DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Office of Regulatory Affairs
12420 Parklawn Drive
Rockville, Maryland 20857

MEMORANDUM

DATE: _____, 2016

FROM: Assistant Commissioner for Compliance Policy

SUBJECT: Five Year, Single-Signature "Long-Term Drug Compounding Information Sharing Agreement" or "Long-Term Drug Compounding ISA"

TO: State Government Officials Involved in the Protection of Public Health

1. The Food and Drug Administration (FDA) would like to offer your agency the opportunity to enter into a confidentiality agreement to facilitate the exchange of non-public information concerning compounded drug products (human and veterinary drugs) and related public health, and safety information (referred to as non-public compounding information) for a five-year period that will begin on . This new Long-Term Drug Compounding Information Sharing Agreement (ISA) does not require that each individual in the State government agency who has a need to know or official interest in the non-public information sign the confidentiality agreement. Rather, it allows for the head of the State agency to affirm that the non-public information provided by FDA will not be disclosed with anyone outside of their agency without written confirmation from FDA that such information can be released to the public. Previous 20.88 confidentiality agreements regarding compounding required each individual in the agency sign the agreement prior to viewing non-public information. These streamlined procedures have been developed in response to concerns about sharing non-public information expressed at the Intergovernmental Working Meeting on Pharmacy Compounding held in March 2014.

2. Because we recognize that other individuals in your agency may need to know about and disseminate the non-public information quickly in an emergency such as a recall, although FDA only requires one signature from the head of your agency, non-public drug compounding information can be shared with other members of your agency under the terms of this confidentiality agreement.

3. Under this confidentiality agreement, you are committing, on behalf of your State agency, to protect the non-public information that FDA shares with individuals in your agency. **This may include information for which public disclosure is prohibited by law, and information compiled for enforcement purposes. Any request to share this information outside of your agency must be approved in advance by FDA.**

4. Attachment A provides background information about the streamlined information sharing procedures for utilizing the Long-Term Drug Compounding ISA. Attachment B describes the conditions for sharing of non-public Drug Compounding information with State government officials. Attachment C is the Certification or Confidentiality Commitment, which only needs to be signed by the head of the State government agency. Attachment D is used by the head of the State or government agency to provide the contact information for key individuals in the agency.

5. Attachment C must be completed and signed in order to establish the Long-Term Drug Compounding ISA. Attachment D is optional, but highly recommended.

ATTACHMENTS:

A. Background Information on FDA Sharing of Non-Public Information with State Government Officials using the Single-Signature Long-Term Drug Compounding Information Sharing Agreement

B. Conditions for FDA Sharing of Non-Public Information with State Government Officials

C. CERTIFICATION *(*CONFIDENTIALITY COMMITMENT*)* for State Agencies

D. Designation of Key Points of Contact in State Agencies

ATTACHMENT A

Background Information on FDA Sharing of Non-Public Drug Compounding Information with State Government Officials Using the Single-Signature 20.88 Long-Term Drug Compounding Information Sharing Agreement

The Food and Drug Administration (FDA) published a regulation on sharing non-public information with State officials under 21 CFR 20.88 as a Final Rule in the December 8, 1995 Federal Register (60 FR 63372). The rule allows FDA to share certain confidential FDA records on a discretionary basis with State officials who perform counterpart functions to FDA as part of cooperative law enforcement or regulatory efforts, provided that certain conditions are met. Such disclosures under this provision are never mandatory, and each State request would be processed only after duly considering FDA's concerns for confidentiality, the requester's need for the information, and the benefit to the public health that may result from such sharing.

To facilitate the implementation of the Drug Quality and Security Act (DQSA), which addresses compounding of drugs, among other topics, FDA will be putting a number of new processes into place as part of its overall DQSA implementation strategy. FDA has streamlined the procedures for sharing of non-public information under 21 CFR 20.88(d) and (e) to allow this information to be exchanged more efficiently while still adhering to Freedom of Information Act (FOIA) and disclosure laws. Under the streamlined procedures, FDA can rapidly share non-public information concerning compounded drug products and compounding facilities, including confidential commercial information and pre-decisional information, with State agencies and officials responsible for regulating compounded drugs. Information that can be shared under this agreement includes information pertaining to inspections and regulatory actions, including inspection reports (omitting trade secrets), warning letters, and enforcement actions.

FDA may share non-public information with State government agencies under 21 CFR 20.88 when the requester has certified that they have the authority to protect any shared information from any public disclosure and will not disclose such information without the written confirmation from FDA that such information can be released to the public. FDA will be unable to share non-public information with a State government agency if it cannot certify that the agency has the ability to maintain the confidentiality of all non-public information received from FDA. If a State government agency fails to maintain the confidentiality of non-public information, FDA may refuse to share such information with the State agency in the future. Moreover, unauthorized disclosure of confidential commercial information could result in a civil or criminal violation of United States Law levied upon the disclosing official. The conditions for confidential sharing of non-public information are further described in Attachment B.

The procedures for releasing non-public information to State government officials under the streamlined process are listed below.

1. Directors of State agencies sign the certification form (Attachment C).
2. To request non-public information pertaining to drug compounding, the State agency sends a written request to the FDA District Director who has jurisdiction over that State. The FDA District Director will forward the request to Lauren DiPaola (ORA/Office of Policy and Risk Management (OPRM)) who will determine and inform the FDA District Director when he/she may release the requested information.
3. Upon FDA's initiative, when necessary, and without receiving a formal request (but after getting approval from OPRM), an FDA District Director has the discretion to provide specific non-public drug compounding information to the signatories listed on the certification. This should be done only for special circumstances.

ATTACHMENT B

Conditions for FDA Sharing of Non-Public Information with State Government Officials

The United States Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services, is charged with protecting and promoting the health of the American people. It is responsible for assuring that foods are safe, wholesome, and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and products that emit radiation are safe.

In an effort to enhance regulatory and enforcement cooperation between FDA and State government officials who perform counterpart functions to FDA, FDA promulgated a regulation under 21 CFR 20.88 governing the communication of non-public information with State government officials. 21 CFR 20.88 permits FDA, on a discretionary basis, to release non-public predecisional, confidential commercial, and/or other non-public information regarding FDA-regulated products to State officials. As long as the requirements in 21 CFR 20.88 have been met at the time of the release, FDA's release of non-public information to a State government is not a public disclosure and does not compel FDA, if requested, to release such information to the public. **Non-public information that FDA shares with a State government agency is FDA's property, loaned for the purpose for which it was requested or for other cooperative law enforcement efforts.** FDA may take steps to retrieve the information shared with a State government agency at any time and it may initiate judicial proceedings if necessary [see United States v. Napper, The City of Atlanta, et al., 887 F.2d 1528 (1989)].

Before FDA may share non-public predecisional, confidential commercial, and/or other non-public information with non-commissioned State officials, FDA must receive a written certification from the State or agency that it understands the conditions under which FDA shares non-public information, and certifies that it: (1) has the authority to protect the information from public disclosure and (2) will not disclose such information without written confirmation from FDA that the information no longer has non-public status, or in cases involving confidential commercial information concerning a regulated product-without the consent of the sponsor of the information. FDA will rely on the State government agency's certification about its authority to protect the non-public information from disclosure. If changes occur in the State's statutes, laws, policies, or procedures that may affect the agency's ability to protect the non-public information from disclosure, it: (1) will notify FDA immediately and (2) will not disclose the non-public information without the consent of the sponsor, submitter, individual, or FDA as described above.

In the event a State agency receives a subpoena, court order, or other compulsory process including a request under the Freedom of Information Act to release non-public information received from FDA, it will contact FDA within 48 hours of receipt of the notice and the State agency will take appropriate legal measures to resist the release of such information. The State agency will not release the information until FDA has had the opportunity to consider whether to take appropriate legal measures to resist the disclosure of such information, has determined whether it will take such measures, and has notified the State agency of its determination—which notification shall be made in a timely manner. The certification or confidentiality commitment is provided as Attachment C.

When FDA receives the written certification setting out the commitment on the part of the State agency (Attachment C), it may share the information only when the following determinations are made.

Requests for non-public predecisional information:

The requested information must be reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements (21 CFR 20.88(e)(1)(ii)).

Requests for confidential commercial information:

FDA must determine if (1) the owner of the information or sponsor for the product application has provided written authorization for the exchange or (2) the disclosure of the information would be in the interest of public health by reason of the State government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State government's ability to exercise its regulatory authority more expeditiously than FDA (21 CFR 20.88(d)(1)(ii)).

As a regulatory and law enforcement agency, it is important that FDA avoid providing any company with a competitive advantage, placing a company that submitted information at a disadvantage relative to its competitors, or committing an unwarranted invasion of personal privacy of an individual through unauthorized disclosure of non-public information. It is essential that State government officials engaged in information exchanges with FDA understand and respect the obligations to protect non-public information from unauthorized disclosure. In fact, such unauthorized disclosure could subject persons to criminal or other sanctions. For that reason, it is essential that adequate security measures be taken by State government officials to prevent the unauthorized release of shared non-public information.

Once the Confidentiality Commitment (Attachment C) has been signed, return the signed copy of the certification to Office of Policy and Risk Management, Food and Drug Administration, 12420 Parklawn Drive, Room 4141, Rockville, MD 20857 or send the signed copy to InfoShare-ORA@FDA.HHS.gov.

ATTACHMENT C

CERTIFICATION *(*CONFIDENTIALITY COMMITMENT*)* for State Government Agencies

Statement of legal authority and commitment not to disclose non-public information including, but not limited to, confidential commercial or non-public pre-decisional information shared by the U.S. FOOD AND DRUG ADMINISTRATON (FDA)

Reference: Information regarding drug compounding entities.

FDA may share non-public information concerning its law enforcement or regulatory investigation of the safety, effectiveness, or quality of a product or facility with

State government agency

in accordance with 21 CFR 20.88. **This sharing is in the interest of public health and is for the limited purpose of conducting cooperative law enforcement or regulatory efforts as they relate to investigations of drug compounding entities.**

My agency understands that:

1. Some or all of the non-public information it receives from FDA is considered to be confidential commercial, personal privacy information or non-public pre-decisional information exempt from disclosure under the laws and regulations of the United States and that FDA considers it extremely important that my agency maintain the confidentiality of the information.
2. FDA will follow its regulatory procedures before sharing non-public information with my agency. For example, FDA may require consent from the submitter or owner before it can share confidential commercial information with my agency. FDA must not give any company an unfair competitive advantage or place a sponsor at a disadvantage relative to its competitors through unauthorized disclosure of non-public information.
3. The non-public information received from FDA remains FDA's property. FDA may take steps at any time and may initiate judicial proceedings to retrieve non-public information shared with my agency.
4. Disclosure of information shared by FDA could seriously jeopardize any further cooperative interactions between FDA and my agency. Moreover, unauthorized disclosure of confidential commercial information could be a civil or criminal violation of United States Law and carry consequences for the disclosing official.

Therefore, certifies that it:
State government agency

1. Has the authority to protect the confidential commercial, personal privacy information, and non-public pre-decisional information from disclosure.
2. If requested, has attached copies of the relevant statutes, regulations, court decisions, or other documents that establish this authority or has provided a summary of its legal authority.
3. Subject to the notice provisions of this paragraph, will not disclose the non-public information without the written statement from FDA that the information no longer has non-public status or, in cases involving confidential commercial information concerning a regulated product, without the written consent of the owner of the information.
4. Will inform FDA within 48 hours of any effort made to obtain the information from it by subpoena, court order, or other compulsory process, including a request under any Freedom of Information type of law, and

will refrain from disclosing such information. Under such circumstances, my agency will refrain from disclosing the information until FDA has had the opportunity to take appropriate legal measures to resist the disclosure of such information, has determined whether it will take such measures, and has notified my agency of its determination. FDA will make this determination in a timely fashion. My agency may disclose the information to a court of competent jurisdiction if the court orders such disclosure; my agency has taken legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure, and has notified FDA but failed to receive a timely determination of FDA actions.

5. Will promptly inform FDA of any changes to its laws, policies, or procedures that would affect its ability to maintain the confidentiality of the information FDA shares.
6. Has safeguards, including the adoption of policies and procedures to ensure that the information shared under this agreement shall be shared and used consistent with the Trade Secrets Act [18 U.S.C. 1905], the Food, Drug, and Cosmetic Act (FD&C Act) as amended [21 U.S.C. 301 et seq.], the Privacy Act of 1974, as amended [5 U.S.C. 552a], and the Freedom of Information Act [5 U.S.C. 552]. Pursuant to section 301(j) of the FD&C Act [21 U.S.C. 331(j)], FDA will not reveal to non-commissioned officials any method or process that is entitled to protection as a trade secret.
7. Will restrict access to the non-public information shared under this agreement to the employees, agents, and officials of the Signatory of State Government Officials, who require access to such information to perform their official duties in accordance with the uses of the information as authorized in this agreement, unless otherwise authorized in writing by FDA. All such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards against unauthorized disclosure of confidential information; and (3) the administrative, civil and criminal penalties contained in applicable Federal laws for the unauthorized disclosure of confidential information.
8. Will notify FDA of any actual or suspected unauthorized disclosure of any information shared pursuant to this agreement.

Name of certifying official *Date*

Title of certifying official

Signature

Phone Number

_____

E-mail Address

Attachment D

Designation of Key Points of Contact in State Government Agencies

This Attachment is used by the State government agency to provide FDA with key points of contact. FDA may wish to contact these individuals as primary respondents in emergencies, recipients of certain regulatory action notices, or recipients of pre-decisional information. If more space is needed, please attach a separate page with the name, position, a telephone number, and an e-mail address for the individual(s).

_____ *Name*	*Name*
_____ *Position*	*Position*
_____ *Program Area*	*Program Area*
Phone Number	*Phone Number*
E-mail Address	*E-mail Address*
Name	*Name*
Position	*Position*
Program Area	*Program Area*
Phone Number	_____ *Phone Number*
E-mail Address	_____ *E-mail Address*