FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

FDA FACT SHEET

NON-PUBLIC INFORMATION SHARING

Information Sharing Tools

Any non-public information (NPI) that is procured by FDA or by any official working under FDA contract is owned by FDA. In order to receive information that is classified as non-public (see back for guidelines) 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 they also participate in the aforementioned agreements.

State Employees - Under a 20.88 Agreement

20.88 Agreements are information sharing vehicles whereby
21 CFR 20.88 allows FDA to share 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 Agreement (Food 20.88) allows for the sharing of NPI related to food, animal food and cosmetic with **all** employees who report to the signatory.

Case-Specific 20.88 allows for the sharing of NPI related to a particular incident involving an FDA related industry. A Case Specific 20.88 can be expedited if OPRM is made aware of the need for urgent processing. Each employee who will need access to the information must sign.

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.

Commissioned Officials

FDA Commissioning is a work sharing program whereby
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
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 (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.

Contact Information:

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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Information-Sharing Tools Matrix

The Matrix below provides an overview of the different information-sharing tools that are available, the categories of information that can be shared using each tool, and under what circumstances information can be further disclosed. The FDA is responsible for ensuring that if is necessary to share specific non-public information, that such sharing meets legal requirements. If certain non-public information does not need to be shared – even if legally it can be shared – it should be redacted wherever possible. The FDA is responsible for marking documents as confidential and making clear to the recipient, the restrictions on further sharing this information.

	Access to What Type of Information?	Information Movement	Info Owner	Internal Sharing of Information	External Sharing of Information
20.88 Single-Signature, Long-Term Food	Confidential Commercial Information (CCI), Deliberative Process, Personal Identifying Information[1] (PII), Investigatory Records	Information requested by state or Sent from FDA to states w/o request	FDA	Can be shared amongst all agency employees covered under the agreement	Cannot be further disclosed without written permission from FDA
20.88 Case Specific	CCI, Deliberative Process, PII, Investigatory Records	Information requested by state	FDA	Can be shared w/all signatories to the agreement	Cannot be further disclosed without written permission from FDA
20.88 Associations	Deliberative Process	Information requested by association or Sent from FDA to	FDA	Can be shared amongst all association members covered under the agreement	Cannot be further disclosed without written permission from FDA
Commissioning	Trade Secret (TS) , CCI, Deliberative Process, PII, Investigatory Records	Information originally obtained by the state employee on behalf of FDA	FDA	Can only be shared with other commissioned state agency officials	Cannot be further disclosed without written permission from FDA
State Contracts[2]	TS, CCI, Deliberative Process, PII, Investigatory Records	Information originally obtained by the state employee on behalf of the FDA	FDA[3]	Can be shared with other office employees in the course of completing tasks	Cannot be further disclosed without written permission from FDA[4]

[1] *Any personal privacy information that is contained in a Privacy Act system of records must be disclosed in accordance with the Privacy Act. Certain system of records includes routine uses that permit disclosures to certain state agencies. Please consult with the FDA's Privacy Officer.*

[2] *Includes states, territories, and tribal nations within the United States.*

[3] *Even if the information is obtained under the state's own regulations, if the work that is generated the information was done under a state contract with FDA, FDA owns the information.*

[4] *As per the Special Contract Provisions, Non-Public Information cannot be shared without FDA permission, except under the limited circumstances outlined in Section H, where compelled to under Court Order. If compelled under Court Order, the FDA is still to be notified in advance of release.*

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For more information:

- Commissioning Information
- Info-Sharing Information

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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.

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