SMG 2830.3

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

AGREEMENTS WITH OTHER GOVERNMENT AGENCIES – INTERNATIONAL ARRANGEMENTS WITH FOREIGN GOVERNMENT AGENCIES AND INTERNATIONAL ORGANIZATIONS

CONFIDENTIALITY COMMITMENTS; SHARING OF NON-PUBLIC INFORMATION WITH, AND TREATMENT OF NON-PUBLIC INFORMATION RECEIVED FROM, FOREIGN GOVERNMENT OFFICIALS

Effective Date: 08/23/2019
Changed: 06/15/2020

Non-Public Information and Assurance of No Financial Interest.
Attachment F - Model Owner's Authorization for FDA to Share Confidential Commercial and/or Trade Secret Information with a Foreign Government Agency or International Organization.
Attachment G - Model Notification to Foreign Government Agency or International Organization that Information Received under a Confidentiality Commitment Is Likely Subject to Required Disclosure under the U.S. FOIA

1. PURPOSE

This Staff Manual Guide (SMG) establishes general, FDA-wide policies and procedures for the sharing of non-public information with Foreign Government Officials, including officials from certain International Organizations, and the treatment of non-public information received from these officials. It is important to note that the definition of "sharing information" includes conveying information in any way, **including orally** (whether in person, by phone or videoconference). (See Section 5.C.11 for the full definition of "sharing information.")

The purpose of this FDA-wide SMG is to ensure consistency across FDA Components in the: 1) general approach to requests from Foreign Government Officials for non-public information; 2) understanding of legal requirements relating to sharing non-public information with Foreign Government Officials; 3) management of non-public information received from Foreign Government Officials in ways that ensure the appropriate future handling and use of such information; and 4) understanding of the roles and responsibilities of FDA Components in handling common international information-disclosure issues.

Additional policies and procedures can be found in each FDA Component's written procedures. The policies set forth in this SMG apply whether it is FDA or the Foreign Government Official who initiates the sharing/receipt of the non-public information.

As a general rule, all sharing of non-public information must be pursuant to a signed Confidentiality Commitment from the Foreign Government Agency/International Organization and/or other appropriate written authorizations, as needed.[1],[2] This

[1] FDA may also share certain non-public information under agreements made pursuant to section 710(c) of the Food and Drug Administration Safety and Innovation Act (FDASIA; 21 U.S.C. § 379(c))(section 708(c) of the Food, Drug, and Cosmetic Act (FDCA)). See section 6.A.2.a.(4)(c) of this SMG and Annex: Sharing Trade Secret Information under Section 708(c) of the Federal Food, Drug, and Cosmetic Act

[2] If FDA wants to share information that is non-public solely by reason of being contained in an investigatory file (that is, the information is not also confidential commercial information (CCI), trade secret information (trade secret information), personal privacy information, or privileged information), FDA may share that information without a Confidentiality Commitment, under the terms of 21 C.F.R. § 20.89(a) – (b).

SMG does not address the details of the negotiation of Confidentiality Commitments; contact the Office of Global Policy and Strategy Point of Contact (mailto:OC-OGPS-IA@fda.hhs.gov) for this information.

FDA engages in many government-to-government interactions with Foreign Government Officials (whether pursuant to a cooperative arrangement, such as a memorandum of understanding, or otherwise) that do not involve the sharing of non-public information. This SMG addresses only the sharing and receipt of non-public information with Foreign Government Officials.

2. BACKGROUND

FDA's public health responsibilities have become increasingly complex as: 1) medical product development, authorization, marketing, promotion, and transport have become increasingly globalized; 2) animal and human food-related health issues have become increasingly globalized; and 3) there is increased opportunity for foreign governments to share information that will assist in efforts to reduce the harms from tobacco products. In many areas of FDA's product oversight responsibilities, most products, or components of products, have a foreign origin. Our international work and the relationships with our counterpart agencies around the world are now an integral part of the routine work of the FDA.

FDA officials' interactions with foreign regulatory counterparts enhance public health promotion and protection both in the United States and worldwide. Therefore, FDA has established procedures for entering into information-sharing arrangements with Foreign Government Agencies that allow FDA to share and receive information not available to the public as part of cooperative law enforcement or cooperative regulatory efforts. 21 U.S.C. § 379(c) (§ section 708(c) of the Federal Food, Drug, and Cosmetic Act (FDCA)), hereafter referred to as section 708(c) of the FDCA, and FDA regulations 21 C.F.R. § 20.89 permit, but do not require, FDA officials to disclose certain non-public information to a Foreign Government Agency or International Organization that performs counterpart functions to FDA as part of cooperative law enforcement or regulatory efforts. Regulation 21 C.F.R. § 20.89 also sets out conditions under which FDA may disclose additional non-public information to a Visiting Foreign Government Scientist. In these circumstances, FDA staff may share certain non-public information, provided they comply with this regulation by following the procedures set out in this SMG.[3] Failure to comply with the applicable requirements may result in civil or criminal penalties.

3. POLICY

This SMG describes the legal requirements for the sharing of non-public information with Foreign Government Officials (e.g. the requirement to have a Confidentiality Commitment in place before sharing confidential commercial information). It also

[3] For purposes of this SMG, "share" has the meaning of "disclose," as that term is used in 21 C.F.R. § 20.89.

reflects the Components' policy decisions governing the sharing of some kinds of non-public information (e.g. heightened protection of personal privacy information).

All FDA personnel, including those who are authorized to share non-public information with Foreign Government Officials, should adhere to the procedures set forth in this SMG, as well as to any other specific written procedures provided by their FDA Component, in the sharing of non-public information with, and the treatment of non-public information received from, a Foreign Government Official. **Only those authorized to share non-public information with a Foreign Government Official pursuant to 21 C.F.R. § 20.89 and the relevant delegations are permitted to do so.** Delegations of disclosure authority are found in SMG 1410.66 and each Component's written procedures. **Only those authorized to share non-public information that is trade secret with a Foreign Government Official pursuant to section 708(c) of the FDCA and the relevant delegations are permitted to do so.** Delegations of 708(c) disclosure authority are found in SMG 1410.21 or SMG 1410.65 and each Component's written procedures.

4. SCOPE

This SMG addresses FDA's core policies and procedures for sharing and receiving non-public information from Foreign Government Agencies and International Organizations. These are augmented by additional written policies and procedures developed by FDA Components and found in the Components' written procedures.

This SMG applies to the:

1. General management of requests received from Foreign Government Agencies or International Organizations for non-public information;

2. Sharing of non-public information with Foreign Government Agencies and International Organizations;

3. Management of non-public information received from Foreign Government Agencies and International Organizations; and

4. Sharing of non-public information with a Visiting Foreign Government Scientist; and

5. Sharing certain types of trade secret information with foreign governments under section 708(c) of the FDCA.

This SMG does not apply to:

1. Sharing publicly-available information;

2. Sharing non-public information with U.S. federal government departments or agencies, State or local government officials, courts, or Congress, including Congressional chairpersons who might also direct inquiries by the Government Accountability Office (GAO). For these situations, consult the appropriate regulations in 21 C.F.R. Part 20; or

3. Sharing non-public information that is ONLY protected because it appears in an investigatory record compiled for law enforcement purposes, but NOT if it is also protected for any other reason, for example, because it contains confidential commercial information, see 21 C.F.R. Sec. 20.89(b).[4]

5. DEFINITIONS

A. Definitions Concerning the Foreign Government Agency or International Organization

1. **Counterpart functions** can include, but are not limited to, administrative or regulatory law enforcement, product application review, compliance review, standard-setting, regulatory research, policy development, development and drafting of laws and regulations, and postmarket surveillance.

2. **Foreign Government Agency** means a unit of a foreign government that has within its purview counterpart functions to some or all of those of FDA. Under certain circumstances, supranational entities (e.g. the European Medicines Agency (EMA) or some other institutions of the European Union) or subnational entities (e.g. provinces or states within a foreign country) with appropriate responsibilities may be considered Foreign Government Agencies for purposes of this SMG. Determinations about supranational and subnational entities can be made only by Office of Global Policy and Strategy (OGPS) and the Office of Chief Counsel (OCC) in consultation with your Component POC.

3. **International Organization** refers to an organization established by law, treaty, or other governmental action and having the responsibility to facilitate global or regional harmonization of standards and requirements in FDA's areas of responsibility or to promote and coordinate public health efforts. International groups that do not meet this definition are **not eligible** to sign a Confidentiality Commitment and receive non-public information under 21 C.F.R. § 20.89.

    - Examples of entities considered "International Organizations" for purposes of this SMG include, but are not limited to the World Health Organization

[4] For example, the Office of Criminal Investigations may disclose investigatory record law enforcement information, verbally or otherwise, associated with criminal investigations to foreign government officials performing counterpart functions pursuant to 21 CFR Sec 20.89(b). A confidentiality commitment is, however, required if the information is protected for any other reason.

(WHO), the Pan American Health Organization (PAHO) and other regional offices of WHO, and the Food and Agricultural Organization (FAO) of the United Nations.

- Examples of entities that are not considered "International Organizations" for purposes of this SMG include, but are not limited to, the International Conference on Harmonization of Technical Requirements for Registration of Veterinary Products (VICH), the International Medical Device Regulators Forum (IMDRF), the International Coalition of Medicines Regulatory Authorities (ICMRA), the International Summit of Heads of Medicines Regulatory Agencies, and the Cooperation Centre for Scientific Research Relative to Tobacco (CORRESTA).

4. **Official of a Foreign Government Agency** (or **Foreign Government Official**) includes, but is not limited to, a permanent or temporary employee of, or an agent contracted by, a Foreign Government Agency or an International Organization (as both are defined above).

5. **Visiting Foreign Government Scientist** means a scientist from a Foreign Government Agency that has provided FDA with a Confidentiality Commitment and who is on FDA's premises for an extended period as part of certain joint reviews or long-term cooperative training efforts.[5] The term "Visiting Foreign Government Scientist" does **not** include officials visiting FDA briefly for meetings or as part of a delegation.

   Under certain circumstances, FDA may give a Visiting Foreign Government Scientist access to trade secret information.[6] (This is one of only three situations in which FDA may share trade secret information;[7] see Section 6.C. of this SMG.)

B. Definition of Non-Public Information

FDA's treatment of non-public information is determined by the type of non-public information involved. Each Component, with the aid of its information-disclosure experts (in consultation with OCC, if necessary) and the Component Freedom of Information (FOI) Office, determines whether, under federal law, the relevant information is non-public and, if so, what type of non-public information is involved.

---

[5] Note: A Visiting Foreign Government Scientist is not the same as a foreign-national fellow participating in research and training at FDA through the Oak Ridge Institute for Science and Education (ORISE) Contract Fellowship Training Program.

[6] 21 C.F.R. § 20.89(c)(1)(ii)(C).

[7] The other two situations are: 1) sharing trade secret information (TSI) with the authorization of the Owner of the information, and 2) sharing certain kinds of trade secrets relating to drug facility inspections and investigations under the circumstances and conditions contained in 21 U.S.C. § 379(c) (section 708(c) of the FDCA). See Annex: Sharing Trade Secret Information under Section 708(c) of the Federal Food, Drug, and Cosmetic Act.

Non-public information, as used in this SMG, refers to information that is protected from disclosure to the public by United States law, such as the Freedom of Information Act, the Privacy Act,[8] the Trade Secrets Act, the Economic Espionage Act, the National Childhood Vaccine Injury Act, and the Federal Food, Drug, and Cosmetic Act.

- Examples of non-public information include confidential commercial information, trade secret information, predecisional FDA communications, investigative information, enforcement information, and personal privacy information.

- In this section, examples of documents that may contain a particular type of non-public information are given. **Note, however, that a particular type of non-public information (for example, trade secrets or confidential commercial information) may appear in any document in FDA's possession (e.g., slides, e-mails); therefore, the Component information disclosure experts and the Component FOI Office should carefully consider what types of information are present in any documents before they are shared.**

The following definitions and examples are included for illustrative purposes only; Component information-disclosure experts and the Component FOI Office will make decisions about whether particular information falls into one of the categories of non-public information.

1. **Confidential commercial information** covers information that is related to a business or trade and is "confidential." The definition of "confidential" depends on several factors, including whether the information is maintained as confidential by the owner.

    - Examples of confidential commercial information might include sales statistics, amount or source of income (e.g., a company's list of customers), the existence of investigational product applications, clinical information, profits or losses, expenditures, names of suppliers or subcontractors.

    - An Establishment Inspection Report (EIR) or a medical officer's review or discussions about a review, including strategies related to the review, may contain confidential commercial information.

[8] The Privacy Act applies to certain records maintained on individuals. Important: these records may not be shared without the written consent of the individual or to pursuant to certain exceptions (including a routine use provided under a Privacy Act System of Records Notice). https://www.fda.gov/regulatory-information/freedom-information/privacy-act

2. **Information compiled for law enforcement purposes** includes, but is not limited to, information compiled during or about an investigation for purposes of bringing any potential or actual enforcement activities.

    - Examples include information received from an employee of a company that is the subject of an FDA investigation and that relates to that investigation, information relating to possible criminal prosecution, information about techniques and procedures for law enforcement investigations or prosecutions, guidelines for law enforcement investigations or prosecutions, and information about statements of witnesses or other sources concerning possible violations.

3. **Personal privacy information** is information about an individual that is personal, medical, financial, or similar in nature, the disclosure of which would constitute an unwarranted invasion of personal privacy.

    - Examples include information that identifies an individual, such as the individual's name, initials, home address, telephone number, social security number, or other unique identifiers. Some of these identifiers by themselves are protected as personal privacy information, such as social security numbers. Others, such as initials, are only personal privacy information when associated with other information.

    - Personal privacy information is often found in personnel or medical records, adverse event reports, consumer complaints, law enforcement records, clinical reviews, and EIRs.

    - Confidential informants and nonsupervisory firm employees are generally afforded personal privacy protection.

4. **Predecisional information** refers to opinions and recommendations that are part of FDA deliberations. Please refer to your Component's written procedures to identify the individual(s) responsible for making the policy determination on the appropriate timing for the sharing of predecisional information (which may depend on the stage of the deliberations).

    - Predecisional information includes, but is not limited to, non-public documents (such as regulation and guidance draft versions), draft regulatory initiatives, draft FDA policy or procedural statements, certain inter-governmental communications, and FDA discussions/deliberations about any of those items.

5. **Trade secret information (TSI)** is any commercially valuable plan, formula, "recipe," process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a

direct relationship between the trade secret and the productive process. An example of trade secret information might be information relating to the manufacturing process.

- **Important:** Trade secret information cannot generally be shared by FDA unless the Owner of the information has authorized the sharing (usually by completing Attachment F).[9]

- Trade secret information is frequently found, for example, in EIRs, device Premarket Notifications, "510ks," device Premarket Approval Applications, New Drug Applications, Premarket Tobacco Applications, Tobacco Substantial Equivalence Reports, Biologic License Applications, Investigational New Drug Applications, Investigational Device Applications, Investigational New Animal Drug Applications, certain technical proposals or bids from contractors, FDA reviews, Health Hazard Evaluations, Drug and Veterinary Master Files, Warning Letters, and Untitled Letters

- Examples of trade secrets include information that identifies the type or brand of equipment used in manufacturing, product formulas, product components or ingredients not on the label, specifications that are unique (i.e. not in the U.S. Pharmacopeia), and technical designs.

C. Definitions Concerning FDA Terms

1. **Component** (or **FDA Component**) means an FDA Center (the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Medical Devices and Radiological Health, the Center for Tobacco Products, the Center for Veterinary Medicine, and the National Center for Toxicological Research), the Office of Food Policy and Response, the Office of Clinical Policy and Programs, the Office of Regulatory Affairs, the Office of Global Policy and Strategy, the Office of the Commissioner, or any office within the Office of the Commissioner.

2. **Component Freedom of Information (FOI) Office (Component FOI Office)** refers to the unit within a Component that is responsible for handling requests for information under the Freedom of Information Act (FOIA) and redaction of non-public information from documents that the Component turns over in response to such requests.

[9] Unless one of these two situations apply: 1) sharing TSI with a Visiting Foreign Government Scientist (see Section 6.C. of this SMG), or 2) sharing certain kinds of trade secrets relating to drug facility inspections and investigations under the circumstances described in 21 U.S.C. § 379(c)) (section 708(c) of the FDCA).

3. **Component Point of Contact (Component POC)** refers to a person designated by the Component to address and coordinate issues involving the sharing of non-public information with Foreign Government Officials. The Component POC is responsible for developing Component-level written policies and procedures relating to the sharing of non-public information with, and receipt of non-public information from, Foreign Government Agencies and International Organizations. Consult your Component to identify your Component POC.

4. **Confidentiality Commitment** refers to a document that a Foreign Government Agency or International Organization provides to FDA (Attachment A), or that FDA provides to the Foreign Government Agency or International Organization, that contains, among other provisions, a written statement establishing the agency's **authority to protect** non-public information from public disclosure and a written **commitment not to disclose** any such information provided by the other agency without the written permission of the Owner or written confirmation by the source agency that the information no longer has confidential status. When a Confidentiality Commitment has been received by FDA (and the other requirements of 21 C.F.R. § 20.89 are met), FDA may share certain types of non-public information, including confidential commercial information, with that Foreign Government Agency. Some Confidentiality Commitments may include special language that also satisfies section 708(c) of the FDCA so that FDA may share certain trade secret information with that agency (Attachment B, also referred to as trade secret information confidentiality commitment). A list of Confidentiality Commitments to and from FDA can be found on FDA's website at Confidentiality Commitments.[10]

    - Note that a Confidentiality Commitment alone does not permit the FDA to share trade secret information.[11] FDA's Confidentiality Commitment template contains standard language that lists every type of non-public information.[12] However, the Confidentiality Commitment, alone, does not authorize or require the sharing of all of those information types. There are additional requirements, determined by law or policy, that must be met before FDA can share some kinds of information (e.g., the standard language in the Confidentiality Commitment lists trade secret information, but the Owner must generally consent in writing before FDA can share trade secrets).

[10] http://www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/default.htm
[11] See section 6.A.2.a.(4) of this SMG.
[12] The standard language reads, in part: "some of the information [the foreign government agency] 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, predecisional information" (emphasis added). See Attachment A.

5. **Internal Memorandum: Authorization to Share Non-Public Information and Determination that Sharing Is in the Interest of Public Health (Internal Memorandum)** refers to an FDA-internal document signed by the Commissioner or Commissioner's designee). It authorizes the sharing of non-public information with Foreign Government Officials in reliance on a signed Confidentiality Commitment from that Foreign Government Agency or International Organization. This document contains a determination by the Commissioner or Commissioner's designee that sharing information with the identified partner is in the interest of public health, enabling FDA to share confidential commercial information without the Owner's Authorization with that Foreign Government Agency or International Organization. The OGPS POC prepares and retains the Internal Memorandum (Attachment C, for your information only).

6. **Office of Global Policy and Strategy Point of Contact (OGPS POC)** refers to a person designated by OGPS to address and coordinate issues involving the development or interpretation of Confidentiality Commitments.

    - The OGPS POC applies a global strategy, policy, and legal lens to advise and assist FDA Components on the negotiation, implementation, and use of Confidentiality Commitments from Foreign Government Agencies and International Organizations.

    - The OGPS POC serves as a resource to FDA Components with questions about existing Confidentiality Commitments.

    - Usually at the request of a Component or an OGPS Foreign Office, and when the need for a new Confidentiality Commitment has been established, the OGPS POC generally takes the lead in negotiations with a Foreign Government Agency or International Organization, working closely with the Office of the Chief Counsel (OCC), Component POCs, and the relevant Foreign Office.

    - The OGPS POC is responsible for ensuring appropriate communication within OGPS, as well as across FDA, on matters relating to Confidentiality Commitments. The OGPS POC can be reached at mailto:OC-OGPS-IA@fda.hhs.gov.

7. **OGPS Foreign Office** means the OGPS Office (whether at headquarters or abroad) handling the portfolio that includes responsibility for interactions with and analyses of the relevant Foreign Government Agencies within a particular country/region. E-mail mailboxes for the OGPS Foreign Offices can be found on FDA's OGPS Offices[13] website.

[13] https://www.fda.gov/about-fda/office-international-programs/office-international-programs-offices

- The OGPS Foreign Office draws on its expertise with the government(s) in the country/region, including in-country experience, to advise the OGPS POC and FDA Components on the desirability of a Confidentiality Commitment with a particular Foreign Government Agency in that country/region.

8. **Office of Chief Counsel (OCC)** refers to a person designated by OCC to address issues involving the sharing of non-public information in the international context.

9. **Owner** (of non-public information) refers to the submitter, sponsor, manufacturer, or other entity that FDA considers to have the legal ability to authorize the sharing of its non-public information (particularly trade secret information) by FDA with a Foreign Government Agency or International Organization.

10. **Scope of a Confidentiality Commitment** refers to the description in the Confidentiality Commitment of the subject-matter of the information that can be shared or the circumstances under which it may be shared (when other legal requirements are met).[14] A Confidentiality Commitment (Attachment A) may have a broad scope, covering non-public information relating to all regulated products and activities. Alternatively, it may have a narrower scope, for example covering only non-public information relating to a subset of regulated products, a particular cooperative regulatory activity, or a particular outbreak or product contamination event. **Before sharing non-public information in reliance on a Confidentiality Commitment, a Component should confirm that the scope of the Confidentiality Commitment covers the information that the Component wishes to share.**

    - Example of a broad scope: "[FDA] is authorized under 21 C.F.R. § 20.89 to disclose non-public information to Agency ABC of Country D <u>regarding FDA-regulated products</u> as part of cooperative law enforcement or cooperative regulatory activities. The FDA proposes to share non-public information regarding, among other things, the safety, effectiveness, or quality of FDA-regulated products with Agency ABC." The scope is broad and covers information about all FDA-regulated products.

    - Example of a limited scope: "[FDA] is authorized under 21 C.F.R. § 20.89 to disclose non-public information to Ministry EFG of the Government of H <u>regarding FDA-regulated tobacco products</u> as part of cooperative law enforcement or cooperative regulatory activities." The scope is limited to information about tobacco products.

[14] The scope of a Confidentiality Commitment is <u>not</u> the standard language that is contained in all Confidentiality Commitments that simply lists all the different types of non-public information; FDA must meet additional requirements before sharing some of those types of non-public information. See definition of Confidentiality Commitment, above.

11. **Sharing information** means conveying information in any way (orally, electronically, or in writing), in any format (e.g. paper, CD-ROM, email, USB flash drive, access to electronic databases, telephone conversations, videoconferences, etc.), and in any manner (e.g. transmitting the information or permitting someone to access information). Sharing information applies to instances when a foreign government counterpart or FDA requests the information as well as when information is shared proactively. Take special note that **sharing non-public information orally is also covered by this SMG.**

12. **Owner's Authorization** refers to the signed document that FDA must obtain before sharing trade secret information from the individual or entity with the right to authorize FDA to share that information (Attachment F).

6. RESPONSIBILITIES AND PROCEDURES

Each Component should adhere to the following procedures when sharing non-public information with, or receiving non-public information from, a Foreign Government Agency or International Organization.

A. General Process: Sharing Non-Public Information

Whenever a request is received from a Foreign Government Agency or International Organization for information that is, or may be, non-public, or when a Component seeks to proactively share such information, the following steps should be taken. In cases in which an FDA Component is considering exchanging information proactively *(i.e.*, not in response to a request for information from the foreign counterpart), all of the following steps (except 6.A.1) are relevant and should be followed.

1. Receiving a Request

Requests from foreign government regulatory counterparts for non-public information should generally be made in writing, when possible. When you receive a written request, notify your Component POC.

If a Component receives a request for non-public information that is in the possession of another Component, the request should be forwarded to the appropriate Component's POC for handling. If the Component is unsure how the request should be directed within FDA, the request may be directed to the OGPS POC.

2. Choosing Whether to Share

Note: **An FDA Component is never obligated to share non-public information** with a Foreign Government Agency or International Organization, even if a Confidentiality Commitment with that organization is in place.

a. Special kinds of information:

(1) Draft legislation: As a matter of policy, FDA does not share draft legislative proposals.

(2) Draft regulations: FDA may share drafts of regulations prior to their publication as Proposed Rules. After the Proposed Rule has published, however, Components may not share further drafts without consulting with OCC, in order to maintain the integrity of the rulemaking process.

(3) Information that FDA received from a different Foreign Government Agency or International Organization: If the non-public information was provided to FDA by another Foreign Government Agency or International Organization under condition of confidentiality, the information should not be shared without the consent of the source Foreign Government Agency or International Organization. If the Component deems that it would be useful to share the information, the Component POC may involve OGPS in discussions with the source organization.

- For example: If Agency A provides non-public information to FDA, and FDA has committed to keep that information confidential, FDA may not share that information with Agency B without the consent of Agency A, even if Agency B has given a Confidentiality Commitment to FDA.

(4) Trade secret information

Trade secret information may be shared with a Foreign Government Agency or International Organization in **only** the following three situations:

(a) Trade secret information shared with the consent of the Owner: Trade secret information may be shared with a Foreign Government Agency or International Organization if: 1) the Foreign Government Agency or International Organization has signed a Confidentiality Commitment (Attachment A); **AND**, 2) the Owner of the trade secret information has consented, in writing, to FDA's sharing of the information (Attachment F).

(i) For Confidentiality Commitments, see 6.A.3.b - c. of this SMG;

(ii) For Owner consent: The Component POC should contact the Owner (e.g., the sponsor or manufacturer) and ask the company to complete the Owner's Authorization form (Attachment F) on company letterhead and return to the Component POC. The Component POC determines whether the scope of the Authorization is sufficient for the Component's needs and whether OCC needs to review any language deviating from that of the template. After this, the Component may share the trade secret information, as described in the Authorization. The Component POC should keep the original signed Authorization on file as per Component written procedures.

If the Owner of trade secret information consents to FDA's sharing of that information with a Foreign Government Agency or International Organization (Attachment F) and a Confidentiality Commitment from that Foreign Government Agency or International Organization that covers the information in question (Attachment A) is in place, that information **remains non-public for all other purposes**. In that case, FDA must not share the information with anyone else.

If the Owner of trade secret information consents to FDA's sharing of that information with a Foreign Government Agency or International Organization (Attachment F) and a Confidentiality Commitment that covers the information in question (Attachment A) is **NOT** in place, the **information loses its non-public status with respect to FDA**. Most Owners would **NOT** want this to happen. For this reason, FDA generally does not ask an Owner to consent absent a Confidentiality Commitment from the receiving Foreign Government Agency or International Organization (Attachment A).

(b) Trade secret information shared with Visiting Foreign Government Scientists: See Section 6(C).

(c) Certain trade secret information relating to drug facility inspections and investigations shared under the circumstances described in section 708(c) of the FDCA. In the Food and Drug Administration Safety and Innovation Act (FDASIA), Congress explicitly provided FDA with a way to share certain types of trade secret information with trusted regulators when certain requirements are met. These requirements are (1) the Secretary's certification of the foreign government as having the authority and demonstrated ability to protect trade secret information from

disclosure,[15] and (2) a written agreement with the foreign government containing a commitment from that government to protect information exchanged under section 708(c) of the FDCA unless and until certain enumerated conditions are met. See Annex: Sharing Trade Secret Information under Section 708(c) of the Federal Food, Drug, and Cosmetic Act for more information.

If considering whether to share trade secret information and unsure whether one of these three situations may apply, consult your Component POC.

b. General Procedure:

Each Component should have written procedures that include guidance on how to evaluate a potential instance of information-sharing. Each Component should consider addressing:

- Ascertaining whether the information is publicly available or, if it is non-public information, the type of non-public information involved in light of the following:
  - The definition and treatment of non-public information can differ in other countries. FDA's definitions and treatment are governed by U.S. law;
  - A record may contain more than one kind of non-public information. For example, a medical officer's recommendations for a review of a pending application might involve both confidential commercial and predecisional information. Any record that FDA is considering sharing and that contains non-public information – even if it also contains publicly-available information – is subject to this SMG.
- Ensuring that staff know that publicly-available information may be shared freely;
- Ensuring that staff know that, in general, non-public information may not be shared without a Confidentiality Commitment in place and that other restrictions may apply as described below;
- <u>For Components handling information related to medical devices:</u> Ascertaining whether the medical device-related information is of the

[15] In 2015, the Acting Commissioner, with delegated authority from the Secretary, certified the European Commission—including the European Medicines Agency (EMA) and the European Commission's Directorate General for Health and Food Safety (DG SANTE)—as well as the national competent authorities for drug regulation in each European Union Member State pursuant to section FDCA 708(c)(1).

kind described in 21 U.S.C. § 360j(c), in which case FDA's ability to share that confidential commercial information is limited, and Attachment F may be used to seek Owner Authorization;

- For Components handling information related to tobacco products: Ascertaining whether the tobacco product-related information is of the kind described in 21 U.S.C. § 387f(c), in which case FDA's ability to share that confidential commercial information is limited, and Attachment F may be used to seek Owner Authorization;

- For Components handling information relating to drugs (including drug ingredients/components as well as finished product): Ascertaining whether trade secret information related to drug facility inspections and investigations meets the criteria of section 708(c) of the FDCA, in which case FDA may be able to share the information; see Annex: Sharing Trade Secret Information under Section 708(c) of the Federal Food, Drug, and Cosmetic Act for more information and Attachment B. If these criteria are not met, Attachment F may be used to seek Owner Authorization.

- Determining whether information that is non-public solely by reason of being contained in an investigatory file (that is, the information is not also confidential commercial, trade secret, personal privacy, or privileged information) may be released without a Confidentiality Commitment, under the terms of 21 CFR § 20.89(a)-(b);

- Determining whether FDA has a Confidentiality Commitment from that Foreign Government Agency or International Organization (see list of existing Confidentiality Commitments on FDA's website at Confidentiality Commitments[16]);

- If a Confidentiality Commitment exists, determining whether its scope covers the non-public information in question;

- If the information is non-public, determining whether the Component will consent to the sharing;

- If the information is predecisional, determining the appropriate time for the sharing; and

- If the requested information is relevant to more than one Component, determining whether OGPS's assistance is desired in coordinating a response to the requester.

[16] http://www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/default.htm

3. Acting on a Decision Regarding Sharing

a. Decision not to share information: If the Component decides not to share the non-public information, the Component POC notifies the requesting Foreign Government Agency or International Organization. The Component POC may also refer the requesting organization to the FDA website for access to publicly-available information there or, in accordance with the Component's own written procedures, send the records to the Component Freedom of Information (FOI) Office for redaction of all non-public information and subsequently share the redacted document.

b. Decision to share, but no applicable Confidentiality Commitment in place yet: Until a Confidentiality Commitment (Attachment A) is in place, **non-public information may not be shared.**[17]

(1) If the Component decides that a Confidentiality Commitment is warranted, the Component POC should consult with the OGPS POC to begin the process of putting a Confidentiality Commitment in place.

(2) The OGPS POC works with OCC and the FDA Components to negotiate the Confidentiality Commitments with the Foreign Government Agency or International Organization.

(3) Once the Confidentiality Commitments have been negotiated, the OGPS POC arranges for signature of the Confidentiality Commitments by an appropriate official of the Foreign Government Agency or International Organization and the FDA Commissioner or the Commissioner's designee, consulting with the Component POC(s) as necessary.

(4) When the Foreign Government Agency or International Organization has signed its Confidentiality Commitment to FDA, the OGPS POC arranges for the Commissioner or Commissioner's designee to sign the required Internal Memorandum Authorizing Disclosure with Optional Public Health Interest Finding (Internal Memorandum; Attachment C), which authorizes FDA Components to share non-public information with that Foreign Government Agency or International Organization.

(5) The OGPS POC notifies all FDA Component POCs whenever a new Confidentiality Commitment has been implemented (i.e. when the Confidentiality Commitment from the Foreign Government Agency or International Organization has been received, the Internal

[17] For certain information related to drug facility inspections or investigations to be released under a 21 U.S.C. § 379(c) (section 708(c) of the FDCA) agreement, or certain information contained in investigatory files, see your Component POC.

Memorandum has been signed, and the Confidentiality Commitments have been posted on the FDA website).

(6) Components may not share non-public information until they are notified by their Components' POCs that the Internal Memorandum is in place and that the Confidentiality Commitment may be relied upon.

(7) The OGPS POC maintains the signed Confidentiality Commitment and Internal Memorandum.

c. Decision to share, with an applicable Confidentiality Commitment already in place: If the Component decides to share the non-public information and if a Confidentiality Commitment (Attachment A or Attachment B) with an appropriate scope is already in place, the Component POC determines whether it is necessary to send the material to the Component FOI Office, in accordance with that Component's own written procedures, for appropriate redaction of non-public information that cannot be shared even with a Confidentiality Commitment, such as trade secret information. (For the sharing of trade secret information, see 6.A.2.a(4), above.)

(1) The Component is responsible for determining the agency or Component staff member(s) who may share the information, in accordance with SMG Part 1410, Regulatory Delegations of Authority.

(2) The Component POC may request that OGPS assist with the sharing by contacting the appropriate FDA Foreign Office mailbox or the OGPS POC.

(3) The Component POC will determine the appropriate Foreign Government Official authorized to receive the information, consulting with the appropriate FDA Foreign Office as necessary.

(4) The Component POC will generally notify the appropriate OGPS Foreign Office, in the manner of his/her choosing, when the Component shares non-public information with a Foreign Government Agency in that country/region. For Component POCs' convenience, Foreign Office e-mailboxes can be found on FDA's website at OGPS Offices.[18] The Component POC may also e-mail or telephone an appropriate individual in that Foreign Office directly.

(5) **If the non-public information is to be shared orally** (in person or by phone): The conversation should be prefaced by the statement: **"The information you are about to receive is being shared with you pursuant to the Confidentiality Commitments signed by our**

[18] https://www.fda.gov/about-fda/office-international-programs/office-international-programs-offices

agencies; the information is non-public information and must be treated as such." This statement is required whenever non-public information is being shared orally in person (*e.g.*, during the visit to FDA of a delegation from a Foreign Government Agency or International Organization; on the sidelines of a conference) or over the telephone.

(6) **If the non-public information is to be shared in writing (by email, fax, or post):** The following minimum safeguards should be observed:

(a) To ensure that users of the information know that FDA considers the information non-public:

- At the beginning of the email or cover page, this statement should appear in uppercase letters: "**THE INFORMATION IN THIS [E-MAIL/FAX/PACKAGE] IS BEING PROVIDED TO YOU UNDER THE TERMS OF OUR CONFIDENTIALITY COMMITMENTS."**

- Each shared page containing non-public information must, where possible, include a header that reads: **"OFFICIAL UNITED STATES FOOD AND DRUG ADMINISTRATION DOCUMENTS SUBJECT TO CONFIDENTIALITY COMMITMENTS. DO NOT DISCLOSE WITHOUT WRITTEN PERMISSION OF U.S. FDA OR THE PERSON WHO OR ENTITY THAT OWNS THE RIGHT TO DISCLOSE THE INFORMATION."**

- In the unusual situation in which non-public information is shared physically (in hard copy or on a media storage device), Components should use the *Model Transmittal Letter for Sharing Non-Public Information Pursuant to a Confidentiality Commitment* (Attachment D). (Attachment D need not be used when non-public information is being shared in non-physical form (e.g. by e-mail) because a sharing by e-mail will include the language in the two bullet points above.)

(b) To ensure the integrity of the shared non-public information:

- When feasible, Components should take steps to protect the integrity of shared non-public information (e.g. conversion of Word documents into pdf files).

(c) Consult your Component's written procedures for any additional, technologically-feasible steps (such as encryption guidelines per any FDA or HHS cybersecurity guidelines) that should be taken to

ensure the appropriate treatment of non-public information being shared with a foreign government.

B. Sharing Information with Short-Term Visitors to FDA: Foreign Government Meeting Attendees, Delegations, and Auditors

FDA Components frequently meet with one or more Officials of a Foreign Government Agency. Such delegations will visit FDA for a relatively short period (several hours or days). In some cases, the delegation may consist of a team of auditors from one or more Foreign Government Agencies who wish to observe FDA's regulatory procedures.

Please Note: All short-term visitors are significantly impacted by federal and HHS directives that require enhanced security measures that restrict visitors' physical access to FDA's facilities and critical infrastructure, including logical access to information systems and applications. Requests to provide foreign nationals with access to systems and applications containing commercial confidential information, trade secrets, or other sensitive information will be carefully reviewed by FDA's Office of Security Operations as this access is generally prohibited. The enhanced security measures apply even if a 21 CFR 20.89 or a 708(c) Confidentiality Commitment (also referred to as trade secret information confidentiality commitment) is in place with the visitor's home Foreign Government Agency. Please contact OSO-FOREIGNVISIT@fda.hhs.gov for information on hosting short-term visitors.

Important: Short-term visitors to FDA do not have special rights to receive non-public information by virtue of being on a visit to FDA. Non-public information may only be shared with officials in a delegation if their home Foreign Government Agency has signed an appropriate Confidentiality Commitment (Attachment A or Attachment B).

FDA may know in advance whether FDA is going to share non-public information with the delegation and, if so, what non-public information will be involved. It is also possible, however, that Officials may make new requests for non-public information during their visit, for example during meetings with FDA staff. Therefore, when planning for such meetings, Components may wish to be prepared to redact documents or seek Owner Authorization (Attachment F) on short notice during the delegation's visit. Components can also provide the requested documents, redacted, at a later time. It is the Component's decision whether and when to share non-public information with the delegation.

To share non-public information with such short-term visitors, Components should follow steps 6.A.2. to 6.A.3, above. This applies whether the request for, or need to share, non-public information is known before the visit or arises during the visit.

FDA **may not share trade secret information** with such short-term visitors without either the authorization of the Owner of the information (see 6.A.2.a.(4), above) (with a Confidentiality Commitment) or a trade secret information confidentiality commitment in place.

C. Sharing Information with Longer-Term Visitors to FDA: Visiting Foreign Government Scientists

FDA Components sometimes receive requests, or decide proactively, to host for an extended period a scientist from a Foreign Government Agency as part of a joint review or long-term training. Components may only host scientists whose home Foreign Government Agency has provided FDA with a Confidentiality Commitment. Such scientists are referred to as Visiting Foreign Government Scientists.[19]

Please Note: All longer-term visitors are significantly impacted by federal and HHS directives that require enhanced security measures that restrict visitors' physical access to FDA's facilities and critical infrastructure, including logical access to information systems and applications. Requests to provide foreign nationals with access to systems and applications containing commercial confidential information, trade secrets, or other sensitive information will be carefully reviewed by FDA's Office of Security Operations as this access is generally prohibited. The enhanced security measures apply even if a 21 CFR 20.89 or a 708(c) Confidentiality Commitment (also referred to as a trade secret information confidentiality commitment) is in place with the visitor's home Foreign Government Agency. Please contact OSO-FOREIGNVISIT@fda.hhs.gov for information on hosting longer-term visitors.

An FDA Component is **never obligated to host** a Visiting Foreign Government Scientist, and can always decline a request to do so.

FDA may give the Visiting Foreign Government Scientist access to confidential commercial information if 1) the review is in the interest of public health; 2) FDA retains physical control over the information; and 3) the scientist signs the *Visiting Foreign Government Scientist's Commitment to Protect Non-Public Information and Assurance of No Financial Interest* (Attachment E).[20]

Furthermore, FDA may also give the Visiting Foreign Government Scientist access to trade secret information, when such disclosures are a necessary part

[19] Note: A Visiting Foreign Government Scientist is not the same as a foreign-national fellow participating in research and training at FDA through the Oak Ridge Institute for Science and Education (ORISE) Contract Fellowship Training Program.
[20] See 21 C.F.R. § 20.89(c)(1).

of the joint review or training.[21] (This is one of only three situations in which FDA may share trade secret information.[22])

However, the Component may choose to restrict the Visiting Foreign Government Scientist's access to non-public information as it sees fit. In addition, FDA must maintain physical control over any trade secret information shared with Visiting Foreign Government Scientists.

Visiting Foreign Government Scientists are prohibited from sharing non-public information learned at FDA, including confidential commercial and trade secret information, with anyone**. This prohibition includes sharing information with others at the scientist's home Foreign Government Agency.** For this reason, staff should refer to their Components' written procedures before treating a Visiting Foreign Government Scientist as a conduit for information that FDA wishes to share with the scientist's home Foreign Government Agency (e.g., asking a Visiting Foreign Government Scientist to pass on non-public information from FDA to his/her home agency).

If an FDA Component wants to host a Visiting Foreign Government Scientist, the Component should:

1. Confirm that FDA has a signed Confidentiality Commitment (Attachment A or Attachment B) in place from the Visiting Foreign Government Scientist's home Foreign Government Agency or International Organization (listed on FDA's website at Confidentiality Commitments[23]);

2. If no Confidentiality Commitment is in place, consult with the OGPS POC to begin the process of putting one into place (see Section 6.A.3.b. of this SMG); and

3. Once the Confidentiality Commitment has been signed by the Foreign Government Agency or International Organization, have the prospective visiting scientist sign *the Visiting Foreign Government Scientist's Commitment to Protect Non-Public Information and Assurance of No Financial Interest* (Attachment E), which should be kept on file with the Component, as per the Component's written procedures.

FDA Components should have written procedures that address processes associated with Visiting Foreign Government Scientists. The following are principles that each Component should consider in developing these written procedures:

---

[21] See 21 C.F.R. § 20.89(c)(1)(ii)(C)
[22] The other two situations are sharing trade secret information with the authorization of the Owner of the information, and sharing certain kinds of trade secrets relating to drug facility inspections and investigations under the circumstances provided by 21 U.S.C. § 379(c) (section 708(c) of the FDCA).
[23] https://www.fda.gov/international-programs/international-arrangements/confidentiality-commitments

1. Ensuring that FDA retains physical control over any trade secret information that is shared with Visiting Foreign Government Scientists.

2. Ensuring that Visiting Foreign Government Scientists understand and comply with the terms of the *Visiting Foreign Government Scientist's Commitment to Protect Non-Public Information and Assurance of No Financial Interest* (Attachment E), including those provisions relating to access, treatment, and removal of non-public information;

3. Ensuring that Component staff understand their Component's policy on asking a Visiting Foreign Government Scientist to serve as a conduit for non-public information that FDA wishes to share with the scientist's home Foreign Government Agency; and

D. Non-Public Information Received from a Foreign Government Agency or International Organization

FDA also receives non-public information from Foreign Government Agencies, whether as a result of a request by FDA for the information or a Foreign Government Agency's or International Organization's proactive decision to share the information with FDA.

1. Receipt of Non-Public Information from a Foreign Government Agency or International Organization

Each Component should have written procedures to address situations in which the Component receives non-public information from a Foreign Government Agency or International Organization. Each Component should consider the following issues:

- Documenting and/or storing the non-public information received, or a description of it, along with information about the source and the date received;

- Marking received information and documents as non-public and/or as having been shared with FDA under the terms of a Confidentiality Commitment in such a way that **future FDA users of the information will recognize its sensitivity;**

- Controlling access to received non-public information;

- Informing staff that non-public information received from a Foreign Government Agency or International Organization will be protected from disclosure only to the extent permitted by U.S. law, and that information received from a Foreign Government Agency or International Organization

cannot be protected solely by the preferences or requirements of the Foreign Government Agency or International Organization;

- Informing staff that there are additional protections under 21 U.S.C. 379(b) whereby disclosures required under U.S. laws are not mandatory for certain categories of non-public information relating to drug products; and

- Handling by the Component of FOIA requests and certain mandatory release situations when non-public information received from a Foreign Government Official under a Confidentiality Commitment is implicated (see D.2.b. of this SMG; *see also* 21 U.S.C. 379(b)).

2. Disclosure of Non-Public Information Received from a Foreign Government Agency or International Organization

a. Voluntary Disclosure

When FDA receives non-public information from a Foreign Government Agency or International Organization, it is usually provided under the terms of a Confidentiality Commitment that FDA has signed. Therefore, it would usually not be appropriate for FDA to voluntarily disclose such information (unless FDA has consulted the Foreign Government Agency or International Organization and it has consented, in writing, to the disclosure).

This is the case even if the organization that wants access to the non-public information is:

(1) Another Foreign Government Agency or International Organization from which we have a Confidentiality Commitment, or

(2) A U.S. government department or agency.

b. Required Disclosure

With the exception of certain non-public information related to drug products as described under 21 U.S.C. § 379(b)(1)(A) – (C), FDA may occasionally be required under U.S. law to disclose information it has received from a Foreign Government Agency or International Organization, for example in response to a FOIA request.

Components should have written procedures addressing required disclosure situations that involve non-public information that has been received from a Foreign Government Agency or International Organization under a Confidentiality Commitment. Components should consider the following principles:

- The Component information disclosure experts and the Component FOI Office should redact the records subject to the disclosure as permitted by U.S. law (and, for information subject to discretionary disclosure, according to the Component's policy decisions);

- When the Component POC determines that non-public information received from a Foreign Government Agency or International Organization will be subject to mandatory disclosure, the Component should promptly notify the OGPS POC and the appropriate Foreign Office;

- There may be situations in which, for policy reasons, the Foreign Office should be involved in communications with the Foreign Government Agency about information to be released;

- Once Component information-disclosure experts and the Component FOI Office have prepared redacted records, and **before any information originating from a Foreign Government Agency or International Organization in reliance on a Confidentiality Commitment is disclosed**, the Component POC should contact the Foreign Government Agency or International Organization that provided the records (involving the OGPS POC and the appropriate Foreign Office as agreed upon);

- In the case of a FOIA request, Components may use the *Model Notification to Foreign Government Agency or International Organization that Information Received under a Confidentiality Commitment Is Likely Subject to Required Disclosure under the U.S. FOIA* (Attachment G) to 1) inform the Foreign Government Agency or International Organization of the mandatory disclosure situation, 2) provide it with a courtesy copy of the record, as redacted, and 3) offer to discuss the proposed redactions;

- It may be helpful to specify a timeframe within which the Foreign Government Agency or International Organization should provide any comments, while considering the timeframe for processing a FOIA request set by statute;

- The Foreign Government Agency frequently has questions or concerns about the proposed redactions; and

- The OGPS POC and the Foreign Office are available to participate in conference calls with the Foreign Government Agency or International Organization to discuss information that will and will not be redacted by FDA.

E. Recordkeeping

Each Component should consider procedures for keeping records on:

- The receipt and disposition of requests from Foreign Government Agencies and International Organizations for non-public information and the proactive sharing of such information with Foreign Government Agencies and International Organizations;

- The receipt of non-public information from Foreign Government Agencies and International Organizations under FDA's Confidentiality Commitments;

- Instances in which FDA shared trade secret information under section 708(c) of the FDCA;

- Instances in which a Foreign Government Agency or International Organization shared non-public information with FDA on the condition that it not be released, and the other provisions of 21 U.S.C. § 379(b) were met; and

- Instances in which FDA withheld information under 21 U.S.C. § 379(b) in response to a FOIA request.

Components may wish to consider keeping records of the following:

- Incoming requests for non-public information by Foreign Government Agencies and International Organizations;

- Component responses to such requests;

- Name/position of the individual within the Component authorizing the sharing (in response to a request or proactively);

- Copies of information shared (as redacted);

- Name/position of the individual or unit within the Component that shares the non-public information; and

- Name/position of the individual or unit within the Foreign Government Agency or International Organization that received the non-public information.

7. CONSULTATIONS

If you have a question about the content of this SMG, consult your Component POC or the OGPS POC.

8. SUPPORTING DOCUMENTS

In order to share non-public information with a Foreign Government Official, appropriate documents must be prepared, signed by the appropriate officials, and kept on file. Examples of these documents are in Section 13 of this SMG, Attachments. These documents include:

A. **Statement of Authority and Confidentiality Commitment (Confidentiality Commitment) (Attachment A or Attachment B)**: This is the document that the Foreign Government Agency or International Organization must sign in order for FDA to be able to share most kinds of non-public information with those Foreign Government Officials. (To share trade secret information, FDA must have additional documentation.) Confidentiality Commitments are kept on file in OGPS and may be viewed on FDA's website at Confidentiality Commitments.[24]

B. **Internal Memorandum: Authorization to Share Non-Public Information and Determination that Sharing Is in the Interest of Public Health (Internal Memorandum) (Attachment C)**: This document is prepared by the OGPS POC and used by the Associate Commissioner, Office of Global Policy and Strategy to authorize the sharing of non-public information with Foreign Government Officials. This document is kept on file in OGPS.

C. **Model Transmittal Letter for Sharing Non-Public Information Pursuant to a Confidentiality Commitment (Attachment D)**: This document should be used by a Component when sharing non-public information in physical form (mail, CD-ROM, etc.) rather than electronic form.

D. **Visitor's Commitment (Attachment E)**: This document must be signed by Visiting Foreign Government Scientists. It enables the scientist to have access to non-public information, including trade secret information, that is required as part of the joint review or training in which the scientist is involved. This document is kept on file in the relevant Component, as per Component written procedures. A Confidentiality Commitment (Attachment A or Attachment B) must also always have been signed by the Visiting Foreign Government Scientist's home Foreign Government Agency or International Organization.

E. **Owner's Authorization (Attachment F)**: This document is required before the Component can share trade secret information; it must be signed by the individual or entity with the right to authorize FDA to share the information. If there is a need to share trade secret information, contact the appropriate Component POC.

F. **Model Notification to Foreign Government Agency that Information Received under a Confidentiality Commitment is Likely Subject to Required Disclosure under the U.S. FOIA (Attachment G)**: When a Component receives

[24] https://www.fda.gov/international-programs/international-arrangements/confidentiality-commitments

a FOIA request for which some of the responsive documents are ones that were shared by a Foreign Government Agency or International Organization, the Component should use this document to inform the Foreign Government Agency or International Organization of the situation, provide it with a courtesy copy of the record, as redacted, and offer to discuss the proposed redactions.

9. SMG 2830.3 ANNEX: SHARING TRADE SECRET INFORMATION UNDER SECTION 708(c) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

1. Purpose

The purpose of this Annex is to complement the above Staff Manual Guide, which addresses the sharing of non-public information with Foreign Government Officials[25] and to provide FDA staff with information about the sharing of certain types of trade secret information with foreign governments under section 708(c) of the FDCA.

The purpose of this SMG and this Annex is to ensure consistency across FDA Components in (1) the general approach to requests from Foreign Government Officials for non-public information; (2) understanding legal requirements relating to sharing non-public information with Foreign Government Officials; (3) the management of non-public information received from Foreign Government Officials in ways that ensure the appropriate future handling and use of such information; and 4) understanding the roles and responsibilities of the Office of Global Policy and Strategy (OGPS) and other FDA Components in handling common international information-disclosure issues.

Additional policies and procedures can be found in the main body of this SMG and in each FDA Component's written procedures. The information in this Annex applies whether it is FDA or the Foreign Government Official who initiates the sharing of non-public information.

2. Background

Certain types of information that FDA acquires as part of its regulatory mission is considered to be "non-public." Non-public information refers to information that is protected from disclosure to the public by United States law, such as the Freedom of Information Act, the Privacy Act, the Trade Secrets Act, the Economic Espionage Act, the National Childhood Vaccine Injury Act, and the FDCA. Examples of non-public information include confidential commercial information, trade secret information, predecisional FDA communications, investigative information, enforcement information, and personal privacy information.

[25] For definitions of capitalized terms, such as "Foreign Government Officials", please consult the main body of this SMG.

Generally, the sharing of non-public information must be pursuant to a signed Confidentiality Commitment from the Foreign Government Agency/International Organization and/or pursuant to appropriate written authorizations, as needed. For a detailed description of different types of non-public information, as well as the sharing of such information under a 21 C.F.R. § 20.89 Confidentiality Commitment, please refer to the main body of this SMG.

Trade secret information that is subject to section 301(j) of the FDCA is a category of non-public information with additional protections, and FDA generally cannot disclose trade secret information without explicit, written owner consent.[26] However, the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) has altered this legal framework by amending the FDCA, permitting FDA to share certain types of trade secret information relating to drug facility inspections and investigations—without first obtaining written sponsor/owner consent—with a foreign government, provided certain conditions are met. Those conditions require:

(1) Certification by the Secretary that the foreign government has the authority and demonstrated ability to protect trade secret information from disclosure[27]; and

(2) A written agreement that includes a commitment from the foreign government to protect the information exchanged from disclosure unless and until the information's sponsor provides written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act.[28]

Even if FDA has the requisite certification and written agreement in place, additional restrictions apply when sharing trade secret information under section 708(c) of the FDCA without written owner's consent. Those restrictions are discussed in detail in Section 2, below.

In 2015, the Acting Commissioner, with delegated authority from the Secretary,[29] certified the European Commission—including the European Medicines Agency (EMA) and the European Commission's Directorate General for Health and Food Safety (DG SANTE)—as well as the national competent authorities for drug regulation in each European Union Member State pursuant to section FDCA 708(c)(1). Beginning in July 2017, FDA started entering into Confidentiality Commitments that satisfy the requirements of 21 C.F.R. § 20.89 and FDCA section 708(c)(2), providing the written agreement that allows FDA to share confidential commercial information (as well as predecisional/deliberative

[26] *See* 21 U.S.C. § 331(j).
[27] 21 U.S.C. § 379(c)(1) (section 708(c)(1) of the Food, Drug, and Cosmetic Act
[28] 21 U.S.C. § 379(c)(2).
[29] *See* SMG 1410.10. Responsibility for this certification cannot be delegated to any officer or employee other than the Commissioner.

information) and trade secret information without sponsor/owner consent. The first of these new "trade secret information Confidentiality Commitments" was completed with EMA and DG SANTE on August 11, 2017. Trade secret information Confidentiality Commitments are expected to be completed with the competent authorities for each European Union Member State. It is important to note that the trade secret information Confidentiality Commitments are limited in scope to drugs only. If there is a confidentiality commitment in place, FDA can assume conditions 1 and 2, outlined above, have been met. A list of Confidentiality Commitments to and from FDA can be found on FDA's website at Confidentiality Commitments.

3. Sharing Trade Secret Information under FDCA Section 708(c)

A. Sections 708(c)'s Requirements

In addition to the Commissioner's certification and the written agreement (Confidentiality Commitment) described above, section 708(c)(3)(A) permits the sharing of trade secret information with a foreign government without written owner consent in only the following circumstances:

- The information relates to "**drugs**," as defined by the FDCA;
- The information **concerns the inspection of a facility**; and
- The written agreement establishes that the foreign government has the authority to otherwise obtain such trade secret information **and** limits its use of the trade secret information to civil regulatory purposes.

The trade secret information Confidentiality Commitments established with the EMA, DG SANTE, and the European Union Member State competent authorities contain a statement from the foreign government that it has the authority to otherwise obtain the trade secret information and will limit its use of such to civil regulatory purposes. Therefore, each instance of sharing trade secret information, whether in writing or orally, must involve an evaluation of the remaining criteria—a determination that the trade secret information relates to drugs and concerns the inspection of a facility.

The term "drugs," as used in section 708(c), includes human and animal drugs as well as biological products, but does not include products that are regulated as dietary supplements in the United States. FDA interprets "facility" to include not only those sites engaged in the drug-supply chain but also sites where clinical investigations are conducted[30].

[30] Records created or collected during inspections or investigations of clinical investigators (for example, related to possible violations of statutes or regulations governing clinical investigations of FDA-regulated products) may be shared pursuant to System of Records Notice 09-10-0010 Bioresearch Monitoring Information System (Routine Use 1)

Alternatively, section 708(c)(3)(B) provides that trade secret information not described above may be provided as part of an investigation—or to alert the foreign government to the potential need for investigation—if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to human or animals ("SAHCODHA"). This section provides alternative grounds for sharing trade secret information, though it still requires certification by the Commissioner and a trade secret information Confidentiality Commitment to be in place. The authority to trigger trade secret information-sharing under this particular section is delegated from the Secretary to the Commissioner in SMG 1410.10 and is further delegated to the FDA officers listed in SMG 1410.21 and SMG 1410.65. Therefore, to share trade secret information under section 708(c)(3)(B), one of the FDA officers listed in SMG 1410.21 or SMG 1410.65 must have reasonable grounds to believe that a drug has a reasonable probability of causing SAHCODHA. In practice, this means that the FDA Component should determine or confirm its procedures for communicating with the appropriate FDA official listed in 1410.21 or 1410.65.

B. Examples

Below is a list of the types of documents and/or information that FDA may want to share with a foreign counterpart. This list, which is not exhaustive, is meant to help inform the FDA Component's decision as to whether trade secret information can be shared with a foreign government under a trade secret information Confidentiality Commitment. It is important to remember that each instance of information-sharing should be evaluated on a case-by-case basis, and any questions or concerns about sharing non-public information with a foreign government should be directed to disclosure experts in the relevant FDA Component, the Office of the Chief Counsel, or the OGPS Point of Contact.

1. Establishment Inspection Reports, Form FDA 483, and Accompanying Exhibits/Evidence and Inspectional Correspondence:

Establishment Inspection Reports (EIRs), 483s, inspectional correspondence, and accompanying documentation contain written information about inspectional findings and may contain both confidential commercial information and trade secret information. Although each instance of sharing trade secret information with a foreign government should be evaluated to confirm that all section 708(c) criteria are met, these documents should almost always fall within the language of section 708(c)(3)(A) and be eligible for sharing with a trade secret information Confidentiality Commitment in place. EIRs, 483s, and related firm

https://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/ucm164775.html. This disclosure requires an accounting under 21 CFR 21.71.

correspondence (such as 483 responses) most clearly concern the inspection of a facility. But even accompanying exhibits—which are collected from or received by firms and would not normally be released pursuant to a FOIA request—would be shareable under a trade secret information Confidentiality Commitment because of their relevance to the inspection itself and the primary documents/resulting reports to which they are attached.

2. **Advisory notices such as warning letters, untitled letters:**

   A Warning Letter (or Untitled Letter, depending on the significance of the violation) is an informal and advisory correspondence that notifies regulated industry about apparent violations of FDA-administered statutes and regulations. Typically, a warning letter notifies an individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of applicable federal law or FDA regulations. These letters contain detailed descriptions of the apparent violations observed or discovered, and they provide legal citations, providing the recipient with both the legal and factual bases for the warning.

   Warning and Untitled Letters may contain confidential commercial information and trade secret information, but they are not always issued following the inspection of facility. They may, for example, be issued in response to an advertising or promotional labeling violation that's been discovered or in response to the discovery of the illegal online sale of prescription drugs. Whether the Letter in question can be shared under a Confidentiality Commitment without redacting any trade secret information it contains requires an evaluation of whether the trade secret information relates to drugs and concerns the inspection of a facility—or whether it can be shared as part of an investigation (or to alert the foreign government to the potential need for investigation) as described in section 708(c)(3)(B).

3. **Draft complaints and other documents submitted to the Department of Justice to support injunction or seizure actions:**

   The underlying trade secret information in a draft complaint or other document submitted to the Department of Justice (DOJ) to support an enforcement action will likely be found in documentation that precedes the initiation of the enforcement action and, therefore, may more closely "concern an inspection" so that it will probably not be necessary to disclose draft complaints or other documents submitted to DOJ. In other words, there should be documentation more appropriate for sharing that is more closely linked to the inspection of a facility and upon which any draft

complaint was based. It is this inspection related documentation that should be evaluated under section 708(c).

Documents submitted to DOJ are generally subject to the attorney-client, deliberative process, and investigative files privileges and therefore are not appropriate to share. The trade secret information should be located in earlier documentation that can be linked to an inspection.

4. **Internal FDA memoranda explaining decisions on proposed regulatory actions:**

   Internal FDA memoranda may contain predecisional and deliberative information, confidential commercial information, and trade secret information. With a trade secret information Confidentiality Commitment in place, un-redacted trade secret information may be shared so long as it relates to drugs and concerns the inspection of a facility or meets the requirements of 708(c)(3)(B). Because the nature of internal memoranda can vary so greatly, a careful evaluation of the section 708(c) criteria should be conducted, consulting with Component information disclosure experts or with OCC as necessary, before sharing any trade secret information with a foreign government.

5. **FDA laboratory records documenting tests of regulated products as defined by FDASIA:**

   Laboratory records documenting tests of regulated products may be protected from public disclosure under certain circumstances as predecisional documents. They may, but rarely, contain confidential commercial information or trade secrets. To the extent that such documents do contain trade secrets, they may be disclosed under 708(c)(3)(A) if they “concern an inspection of a facility” or under 708(c)(3)(B) if they are part of an investigation, or to alert the foreign government of the potential need for investigation, if the Commissioner, or FDA officer with delegated authority, has reasonable grounds to believe that the drug to which it relates has a reasonable probability of causing SAHCODHA. If the documents do not contain trade secret information, they may be disclosed as other predecisional information under the relevant SMG 2830.3 provision.

6. **Defect reports and summaries of defect reports submitted to FDA, including MedWatch reports, Field Alert Reports, Consumer Complaints and Biological Product Defect Reports (with patient-specific information redacted):**

   Through MedWatch, FDA receives information about adverse events that the reporter has observed or suspects for human medical products,

including serious drug side effects, medication errors/product use errors, product quality problems, and therapeutic failure. Field Alert Reports are required to be submitted by applicant holders of approved new drug applications and abbreviated new drug applications soon after becoming aware of a reportable quality failure; they are intended to quickly identify quality defects in distributed drug products. Biological Product Defect Reports require licensed manufacturers of biological products to report certain defects and problems that may affect the safety, purity, or potency of a distributed licensed product. Consumer Complaints (not handled through MedWatch or other means) may be received by FDA Consumer Complaint coordinators in the field and may relate to products, firms, or other matters.

Any of these reports could contain confidential commercial information or trade secret information. In order to qualify for sharing, they must "concerns the inspection" of a facility, which will be a case-specific inquiry. To what extent the trade secret information in one of these reports concerns the inspection of a facility may vary. The more closely the trade secret information relates to a planned or scheduled inspection or the need for an inspection in the foreseeable future, the more likely it will meet the criteria in § 708(c)(3)(A). Disclosure of these reports should be done in accordance with any policy decisions that the FDA component might have made for protecting personal privacy information.

7. Combination Products

A combination product is a product composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product. Under 21 CFR 3.2 (e), a combination product is defined to include:

1. A product comprised of two or more regulated components (i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity [often referred to as a "single-entity" combination product];

2. Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products [often referred to as a "co-packaged" combination product];

3. A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use,

indication, or effect and where, upon approval of the proposed product, the labeling of the approved product would need to be changed (e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose) [often referred to as a "cross-labeled" combination product]; or

4. Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect [another type of "cross-labeled" combination product].

   With a trade secret information Confidentiality Commitment in place, un-redacted trade secret information for a combination product may be shared if (1) no trade secret information or confidential commercial information is shared for the device component, and (2) the lead center with primary jurisdiction over the product is the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

10. REFERENCES

A. 21 C.F.R. § 20.89, Communications with foreign government officials, as amended, March 7, 2000.

B. 21 C.F.R. Part 20, Public information.

C. 21 U.S.C. § 360j(c) (provision in the Federal Food, Drug and Cosmetic Act providing for additional limitations on the release of certain medical device-related information).

D. 21 U.S.C. § 387f(c) (provision in the Federal Food, Drug and Cosmetic Act providing for additional limitations on the release of certain tobacco product-related information).

E. 21 U.S.C. § 379(c) (provision in section 708(c) of the Food, Drug, and Cosmetic Act providing for sharing of certain trade secret information).

F. Economic Espionage Act, 18 U.S.C. § 1831.

G. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

H. Freedom of Information Act (FOIA), 5 U.S.C. § 552.

I. National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 300aa-34.

J. Privacy Act, 5 U.S.C. § 552a.

K. Staff Manual Guide 1410.66: Disclosure of Non-Public Information to Foreign Government Officials or Receipt of Non-Public Information from Foreign Government Officials.

L. Staff Manual Guide Part 1410, Regulatory Delegations of Authority.

M. Staff Manual Guide 1410.65, Disclosure of Trade Secret Information to Foreign Governments

N. Trade Secrets Act, 18 U.S.C. § 1905.

11. EFFECTIVE DATE

The effective date of this SMG is August 23, 2019.

12. Document History - SMG 2830.3, "Confidentiality Commitments; Sharing of Non-Public Information with, and Treatment of Non-Public Information Received from, Foreign Government Officials"

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	10/18/2005	N/a	Office of International Programs, HF-3	Murray M. Lumpkin, M.D., Deputy Commissioner
Change	03/21/2006	5(A)(2)(a)	Office of International Programs, HF-3	Murray M. Lumpkin, M.D., Deputy Commissioner
Revision	08/21/2019	N/a	Office of Global Policy and Strategy, HF-3	Mark Abdoo, Associate Commissioner for Office of Global Policy and Strategy
Change	08/26/2019	2830 Series Title	Office of Global Policy and Strategy, HF-3	Mark Abdoo, Associate Commissioner for Office of Global Policy and Strategy
Change	06/15/2020	Section 3 and 10: replace reference SMG 1410.24 with 1410.66	Office of Global Policy and Strategy, HF-3	Mark Abdoo, Associate Commissioner of Global Policy and Strategy

Back to General Administration, Volume III (2000-3999)

SMG 2830.3 ATTACHMENT A

STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT FROM
[Insert name of foreign GOVERNMENT 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 to disclose non-public information to *[insert name of Foreign Government Agency or International Organization (abbreviation)]* regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

[Insert abbreviation of foreign agency] 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, predecisional information.[1] *[Insert abbreviation of foreign agency]* understands that this non-public information is shared in confidence and that FDA considers it critical that *[insert abbreviation of foreign agency]* maintain the confidentiality of the information. Public disclosure of this information by *[insert abbreviation of foreign agency]* could seriously jeopardize any further scientific and regulatory interactions between FDA and *[insert abbreviation of foreign agency]*. FDA will advise *[insert abbreviation of foreign agency]* of the non-public status of the information at the time that the information is shared.

Therefore, *[insert abbreviation of foreign agency]* certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to *[insert abbreviation of foreign agency]* in confidence by FDA;

[1] This Confidentiality Commitment, alone, does not authorize FDA to share of all of these types of non-public information, since there may be additional requirements that must be met before some of this information can be shared (e.g., before FDA can share trade secrets, the owner of that information must generally consent).

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

3. will inform FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from *[insert abbreviation of foreign agency]*. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, *[insert abbreviation of foreign 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

4. will promptly inform FDA of any changes to *[insert name of foreign country]*'s laws or regulations, or to any relevant policies or procedures, that would affect *[insert abbreviation of foreign agency]*'s ability to honor the commitments in this document.

[Signature of Foreign Government Agency Head]

_____ _____

Print/Type name of Foreign Government Agency Official Date

Title of foreign agency official

Name of foreign agency

Address:

Telephone:

Fax:

SMG 2830.3 ATTACHMENT B

STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT FROM [*FOREIGN COUNTERPART*] 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 [*foreign counterpart*] 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 [*foreign counterpart*] as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide [*foreign counterpart*] with certain types of trade secret information at FDA's discretion and upon request by [*foreign counterpart*], based on the following certifications.

[*Foreign counterpart*] 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, predecisional information. [*Foreign counterpart*] understands that this non-public information is shared in confidence and that it is critical that [*foreign counterpart*] maintains the confidentiality of exchanged non-public information. Public disclosure of exchanged non-public information by [*foreign counterpart*] could seriously jeopardize any further scientific and regulatory interactions between [*foreign counterpart*] and FDA. FDA will advise [*foreign counterpart*] of the non-public status of the information at the time that the information is shared.
Therefore, [*foreign counterpart*] certifies that it:

(1) has the authority to protect from public disclosure such non-public information provided to [*foreign counterpart*] in confidence by FDA;

[1] United States Code of Federal Regulations, Title 21, section 20.89.

[2] United States Code, Title 21, section 379(c).

(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 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 [*foreign counterpart*] 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 [*foreign counterpart*]. If such judicial or legislative mandate requires disclosure of FDA-provided non-public information, [*foreign counterpart*] 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 [*foreign country's*] laws, or to any relevant policies or procedures, that would affect [*foreign counterpart's*] ability to honor the commitments in this document.

[*Foreign counterpart*] 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. [*Foreign counterpart*] 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 [foreign counterpart]

_____ _____

Name of foreign counterpart official Date

Title of foreign counterpart official

Name of foreign counterpart

Address:

SMG 2830.3 ATTACHMENT C

For FDA-internal OPLIA/OGPS use only:

INTERNAL MEMORANDUM:
AUTHORIZATION TO SHARE NON-PUBLIC INFORMATION WITH *[NAME OF FOREIGN GOVERNMENT AGENCY]* AND DETERMINATION THAT SHARING IS IN THE INTEREST OF PUBLIC HEALTH

From: *[Name],* Associate Commissioner,
Office of Global Policy and Strategy

Subject: Authorization to share non-public information with *[name of Foreign Government Agency or International Organization]* and determination that sharing will be in the interest of public health

To: *[Name]*, Director for Office of Trade, Mutual Recognition and International Arrangements , Office of Global Policy and Strategy

Pursuant to 21 C.F.R. § 20.89, I authorize the sharing of non-public information in FDA's files, including confidential commercial, predecisional and other non-public information, as well as trade secret information with sponsor consent or when the requirements of section 708(c) of the Federal Food, Drug, and Cosmetic Act are met, with officials of *[name of Foreign Government Agency or International Organization],* who perform counterpart functions to the FDA as part of cooperative law enforcement and regulatory efforts.

I am making this determination in furtherance of the *[title of Confidentiality Commitment from Foreign Government Agency or International Organization to FDA]*, signed on *[date]*.

In addition, I have determined that sharing this information would be in the interest of the public health by reason of *[name of Foreign Government Agency or International Organization's]* possessing information concerning the safety, efficacy, or quality of products or information concerning investigations.

_____ _____

[name] Date

Associate Commissioner

SMG 2830.3 ATTACHMENT D

MODEL TRANSMITTAL LETTER
FOR SHARING NON-PUBLIC INFORMATION
PURSUANT TO A CONFIDENTIALITY COMMITMENT

[Date]
[Name]
[Title]
[Address]

Dear [*insert name of Foreign Government Agency official*]:

The enclosed information is being provided in response to a request dated *[insert date]* from *[insert name of requester]* for *[insert description of requested information]*.

In accordance with U.S. 21 C.F. R. § 20.89 and section 708(c) of the Federal Food, Drug, and Cosmetic Act, when the requirements therein are met, this information is being shared in reliance upon the *[insert full title of Confidentiality Commitment from Foreign Government Agency to FDA]* signed on *[date]*.

The information being shared may contain non-public information that is exempt from disclosure under the laws and regulations of the United States. Such information is being provided for official use only. It is being shared with the *[insert name of Foreign Government Agency or International Organization (abbreviation)]* in confidence, and **should not be disclosed to the public or persons outside your organization**. FDA considers it critical that *[abbreviation]* maintain the confidentiality of this information and abide by the obligations contained in the Confidentiality Commitment referenced above.

Please take steps to ensure that all *[abbreviation]* personnel who will have access to this information are aware of the importance of protecting the information from public disclosure and of the obligations to protect the confidentiality of the information as agreed in the Commitment cited above.

Please confirm receipt of this information by *[insert desired method of response]*. If you have any questions, please contact *[insert name of contact].*

Sincerely,

Bcc: (on separate page)*[FDA Foreign Office e-mail mailbox]*

SMG 2830.3 ATTACHMENT E

VISITING FOREIGN GOVERNMENT SCIENTIST'S COMMITMENT TO PROTECT NON-PUBLIC INFORMATION AND ASSURANCE OF NO FINANCIAL INTEREST

I, *[name of Visiting Foreign Government Scientist]*, a representative of *[name of scientist's home Foreign Government Agency or International Organization]*, am visiting the United States Food and Drug Administration (FDA) for the purpose of *[to be filled in by the hosting FDA Component(s)]*.

COMMITMENT TO PROTECT INFORMATION

I certify that I have the authority to protect the confidentiality of the information I view on FDA premises. I agree to protect non-public information, including, but not limited to, confidential commercial or trade secret information, entrusted to me by:

1. Storing the non-public information in the secured offices of FDA, and
2. Granting access to the non-public information only to known FDA personnel or to such other persons as may be designated in writing by FDA.

Further, I agree to:

1. Assist in reviewing the security measures I will employ in protecting non-public information,
2. Return all confidential commercial, trade secret, or other non-public information and notes pertinent thereto to FDA upon completion of my assignment, or upon FDA's request,
3. Report in writing to an FDA official all incidents in which unauthorized persons might have gained access to non-public, including confidential commercial or trade secret, information entrusted to me, and
4. Not disclose, publish, or share non-public information without the written permission of FDA.

I agree <u>not to share</u> trade secret and personal privacy information learned during the course of my activities at FDA <u>with my home government institution, including with colleagues or superiors there</u>.

ASSURANCE OF NO FINANCIAL INTEREST

Furthermore, I certify that I do not have any ownership or other financial interest in products regulated by *[name of FDA Component Center(s) or Office(s)]*.

I understand that unauthorized disclosure of non-public information may subject me to criminal penalties under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331(j)), the Economic Espionage Act (18 U.S.C. § 1831-39), and the Trade Secrets Act (18 U.S.C. § 1905)).

_____ _____

SIGNATURE DATE

_____

TYPED OR PRINTED NAME OF VISITOR

WITNESSED:

_____ _____

SIGNATURE DATE

_____

TYPED OR PRINTED NAME OF WITNESS

SMG 2830.3 ATTACHMENT F

MODEL OWNER'S AUTHORIZATION FOR FDA TO SHARE CONFIDENTIAL COMMERCIAL AND/OR TRADE SECRET INFORMATION WITH A FOREIGN GOVERNMENT AGENCY OR INTERNATIONAL ORGANIZATION

(OWNER[1] OF THE NON-PUBLIC INFORMATION SHOULD PREPARE ON ITS LETTERHEAD)

[FDA Component contact name]
[Title]
[Office]
[Center]
U. S. Food and Drug Administration
[Address]

RE: FDA's Sharing of Non-Public Information concerning *[Insert Name of Regulated Product(s) and/or facility]* with *[Insert name of Foreign Government Agency or International Organization]*

Dear [FDA Component contact],

On behalf of *[insert name of owner of the information]*, the sole owner of trade secret information related to the above-referenced regulated product(s), I authorize the United States Food and Drug Administration (FDA) to share the information described below with the *[insert name of Foreign Government Agency or International Organization]* solely for the purpose of *[insert description of purpose].* I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 5 U.S.C. § 552(b)(4), 21 U.S.C. § 306j(c), and 21 U.S.C. § 387f(c) that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with *[insert name of Foreign Government Agency or International Organization]*.

Information to be shared: *[provide description of information]:*

Authorization is given to FDA to share the above-mentioned information without deleting confidential commercial or financial or trade secret information. As indicated by my

[1] The term "owner" (of non-public information) refers to the submitter, sponsor, manufacturer, or other entity that has the legal ability to authorize the sharing of its non-public information (particularly trade secret information) by FDA with a Foreign Government Agency or International Organization.

signature, I am authorized to provide this consent on behalf of *[insert name of company]* and my full name, title, address, telephone number, and fax number are set out below for verification. I am sending a copy of this letter to *[the Foreign Government Agency or International Organization]* with which FDA may share the information.

Sincerely,

_____

(Signature)

_____

(Printed name)

_____

(Title)

_____

(Telephone & Fax Numbers)

cc: *[the Foreign Government Agency or International Organization]*

SMG 2830.3 ATTACHMENT G

MODEL NOTIFICATION
TO FOREIGN GOVERNMENT AGENCY OR INTERNATIONAL ORGANIZATION THAT INFORMATION RECEIVED UNDER A CONFIDENTIALITY COMMITMENT IS LIKELY SUBJECT TO REQUIRED DISCLOSURE UNDER THE U.S. FOIA

Dear Colleagues,

We have received a request under the U.S. Freedom of Information Act (FOIA), 5 U.S.C. § 552, for access to the following documents: *[description of documents as requested in the FOIA request]* (please see the attached request, #20XX-XXXX).

FDA has identified records relating to *[name of Foreign Government Agency or International Organization]* that is responsive to this request. This record is *[brief description of the responsive record, e.g. "an e-mail sent from FDA staff member X to Foreign Government Agency staff member Y" discussing Z]*.

In accordance with our *[year of signing]* Confidentiality Commitment(s) with *[name of Foreign Government Agency or International Organization]*, we are notifying you of this FOIA request and our proposed release of this record, with non-public information redacted and therefore protected from public disclosure. For your information, the redacted record is attached; the portions of the text outlined in red will <u>not</u> be released.

We wanted to give you the opportunity to review this email and provide feedback regarding the redactions. Because there are strict legislative timeframes associated with the processing of FOIA requests, we would appreciate your input by *[date]*.

Please let me know if you would like to discuss.

Regards,