STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT FROM
DANISH MEDICINS AGENCY
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[1] to disclose non-public information to Danish Medicins Agency regarding FDA-regulated drugs, including pre- and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities. FDA is further authorized under section 708(c) of the Federal Food, Drug, and Cosmetic Act[2] to share with a foreign government, as it deems appropriate and under limited circumstances, certain types of trade secret information.

The Commissioner of Food and Drugs has certified Danish Medicins Agency as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide Danish Medicins Agency with certain types of trade secret information at FDA's discretion and upon request by Danish Medicins Agency, based on the following certifications.

Danish Medicins Agency understands that some of the information it receives from FDA may include non-public information exempt from public disclosure, such as commercially confidential information; trade secret information; personal privacy information; law enforcement information; designated national security information; or internal, pre-decisional information. Danish Medicins Agency understands that this non-public information is shared in confidence and that it is critical that Danish Medicins Agency maintains the confidentiality of exchanged non-public information. Public disclosure of exchanged non-public information by Danish Medicins Agency could seriously jeopardize any further scientific and regulatory interactions between Danish Medicins Agency and FDA. FDA will advise Danish Medicins Agency of the non-public status of the information at the time that the information is shared.

Therefore, Danish Medicins Agency certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to Danish Medicins Agency in confidence by FDA[3];

2. will not publicly disclose such FDA-provided non-public information without the written authorization of the owner of the information, the written authorization from the

[1] United States Code of Federal Regulations, Title 21, section 20.89.
[2] United States Code, Title 21, section 379(c).
[3] Danish Public Administration Act (forvaltningsloven), Section 27, and Danish Access to Public Administration Files Act (offentlighedsloven), Section 32.

individual who is the subject of the personal privacy information, or a written statement from FDA providing that the information no longer has non-public status;

3. will protect trade secret information that FDA may provide from disclosure unless and until Danish Medicins Agency is in possession of a written permission for disclosure by the sponsor of the information provided by FDA, or alternatively of a declaration from the Commissioner of Food and Drugs of a public health emergency under section 319 of the Public Health Service Act that is relevant to the information;

4. with respect to trade secret information concerning the inspection of a drug facility, has the authority to otherwise obtain such information and will use such FDA-provided information only for civil, administrative regulatory purposes in the context of its mission;

5. will inform FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from Danish Medicins Agency. If such judicial or legislative mandate requires disclosure of FDA-provided non-public information, Danish Medicins Agency 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; and

6. will promptly inform FDA of any changes to the danish laws, or to any relevant policies or procedures, that would affect Danish Medicins Agency ability to honor the commitments in this document.

Danish Medicins Agency understands that FDA-provided information may come to it from the European Medicines Agency (EMA) and/or the European Commission's Directorate-General for Health and Food Safety (DG SANTE) as a result of the Cooperation Agreement between EMA and the EU Member States Regulatory Authorities. Danish Medicins Agency will protect such FDA-provided non-public information from public disclosure to the same extent that it will protect non-public information provided to it directly by FDA.

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

Signed on behalf of Danish Medicins Agency

_____/s/_____ 10 August 2017
Karsten Jorgensen Date
Chief Legal Officer

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