U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

Information Sharing: 20.88 Agreements & Commissioning

Information Sharing Vehicles:

Any non-public information (NPI) that is procured by FDA or by any official working under FDA authority or contract is owned by FDA. In order to receive information that is classified as non-public, state agencies and organizations must participate in a work sharing or information sharing agreement with FDA. Further disclosure by the individual who receives information from FDA to someone else is prohibited unless authorized.

Overview of 20.88 Information Sharing Initiatives:

- **General 20.88 Agreements** are information sharing vehicles whereby FDA shares confidential commercial information (CCI), deliberative documents, personal privacy information (PPI) and open investigatory records with state and local government officials. Such agreements do NOT allow the transmission of trade secret information.
- **Single-Signature Long-Term Food Information Sharing Agreements** allow for the sharing of NPI related to food, animal food and cosmetic with **all** employees who report to the signatory.
- **Case-Specific 20.88 Agreements** allow for the sharing of NPI related to a particular incident involving an FDA related industry. A Case Specific 20.88 can be expedited if the Office of Policy and Risk Management is made aware of the need for urgent processing.
- **20.88 with Associations** allows for the sharing of non-public deliberative processes and pre-decisional information **only**.
- FDA's Office of Strategic Planning and Operational Policy (OSPOP) administers all 20.88 agreements to share information.

Overview of FDA Commissioning for Information Sharing:

- Through the Food Drug and Cosmetic Act, state and local food and drug officials are granted the authority to conduct examinations and investigations under the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- FDA can share all documents and records containing: trade secret information, CCI, deliberative documents, and PPI.
- FDA's Office of Partnerships (OP) administers the commissioning program at the national level.

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Guidelines for Non-Public Information

Trade Secret Information includes, but is not limited to:

- Product Composition, (if different from what is declared on the label)
- Quantitative and semi-quantitative formula
- Manufacturing methods
- Product or component specifications
- Raw data submitted by the company
- Unique equipment or processes
- Sterilization techniques

Confidential Commercial Information (CCI) includes, but is not limited to:

- Identity of contract testing/analytical laboratory and personnel
- Brand name of equipment used
- Product failure rates
- Inventory amounts
- Existence of, or references to, an unapproved application, supplement or contract (unless said information was released by the manufacturer)
- Inventory
- Batch size / production volume (quantity produced)
- Identity of sub-contracting manufacturer, if not indicated on labeling
- Identity of suppliers

Personal Privacy Information (PPI):

- Any Personal Privacy Information that is contained in a Privacy Act system of records must be disclosed in accordance with the Privacy Act. Certain systems of records include routine uses that permit disclosures to certain state agencies. Please consult with the FDA's Privacy Officer.

Deliberative Information (pre-decisional) includes, but is not limited to:

- Draft rules, draft guidance
- Intra-agency or inter-agency communications containing deliberations about potential actions or possible policy decisions.

Follow Up Inquiries may be submitted to:

- For questions regarding the commissioning program contact your FDA State Liaison, or the Office of Partnerships at StateCommissioning@fda.hhs.gov.

- For questions regarding 20.88 Agreements contact OSPOP at InfoShare-ORA@fda.hhs.gov.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.