

**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT
FROM
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY
THE UNITED KINGDOM'S HUMAN FERTILIZATION AND EMBRYOLOGY
AUTHORITY**

The United Kingdom's Human Fertilization and Embryology Authority (HFEA) is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding HFEA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

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

It is the considered view of both FDA and HFEA 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, FDA affirms that it has authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by HFEA 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, HFEA informs FDA 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 HFEA

and FDA. In the event that FDA receives a request under the Freedom of Information Act (FOIA) for disclosure of the non-public information provided by HFEA that is held by FDA, FDA shall in good faith rely on any available exemptions under FOIA (including Exemption (b)(4), which covers trade secrets and confidential commercial or financial information) to withhold the non-public information from disclosure and shall consult with HFEA about how to respond to the request. FDA will inform HFEA promptly of any effort made by judicial or legislative mandate to obtain HFEA-provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of HFEA-provided non-public information, FDA 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, FDA will promptly inform HFEA of any changes to the United States of America's laws, or to any relevant policies or procedures that would affect FDA's ability to honor the commitments in this document.

Signed on behalf of FDA:

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Date