

**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT
FROM THE EUROPEAN COMMISSION'S DIRECTORATE-GENERAL FOR
INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs
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 Directorate responsible for Health Technology and Cosmetics of the European Commission's Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (abbreviated DG GROWTH) regarding FDA-regulated cosmetics and medical devices, including pre- and post-market activities, as part of cooperative law enforcement or cooperative regulatory activities.

DG GROWTH 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. DG GROWTH understands that this non-public information is shared in confidence and will take into account when assessing the public interest as regards international relations that FDA considers it critical that DG GROWTH maintain the confidentiality of the information. Public disclosure of this information by DG GROWTH could seriously jeopardize any further scientific and regulatory interactions between FDA and DG GROWTH. FDA will advise DG GROWTH of the non-public status of the information at the time that the information is shared.

Therefore, DG GROWTH certifies that it:

1. has the authority¹ to protect from public disclosure such non-public information provided to DG GROWTH in confidence by FDA if and in so far as that information is covered by the exceptions provided for in Article 4 of Regulation (EC) N° 1049/2001² as interpreted by the Court of Justice of the European Union³;
2. in the event that DG GROWTH receives a request for disclosure of the non-public information provided by FDA that is held by DG GROWTH, DG GROWTH will in good

¹ Without prejudice to the treatment of possible confirmatory requests in the meaning of Article 7.2 of Regulation 1049/2001 which are dealt with by the Secretary General on behalf of the Commission.

² Regulation (EC) N° 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (Official Journal L 145, 31/05/2001, p. 43-48).

³ Protection of public interest as regards public security, defense and military matters, international relations, the financial, monetary or economic policy of the Union or a Member State; protection of privacy and integrity of the individual, in particular in accordance with Union legislation regarding the protection of personal data and exceptions pertaining to protection of commercial interest of a natural or legal person, including intellectual property, court proceedings and legal advice, the purpose of inspections investigations and audits, protection of the institution's decision-making process unless there is an overriding interest in disclosure.

faith rely on any appropriate exceptions provided for in Article 4 of Regulation (EC) N° 1049/2001, to refuse disclosure of non-public information;

3. will inform FDA promptly of any effort made by judicial mandate or parliamentary inquiry to obtain FDA-provided non-public information from DG GROWTH, insofar as it does not harm that judicial investigation or parliamentary inquiry. DG GROWTH will request permission from the respective Parliament or Court to inform FDA of the existence of such a mandate or inquiry. If such judicial mandate or parliamentary inquiry requires disclosure of FDA-provided non-public information, DG GROWTH will take all appropriate measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and
4. will promptly inform FDA of any changes to the European Union's laws, or to any relevant policies or procedures, that would affect DG GROWTH's ability to honor the commitments in this document.

This text is not intended to create rights and obligations under international or other law.

Signed on behalf of DG GROWTH:

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Lowri Evans
Director-General
Directorate General for Internal Market,
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11 NOV. 2016

Date