

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

	Who Can Sign On?	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	Authorized State Official - Head of Public Health Agency (or Relevant Division/Section) signs for all employees	Confidential Commercial Information (CCI), Deliberative Process, Personal Privacy Information ¹ (PPI), 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	State officials sign individually for coverage	CCI ⁵ , Deliberative Process, PPI, 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 Pharmacy Compounding	Authorized Heads of Boards of Pharmacy sign for all employees	CCI, Deliberative Process, PPI, Investigatory Records	Information Requested by Board of Pharmacy	FDA	Can be shared amongst all Boards of Pharmacy members covered under the agreement	Cannot be further disclosed without written permission from FDA
20.88 Associations	Authorized Heads of Associations sign for all employees	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	State officials employed at a Public Health Regulatory Agency	Trade Secret (TS) , CCI, Deliberative Process, PPI, Investigatory Records	Information originally obtained by the state employee on behalf of FDA	FDA	Can only be shared with other commissioned state agency officials within the same commodity area	Cannot be further disclosed without written permission from FDA
State Contracts²	State public health regulatory agencies	TS, CCI, Deliberative Process, PPI, 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 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.

⁵ CCI obtained during a device inspection may not be shared under a 20.88 Agreement. This also extends to combination products where a device is involved.

NOTE: 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.