U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To: State Involved in the Protection of Public Health

From: Steven Tave, Director, Office of Policy, Compliance and Enforcement

Date:

Subject: Single-Signature, Long-Term Food, Feed and Cosmetics Information Sharing Agreement

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) dietary supplements and cosmetic related information (referred to as non-public food information) that will begin on the date above until June 30, 2029. This Long-Term Food, Feed and Cosmetics Information Sharing Agreement (ISA) allows for the (division) head of the State, local, or U.S. territory government agency (hereby referred to as 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 everyone in the agency who has a need to know or official interest in the non-public information to sign the confidentiality agreement.

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, recall, or a report of a suspect product in the supply chain. 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 certifying, on behalf of your agency, that the agency has the legal authority to protect all non-public food information that FDA shares with individuals in your agency and committing not to disclose such information. The reference to "non-public information" covered by this agreement includes information subject to limitations on public disclosure under federal law and regulations. For FDA documents shared under this agreement, this may include confidential commercial information, personal privacy information, pre-decisional information, deliberative information, and law enforcement records. Trade secrets may not be shared under this agreement. Any request to share non-public information outside of your agency must be approved in advance by FDA.

4. Attachment A provides background information about the information sharing procedures utilizing the Long-Term Food, Feed and Cosmetics ISA. Attachment B describes the conditions for sharing of non-public food information with State government officials. Attachment C must be completed and signed to establish the Long-Term Food, Feed and Cosmetics ISA. Attachment D is optional, but highly recommended. Please send a copy of entire agreement (pages 1-9) and an organizational chart to the email address ORAInfoShare@fda.hhs.gov.

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Director, Office of Policy, Compliance and Enforcement

Attachments:

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

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

C. CONFIDENTIALITY COMMITMENT for State Government Agencies.

D. Designation of Key Points of Contact in State Government Agencies

ATTACHMENT A

Background Information on FDA Sharing of Non-Public Food, Dietary Supplement and Cosmetic Information with State Agency Officials Using the Single-Signature

Under 21 CFR § 20.88 FDA may share certain non-public Agency records **on a discretionary basis** with State government officials who perform counterpart functions to FDA as part of cooperative law enforcement or regulatory efforts provided that certain conditions are met. Information sharing under this provision is never mandatory and each State government request will 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 State agencies and officials responsible for food (food includes human food, animal feed) dietary supplements and cosmetic inspection programs and laboratories that are associated with investigating adverse events. This includes but not limited to the sharing of food-related product information, inspection reports (omitting trade secrets), enforcement actions, foodborne illness investigation data, trace back information, and warning letters.

Under this agreement, State agencies must provide a written statement that they have the legal 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 related information with your agency if it cannot certify that it can and will maintain the confidentiality of all non-public information received from FDA. If State agency fails to maintain the confidentiality of non-public information, FDA may refuse to share such information with the State agency in the future. The conditions for confidential sharing of non-public information are further described in Attachment B.

If the State agency does not sign the Confidentiality Commitment in Attachment C, it will not receive non-public information and may be excluded from conference calls and meetings with FDA where non-public information is discussed, including, and not limited to outbreak and recalls.

The procedures for releasing non-public information to State agencies are listed below.

1. Directors of State agencies sign the certification form.
2. To request non-public information pertaining to food protection, the State agency sends a written request to the FDA District Director or State Liaison who has jurisdiction over that State or to Division of Information Disclosure Programs (DIDP) at ORAInfoShare@fda.hhs.gov.
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 Confidentiality Commitment. This should be done only for special circumstances.

ATTACHMENT B

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

The 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.

To enhance regulatory and enforcement cooperation between FDA and State agency 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 agency officials. 21 CFR § 20.88 permits FDA, on a discretionary basis, to release non-public pre-decisional, confidential commercial, and/or other non-public information regarding FDA-regulated products to State agency 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 agency 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 State agency belongs exclusively to FDA 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 pre-decisional, confidential commercial, and/or other non-public information with State agency officials, FDA must receive a written Confidential Commitment (Attachment C) from the State 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 owner of the information (e.g., drug sponsor). FDA will rely on the State agency's Confidentiality Commitment regarding its authority to protect FDA non-public information from disclosure. If changes occur in the State agency's statutes, laws, policies, or procedures that may affect the agency's ability to protect FDA 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 owner, 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 a state public records act or Freedom of Information act to release non-public information received from FDA, it will contact FDA within **five business days** of receipt of the notice and the 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 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 shall be made in a timely manner. The Confidentiality Commitment is provided as Attachment C.

When FDA receives the Confidentiality Commitment from the State agency, it may share the information only when the following determinations are made.

Requests for non-public pre-decisional 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 agency possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State agency's ability to exercise its regulatory authority more expeditiously than FDA.

As a regulatory and law enforcement agency, it is important that FDA avoid unauthorized disclosure of non-public information, particularly disclosures that might provide any company with a competitive advantage, place a submitting company at a disadvantage relative to its competitors, or result in an unwarranted invasion of personal privacy of an individual It is essential that State agency officials engaged in information exchanges with FDA understand and respect the obligations to protect FDA non-public information from unauthorized disclosure and take adequate security measures to prevent the unauthorized release of shared FDA non-public information.

Once the agreement has been signed, send the signed copy to ORAInfoShare@fda.hhs.gov.

ATTACHMENT C

CONFIDENTIALITY COMMITMENT for State 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 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 the safety, effectiveness, or quality of a product with

San Bernardino County Department of Public Health
(State Agency)

in accordance with 21 CFR 20.88. **This sharing is in the interest of public health and is for the limited purpose conducting cooperative law enforcement or regulatory efforts as they relate to human food, animal feed, dietary supplements, or cosmetics.**

My agency understands that:

1. Some or all of the non-public information it receives from FDA is 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 belongs exclusively to FDA and does not belong to my state agency. FDA may take steps at any time and may initiate judicial proceedings to retrieve non-public information shared with my agency.
3. Disclosure of non-public information shared by FDA could seriously jeopardize any further cooperative information sharing between FDA and my agency.
4. **FDA will not reveal to a non-commissioned official any method or process that is entitled to protection as a trade secret under section 301(j) of the FD&C Act [21 U.S.C. 331(j)].**

Therefore, San Bernardino County Department of Public Health certifies that it:
(State Agency)

1. Has the legal authority to protect FDA non-public information from disclosure, including but not limited to confidential commercial information, personal privacy information, and pre-decisional information.

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 FDA 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 owner of the information. My agency will inform FDA within **five 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 state public records act or Freedom

of Information Act 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 1) the court orders such disclosure, 2) the agency has taken legal measures to ensure that the information will be disclosed in a manner that protects the information from public disclosure and, 3) the agency 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 will not be further disclosed consistent with the rest of this agreement.
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.

Dawn Rowe _____ _____

Name of certifying official *Date*

Chair, Board of Supervisors

Title of certifying official

_____

Signature of certifying official

909-387-4855

Phone Number of certifying official

Supervisor.Rowe@bos.sbcounty.gov

E-mail Address of certifying official

ATTACHMENT D

Designation of Key Points of Contact in State Agencies

This Attachment is used by the State 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, dietary supplements, or cosmetics), a telephone number, and an e-mail address for the individual(s).

Please include an agency/division organizational chart.

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

*This person is a: Public Records Administrator

Mayra Barcenas	Adela Evans
Name	*Name*
Program Coordinator	Chief of Environmental Health Services
Position	*Position*
Environmental Health Services	Environmental Health Services
Program Area	*Program Area*
Mayra.Barcenas@dph.sbcounty.gov	Adela.Evans@dph.sbcounty.gov
E-mail Address	*E-mail Address*
Kristian Alfelor	
Name	*Name*
Program Manager	
Position	*Position*
Environmental Health Services	
Program Area	*Program Area*
Kristian.Alfelor@dph.sbcounty.gov	
E-mail Address	*E-mail Address*

Name	*Name*
Position	*Position*
Program Area	*Program Area*
E-mail Address	*E-mail Address*
Name	*Name*
Position	*Position*
Program Area	*Program Area*
E-mail Address	*E-mail Address*
Name	*Name*
Position	*Position*
Program Area	*Program Area*
E-mail Address	*E-mail Address*