



## **INFORMATION PAPER**

### **OVERVIEW OF COMMISSIONING AND INFORMATION SHARING AGREEMENTS WITH STATE AND LOCAL GOVERNMENT OFFICIALS**

#### **INTRODUCTION**

As part of the cooperative regulatory and enforcement efforts between FDA and its State and local counterparts, there is often a need for State and local officials to have access to non-public information. As described below, State and local officials who are commissioned under section 702(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 372] are acting under FDA's authority and, therefore, they have access to non-public information in this capacity. For non-commissioned officials, FDA can share certain non-public information, such as deliberative and confidential commercial information (CCI), in accordance with its disclosure regulations at 21 Code of Federal Regulations (CFR) section 20.88 (21 CFR 20.88). Under these regulations, FDA may only share CCI with State and local officials under a written confidentiality agreement (referred to as a 20.88 agreement).

The Office of Partnerships (OP) in the FDA's Office of Regulatory Affairs (ORA) manages the FDA Commissioning Program and 20.88 agreements with many State agencies that provide a streamlined process for information sharing related to food, including animal feed and dietary supplements (referred to as the "Food Information Sharing 20.88 Agreement"). ORA's Office of Policy and Risk Management (OPRM) manages and administers all other 20.88 agreements, including for information related to drugs, biologics, medical devices, and tobacco.

#### **OVERVIEW**

##### **(1) COMMISSIONING**

Commissioning is a process that permits State and local officials to conduct examinations and investigations under the authority of the FD&C Act. In other words, State and local officials who are commissioned can conduct examinations, inspections, and investigations, as well as collect and obtain sample, and copy and verify records under the FD&C Act even when their own State and municipal laws do not give them this authority. Because they are acting under FDA's authority, commissioned officials may have access to non-public information, including deliberative documents, CCI, and trade secret information.

State and local officials who are directly linked to an inspection program under a FDA food inspection contract must be commissioned if they will be performing examinations and investigations under the FD&C Act. Under the procedures in Chapter 3 of the Regulatory Procedures Manual (RPM), FDA may either issue pocket credentials or a certificate to commissioned State and local officials. Commissions with pocket credentials are typically issued to State and local officials who are routinely involved in facility inspections. In order for an individual to receive a pocket credential commission, the individual will have to

undergo a level five (5) public trust background investigation. Commissions with certificates are typically issued to executive and senior-level State Agency officials. Although FDA may choose to conduct a background investigation for commissions with certificate, background investigations are not mandatory. FDA will not commission any official determined to have a conflict of interest. With either the commission with credential or certificate, a State or local official is authorized to receive non-public information, including deliberative, CCI, and trade secret information obtained under the FD&C Act only for the purposes their work with the FDA (see 21 CFR 20.84).

As FDA deems appropriate, a health, food, or drug officer or employee of a State, territory, or a political subdivision thereof can be commissioned as an officer of the Department of Health and Human Services. Each commission is issued for a period of five years. Towards the end of this period, FDA will review each commission and determine whether it should be renewed.

## **(2) 20.88 CONFIDENTIALITY AGREEMENT**

A 20.88 agreement permits FDA to share certain non-public information with various State and local officials who have signed a written agreement in accordance with 21 CFR 20.88. In the agreement, the State or local government agency confirms it has the authority to protect non-public information from public disclosure and it promises not to further disclose such information without written permission from FDA. Unlike Commissioning, the FDA cannot share trade secret information under 20.88 agreements.

Most 20.88 agreements are administered on a case-specific basis. However, as previously mentioned, FDA established certain 20.88 agreements that provide a streamlined process for sharing information related to food and feed. Such streamlined agreements are administered by the OP and cover a period of several years. Under the streamlined procedures, FDA can rapidly share, under certain circumstances, certain non-public information, including deliberative documents and CCI, but not trade secret information, with State and local agencies responsible for food inspection programs and laboratories regarding food-related product information, inspections, enforcement actions, and foodborne illness investigation data and traceback information when they have provided a written commitment to not further disclose this information. FDA can only share CCI with State and local officials in circumstances where FDA has determined that sharing such non-public information is in the interest of public health because either (1) the State or local agency needs the information because it concerns the safety, effectiveness, or quality of a product or information concerning an investigation; or (2) the State or local agency is able to exercise its regulatory authority more expeditiously than the FDA.

All 20.88 agreements for food and feed expire on December 31, 2013 and will be renewed for another three years.

### **(3) DIFFERENT TYPES OF NON-PUBLIC INFORMATION**

#### **(A) COMMERCIAL CONFIDENTIAL INFORMATION AND TRADE SECRET INFORMATION**

Pursuant to 21 C.F.R. § 20.61, CCI is defined as valuable data or information which is used in a business and is of such type that it is customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the entity to whom it belongs. Examples of CCI would include business documents related to production, distribution, and quality assurance.

A trade secret is defined under 21 C.F.R. § 20.61 as any commercially valuable plan, formula, process, or device that is used for making, preparing, compounding, or processing of commodities, and it can be said to be the end product of either substantial effort or innovation. In order for confidential information to be considered a trade secret, there must be a direct relationship to the manufacturing methods and processes. An example of a trade secret would be the formula for the natural flavorings in a carbonated soft drink.

The Trade Secrets Act (TSA), 18 U.S.C. § 1905, prohibits government employees from disclosing CCI and trade secret information unless the disclosure is authorized under regulation. Section 301(j) of the FD&C Act prohibits most disclosures of trade secrets without the sponsor's authorization. In addition, CCI and trade secret information are exempt from public disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

#### **(B) DELIBERATIVE INFORMATION**

Deliberative information (sometimes referred to as pre-decisional information) includes, but is not limited to, draft rules, draft guidance, and intra-agency or inter-agency communications containing deliberations about potential actions or possible policy decisions. Pre-decisional documents are exempt from public disclosure under FOIA. In addition, some pre-decisional documents may also contain information, such as CCI, which is prohibited from public disclosure.

### **(4) DIFFERENCES BETWEEN COMMISSIONING AND 20.88 CONFIDENTIALITY AGREEMENT**

By way of comparison, it is less burdensome for FDA to execute a 20.88 agreement, which can cover multiple State and local officials, than to issue a single commission. Moreover, the case-specific 20.88 agreements can be executed quickly. Not only can 20.88 agreements be established relatively quickly, but they can also be easily updated and amended. Whereas to establish, update, or amend a commission with credentials, FDA would need to conduct an official background investigation.

Further, a 20.88 agreement permits sharing deliberative documents and CCI with State and local officials, but not trade secret information. Although trade secret information may not be shared under a 20.88 agreement, most information that is shared between FDA and the States does not involve trade secrets. Therefore, it is not necessary or appropriate to commission large numbers of State or local employees to receive non-public information from FDA.

Another key difference between the two processes is the legal status that is conferred upon the State or local official. A Commissioned State or local official is considered an FDA employee when he is performing activities under the FD&C Act.

For the purpose of information sharing only with State or local officials, the use of the 20.88 agreement is generally sufficient. Only State and local officials that perform examinations and investigations for the purpose of the FD&C Act need to be commissioned.

**(5) DIFFERENCES BETWEEN 20.88 CONFIDENTIALITY AGREEMENT FOR FOOD/FEED AND 20.88 CONFIDENTIALITY AGREEMENT FOR OTHER PROGRAM AREAS**

The 20.88 agreement for food and feed, which is managed and administered by the OP, is for a specified period of time (e.g., 3 years) and can cover the sharing of CCI and deliberative documents pertaining to food/feed during the entire period of time covered by the agreement. On the other hand, the 20.88 agreement that is used for other program areas (e.g., drugs, devices, biologics, etc.), which is managed and administered by ORA's OPRM, is "event-specific" and covers the sharing of certain CCI and deliberative documents related to the event specified in the agreement.