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

12420 Parklawn Drive
Element Building Room 4029
Rockville, MD 20852-1740

Memorandum

To: State Officials Involved in the Protection of Public Health

From: Director, Office of Enforcement and Import Operations

Date: 10/11/2018

Subject: Five Year, Single-Signature "Long-Term Food Information Sharing Agreement" or "Long-Term Food ISA"

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 food (human food, pet food, and animal feed) and cosmetic regulatory, public health, and safety information (referred to as non-public food information) for a five-year period that will begin on July 1, 2014. This new Long-Term Food Information Sharing Agreement (ISA) allows for the (division) 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. Furthermore, this new agreement does not require that each individual in the agency who has a need to know or official interest in the non-public information to sign the confidentiality agreement. These streamlined procedures are in contrast to past 20.88 confidentiality food agreements that required each individual in the agency sign the agreement prior to viewing non-public information.

2. Although FDA only requires one signature from the (division) head of your agency to permit the legal exchange of non-public food information under this confidentiality agreement, 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 foodborne outbreak. To facilitate this, we ask that you provide us with the names and contact information for key individuals in your agency for food along with their title, specialty, or subject matter expertise. For example, the Commissioner of a State department of agriculture may want to provide contact information for division directors or managers in charge of laboratories or inspections.

3. Under this confidentiality agreement, you are committing on behalf of your 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 utilizing the Long-Term Food ISA. Attachment B describes the conditions for sharing of non-public food information with local and State government officials. Attachment C is the Certification or Confidentiality Commitment, which only needs to be signed by the head of the agency. Attachment D is used by the head of the 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 Food ISA. Attachment D is optional, but highly recommended. Please send a copy of Attachment C and Attachment D to the following email address to the attention of Sara Ashton:

   ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov.

6. If you have any questions about this program, please contact Sara Ashton at 202-308-4098 or ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov.

Director, Office of Enforcement
and Import Operations

ATTACHMENTS:

A. Background Information on FDA Sharing of Non-Public Information with State and Local Government Officials using the Single-Signature Long-Term Food Information Sharing Agreement;

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

C. CERTIFICATION (CONFIDENTIALITY COMMITMENT) for State or Local Government Agencies;

D. Designation of Key Points of Contact in State or Local Government Agencies;

ATTACHMENT A

Background Information on FDA Sharing of Non-Public Food and Cosmetic Information with State and Local Government Officials Using the Single-Signature 20.88 Long-Term Food Information Sharing Agreement

Under 21 CFR § 20.88 FDA may share certain confidential Agency records on a discretionary basis with State and local government 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 or local government 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.

Under this agreement, FDA can rapidly share non-public information, including confidential commercial information and pre-decisional information, with local and State agencies and officials responsible for food (food includes human food, animal feed, and dietary supplements) and cosmetic inspection programs and laboratories that are associated with investigating adverse events. The procedures also allow the sharing of food-related product information, inspection reports (omitting trade secrets), enforcement actions, foodborne illness investigation data, and trace back information.

Under these agreements, State and local government agencies must provide a written statement that they have the authority to protect any shared information from any public disclosure and a commitment not to 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 food protection information with your agency if it cannot certify that is has the ability to maintain the confidentiality of all non-public information received from FDA. If an 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. The conditions for confidential sharing of non-public information are further described in Attachment B.

If a State and local agency does not sign the Certification in Attachment C and does not have an official that holds a current FDA commission, it may be excluded from conference calls and meetings with FDA and will be required to request all confidential information according to the procedures set forth in 21 CFR § 20.88.

The procedures for releasing non-public information to State and local governments are listed below.

1. Directors of State or local agencies sign the certification form.
2. To request non-public food information, the State agency sends a written request to FDA District Director who has jurisdiction over that State. FDA District Director may then release the requested information.
3. When necessary and without receiving a formal request, an FDA District Director has the discretion to provide selected non-public information specific to food protection issues to the signatories listed on the certification or to a State official commissioned by FDA. This should be done only for special circumstances.

ATTACHMENT B

Conditions for FDA Sharing of Non-Public Information with State and Local 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 and local 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 and local 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 and local 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 or local 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 the 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 an 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 or local officials, FDA must receive a written certification from the State or local 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 or local government agency's certification about its authority to protect the non-public information from disclosure. If changes occur in the State or local agency'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 an 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 two business days of receipt of the notice and the agency will take appropriate legal measures to resist the release of such information. The State or local agency will not release 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 the State or local agency of its determination–which 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 or local agency, 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.

Requests for confidential commercial information:

FDA must determine if (1) the 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 or local government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State or local government ability to exercise its regulatory authority more expeditiously than FDA.

As a regulatory and law enforcement agency, it is important that FDA avoid providing any company with a competitive advantage, placing a submitting company 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 and local officials engaged in information exchanges with FDA understand and respect the obligations to protect non-public information from unauthorized disclosure, and take adequate security measures to prevent the unauthorized release of shared non-public information.

Once the agreement has been signed, send the signed copy to ORAOSPOPTestimony-InfoSharingTeam@fda.hhs.gov to the attention of Sara Ashton.

ATTACHMENT C

CERTIFICATION (CONFIDENTIALITY COMMITMENT) for State or Local 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 the investigations of food establishments and/or the facilitation of food (human food, animal feed, and dietary supplements) and cosmetic safety.

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

Metropolitan Government of Nashville & Davidson County Public Health Department

State or local 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 food establishments and/or the facilitation of food and cosmetic safety and protection.**

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. 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.
3. Disclosure of information shared by FDA could seriously jeopardize any further cooperative information sharing between FDA and my agency. Moreover, unauthorized disclosure of confidential commercial information could be a civil or criminal violation and carry consequences for the disclosing official.

Therefore, Metropolitan Government of Nashville & Davidson County Public Health Department certifies that it:

State or local 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
consent of the sponsor of the information. My agency will inform FDA within two business days 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. The agency may disclose the information to a court of competent jurisdiction if the court orders such disclosure, the 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.

4. 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.
5. 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 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.
6. Access to the non-public information shared under this agreement shall be restricted to the employees, and officials of the Participants, 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; and the obligation to keep such information confidential; and (2) safeguards against unauthorized disclosure of confidential information.
7. Will notify FDA of any actual or suspected unauthorized disclosure of any information shared pursuant to this agreement.

William S Paul, MD

Name of certifying official

10/11/2018

Date

Director of Health

Title of certifying official

William Paul

Digitally signed by William Paul
DN: cn=William Paul, o=Metro Public Health Department, ou, email=billpaulmd@gmail.com, c=US
Date: 2018.10.11 12:42:48 -05'00'

Signature

615-340-5622

Phone Number

bill.paul@nashville.gov

E-mail Address

Attachment D

Designation of Key Points of Contact in State or Local Government Agencies

This Attachment is used by the State or local 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 (for example, Director of Manufactured Foods), program area (food, feed, or cosmetics), a telephone number, and an e-mail address for the individual(s). **We encourage you to include an agency organizational chart.**

* In the first section, please enter the name of at least one person from your agency who's responsible for release of information to the public (e.g. FOIA/Public Records/Open Records Officer).

*This person is a Other

Brian Todd
**Name*

Public Information Officer
**Position*

Executive Leadership Team
**Program Area*

615-340-2153
**Phone Number*

Brian.Todd@nashville.gov
**E-mail Address*

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Name

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Position

Food and Public Facilities Protection
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SIGNATURE PAGE
FOR
FOOD & DRUG ADMINISTRATION DATA SHARING AGREEMENT

IN WITNESS WHEREOF, the parties have by their duly authorized representatives set their signatures.

METROPOLITAN GOVERNMENT OF NASHVILLE AND DAVIDSON COUNTY

William S. Paul, M.D. — Date: 10.11.2018
Director, Metro Public Health Department

Carol Etherington, MSN, RN, FAAN — Date: 10-11-2018
Chair, Board of Health

APPROVED AS TO AVAILABILITY OF FUNDS:

Talia Lomax-O'dneal — Date: 10-22-18
Director, Department of Finance

APPROVED AS TO RISK AND INSURANCE:

Director of Risk Management Services — Date: 10/23/18

APPROVED AS TO FORM AND LEGALITY:

Metropolitan Attorney — Date: 10/30/18

FILED:

Metropolitan Clerk — Date