



EXHIBIT 8-22-B (With No Commissioned Official)

**CERTIFICATION (“CONFIDENTIALITY COMMITMENT”):
STATE OR LOCAL GOVERNMENT AGENCY
STATEMENT OF LEGAL AUTHORITY AND COMMITMENT
NOT TO DISCLOSE NON-PUBLIC INFORMATION SHARED BY
THE U. S. FOOD AND DRUG ADMINISTRATION (FDA)**

*(OPTIONAL: ADD REFERENCES TO CONFIDENTIAL COMMERCIAL,
TRADE SECRET, OPEN INVESTIGATORY, PREDECISIONAL, OR OTHER NON-PUBLIC,
e.g., PERSONAL PRIVACY INFORMATION)*

The Food and Drug Administration (FDA) may share non-public information concerning its law enforcement or regulatory investigation of the safety, effectiveness, or quality of a product to _____ (*insert formal name of state or local government agency*), in accordance with 21 C.F.R. § 20.88 (“Communications with State and Local Government Officials”). 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 _____.

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, or trade secret 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 needs the submitter’s or owner’s (“sponsor’s”) consent before it can share trade secrets, and except for rare circumstances, 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, including proprietary information;
3. that the non-public information that FDA shares remains FDA's property. FDA may take steps at any time, including initiating judicial proceedings, to retrieve the information from the agency with which FDA shared the information; and
4. disclosure of information shared by FDA could be a criminal violation of United States law and could seriously jeopardize any further cooperative interactions between FDA and my agency.

Therefore, _____ (*state or local government agency*) certifies that it:

1. has the authority to protect the confidential commercial or trade secret information from disclosure;

2. subject to the notice provisions of this paragraph, will not disclose the non-public information without the written authorization of the sponsor of this confidential commercial or trade secret information, or a written statement from FDA that the information no longer has non-public status. My agency 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. 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;

3. will not reveal any non-public information provided by FDA to any other person whose name does not appear as a signatory to this Certification. (Note: More than one individual may sign this Certification, or my agency may submit more than one Certification, each with one or more signatures

Signature of State or local government official	Date
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Please print or type the following:

Name of state or local government official: _____

Title of state or local government official: _____

Name of state or local agency: _____

Address: _____

Telephone and facsimile: _____

Print or type the following:

Name of government official:	Signature
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Title of government official

Name of government official:	Signature
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Title of government official

Name of government official:

Signature

Title of government official

Name of government official:

Signature

Title of government official

Name of government official:

Signature

Title of government official

FDA Form Number 3475