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FDA's Information Sharing with Southern Nevada Health District

21 CFR 20.88

- 21 CFR 20.88 governs FDA's sharing of non-public information with State and local government officials.
- §20.88 enables FDA to share certain types of non-public information (NPI), including deliberative documents and confidential commercial information (CCI), with State and local government officials.

21 CFR 20.88

- Five Year, Single-Signature “Long-Term Food Information Sharing Agreement” or “Long-Term Food ISA”
- July 1, 2014 – June 30, 2019

Non-Public Information Sharing w/States Matrix
20.88, Commissioning and State Contracts

	Provides Access to What Type of Info?	Information Movement	Who "Owns" the Info?	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 <u>or</u> 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 <u>or</u> Sent from FDA to association w/o request	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 iscontained in a Privacy Act system of records must be disclosed in accordance with the Privacy Act. Certain system of records include 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 generated the information was done under a state contract with FDA, FDA owns the info.

[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.

<u>NOTE</u>: The FDA is responsible for ensuring that it is necessary to share specific non-public information and that such sharing meets legal requirements. If certain non-public information does not need to be shared – even if legally it can be shared – is 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.

State Responsibilities

- External information sharing cannot be further disclosed without written permission from the FDA

State Responsibilities

- State and local government agencies should inform FDA if the following situations should arise:
  - A court has requested NPI that was provided by FDA.
  - The Agency has received a request for NPI pursuant to the State's FOI statute or regulation.
  - There are any changes to the State's FOI statutes or regulations, which may impact the Agency's ability to keep its commitment.

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