

**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT
FROM
THE UNITED KINGDOM DEPARTMENT OF HEALTH
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY
THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

The United States Food and Drug Administration (FDA), is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the United Kingdom Department of Health (DH) regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

DH understands that some of the information it receives from FDA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, which is confidential commercial information; trade secret information; personal privacy information; law enforcement information; designated national security information; or internal, pre-decisional information. FDA will advise DH of the non-public status of the information at the time that the information is shared.

DH understands that the FDA 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 DH is that as far as possible it be held in strict confidence by DH. DH further understands that the FDA is of the view that the disclosure by DH of any non-public information provided to it (including its officials and representatives) by the FDA could seriously jeopardize any further scientific and regulatory interactions between DH and FDA and could prejudice the international relations between DH and FDA.

It is the considered view of both DH and FDA that the mutual sharing of non-public health information, of the type described here, strongly contributes to the public health of each other's countries by reducing expenditures on gathering or developing duplicative information, comparing respective scientific analyses as well as adding to the stocks of scientific data available to each party, and learning from each other's regulatory experiences including policy, enforcement, and scientific experiences. As such, this mutual exchange of information between agencies greatly contributes to the public interest of each country and, if such exchanges were to be impaired, such impairment could harm the public interest of each country. Given that each agency holds it to be important that such exchanged non-public information remain confidential, if the recipient agency were to disclose such information publicly, any future exchanges under this arrangement could be immediately terminated thereby forgoing any possible future benefit such an arrangement could offer.

On this basis, DH affirms that it has authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by the FDA, and will take all available 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, FDA informs DH that it no longer considers the information non-public or that it no longer considers that disclosure of the information will harm international relations between DH and FDA. In the event that DH receives a request under the Freedom of Information Act 2000 (FOIA) for disclosure of the non-public information provided by the FDA that is held by DH, DH shall in good faith rely on any available exemptions under FOIA (including s. 27 (International Relations), s. 41

(Information provided in confidence) and s. 43 (Commercial Interests)) to withhold the non-public information from disclosure and shall consult with FDA about how to respond to the request. DH will inform FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from DH. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, DH will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure. Further, DH will promptly inform FDA of any changes to United Kingdom's laws, or to any relevant policies or procedures, that would affect DH's ability to honor the commitments in this document.

Signed on behalf of DH:

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