Compounding Domestic Inspection Information and Sharing Chart

- **Commissioned officials have the same access to all types of information as FDA employees. Commissioned officials can receive this information for use in their work with FDA only.**
- **Confidential commercial information (CCI) and deliberative process information can be shared with state government officials under what is commonly referred to as a "20.88 agreement." The conditions and requirements for sharing such information can be found in 21 CFR § 20.88**
- **Personal Privacy Information (PPI) can be shared under 20.88 agreement, but is not routinely shared given the sensitive nature of the information**
- **If no 20.88 agreement (or agreement does not authorize sharing particular information with a state), follow applicable law (for example, section 301(j) of the Federal Food, Drug, and Cosmetic Act, the Trade Secrets Act, the Privacy Act, and FDA regulations)**

Type of Information that might be related to an FDA inspection	When becomes available to FDA headquarters	Likely To Contain Personal Privacy Information (Yes/No)	Likely To Contain Confidential Commercial Information (Yes/No)	Likely To Contain Trade Secret Information (Yes/No)	Likely To Contain Deliberative Process Information (Yes/No)	Disclosure Likely to Interfere With Investigation?[1] (Yes/No)
Prescription data (whether the firm is receiving prescriptions for identified individual patients for a sample of the products it compounds)	Within 5 days of close of inspection	Yes, if, for example, identifies patient name or other personal identifying information (e.g., patient address, prescription #s, or names of doctors/clinics/ hospitals visited by patient).	Yes, if, for example, identifies customer/supply chain information (such as names of doctors/clinics/hospitals product was sold to), or details on number of prescriptions, lot size, or number of units sold.	No	No	No

[1] Note that this column addresses only one set of circumstances in which FDA may withhold from disclosure records or information for law enforcement purposes. See, e.g., 21 CFR § 20.64.

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Drug product quality testing results (including sample collection reports, sample summaries, and analytical packages, such as drug product microbiological testing results); Does not include environmental sample results (see below).	No fewer than 21 days after sample collection (if expedited)	Yes, if, for example, identifies patient name, or other personal identifying information (e.g., address, prescription #s, date of procedures or death, or names of doctors/clinics/ hospitals visited by patients).	Yes, if, for example, identifies customer/supply chain information (such as names of doctors/clinics/hospitals product was sold to), or details on number of prescriptions, lot size, number of units sold, or contract manufacturer relationship.	Yes, if, for example, testing results disclose non-public information about formulas/ingredients/ preservatives not on label.	No, if results are final	No
Environmental sample results	No fewer than 21 calendar days after sample collection (if expedited)	No	Yes, if, for example, identifies number of pieces or layout of equipment.	Yes, if, for example, identifies the type or brand of equipment used in manufacturing processes, or other information about the manufacturing process.	No, if results are final	No
Photographs	Immediate/ongoing during inspection, completes at close of inspection	Yes, if, for example, identifies faces or other personal identifiers of individuals.	Yes, for example, if identifies number of pieces or layout of equipment.	Yes, if, for example, identifies the type or brand of equipment used in manufacturing processes, or other information about the manufacturing process.	No	Yes, if case is open

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EIR and supporting documentation	Generally within 30 days of inspection closing	Yes, if, for example, identifies names or personal identifying information of patients, complainants, non-managerial staff.	Yes, if, for example, identifies contractor relationships, customer relationships, names of doctors/clinics/ hospitals product was sold to, future business plans, manufacturing scale, lot size, details of SOPs, or the number of pieces of equipment.	Yes, if, for example, identifies the type or brand of equipment used in the manufacturing processes, details of sterilization methods, or formulas/ingredients/ preservatives not on label.	Unlikely once the final inspection classification has been made	Yes, if case is open

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Form FDA 483	Date the inspection ends	Yes, if, for example, identifies names or personal identifying information of patients, complainants, non-managerial staff.	Yes, if, for example, identifies contractor relationships, customer relationships (names of doctors/clinics/ hospitals product was sold to), future business plans, manufacturing scale, lot size, details of SOPs, or the number of pieces of equipment.	Yes, if for example, identifies the type or brand of equipment directly used in the manufacturing processes, details of sterilization methods, or formulas/ingredients/ preservatives not on label.	No	No
Response to 483[2]	Within 15 days of 483 issuance	Yes, if, for example, identifies names or personal identifying information of patients, complainants, non-managerial staff	Yes, if, for example, identifies contractor relationships, customer relationships (names of doctors/clinics/ hospitals product was sold to), future business plans, manufacturing scale, lot size, details of SOPs, or the number of pieces of equipment	Yes, if, for example, identifies the type or brand of equipment directly used in the manufacturing processes, details of sterilization methods, or formulas/ingredients/ preservatives not on label.	No	No

[2] Firms not required to respond to 483; if a firm does respond, FDA will consider the response if submitted within 15 business days.

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Recall information (e.g., information concerning scope or status of a recall, distribution records, recall strategy, or a firm's response to FDA's formal or informal request for a firm to voluntarily recallproducts and/or cease sterile operations)	When the firm provides the information to FDA	Yes, for example, if contains customer/ distribution lists, or adverse event reports	Yes, for example, if contains customer/ distribution lists, quantity distributed, audit findings on success of recall	No	No	No
Other FDA communications with inspected party such as close-out letters, follow-up communications on a warning letter response	When issued	No	Yes	No	No	Yes, if further action is contemplated
Response to warning letter	Within 15 days of warning letter issuance	Yes, if, for example, identifies names or personal identifying information of patients, complainants, non-managerial staff	Yes, if, for example, identifies contractor relationships, customer relationships (names of doctors/clinics/ hospitals product was sold to), future business plans, manufacturing scale, lot size, details of SOPs, or the number of pieces of equipment	Yes, if, for example, identifies the type or brand of equipment directly used in the manufacturing processes, details of sterilization methods, or formulas/ingredients/ Preservatives not on label.	No	Yes, if further action is contemplated

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Patient data (contamination or adverse event investigations)	Immediately/rolling basis	Yes, if, for example, identifies patient name, personal identifying information such as address, prescription #s, date of procedures or death, or names of doctors/clinics/ hospitals visited by patient.	Yes, if, for example, identifies customer/supply chain information, such as names of doctors/clinics/hospitals product was sold to, or a contract manufacturer relationship	No	No	No
Clinic/hospital records (contamination or adverse event investigations)	Upon collection	Yes, if, for example, identifies patient name, or other personal identifying information such as address, prescription #s, date of procedures or death, or names of doctors/clinics/ hospitals visited by patient.	Yes, if, for example, identifies customer/supply chain information, such as names of doctors/clinics/hospitals product was sold to, or a contract manufacturer relationship.	No	No	No
Complaints	Upon close of inspection, if one is conducted, or when the evaluation is otherwise completed	Yes, if, for example, identifies complainant or patient name, or other personal identifying information such as address, prescription #s, date of procedures or death, or names of doctors/clinics/ hospitals visited by patients.	Yes, if, for example, identifies customer/supply chain information, such as names of doctors/clinics/hospitals product was sold to or a contract manufacturer relationship.	Yes, if, for example, identifies the type or brand of equipment used in manufacturing processes, or other information about the manufacturing process.	No	No

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Internal FDA Documents such as inspection assignment memos, health hazard evaluation, evaluation of a warning letter response)	When completed	Yes, if, for example, identifies names of doctors/clinics/ hospitals visited by patients in relation to an adverse event, but unlikely.	Yes, if, for example, identifies customer/supply chain information such as names of doctors/clinics/hospitals product was sold to, or a contract manufacturer relationship.	Yes, if, for example, identifies the type or brand of equipment used in manufacturing processes, or other information about the manufacturing process.	Yes	Yes, if assignments/ investigation open, or further action contemplated