender the information to the court, legislature or body concerned. If such an order is received for otherwise non-public information received from the other party, the regulatory authority under order to produce the information will so inform the other party immediately and will take all measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

Duration, Change, and Termination of Commitment:

This commitment will remain in effect for five years from the date of signature. It may be changed at any time upon mutual agreement of the parties, and termination of this commitment may terminate at any time upon 30 days' notice to the other party.

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drugs
14 February 2005