



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

July 13, 2009

Mr. Marc Allen Connelly
Deputy General Counsel
Texas Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

OR2009-09573

Dear Mr. Connelly:

You ask whether certain information is subject to required public disclosure under the Public Information Act (the "Act"), chapter 552 of the Government Code. Your request was assigned ID# 348742 (DSHS File No. O15136-2009).

The Texas Department of State Health Services (the "department") received a request for information regarding three specified inspection reports. You claim that the requested information is excepted from disclosure under federal law. We have considered your arguments.

You state that the Food and Drug Administration (the "FDA") contracts with the department to conduct inspections under the authority of federal law and that the inspections are conducted by department employees who are commissioned officers of the FDA. You inform this office that the inspection reports created by the department are then submitted to the FDA. You assert that the FDA has informed the department that the reports and any information obtained from the inspections are confidential pursuant to sections 301 and 331(j) of title 21 of the United States Code. Further, you indicate the requested documents consists of information, compiled by department investigators as FDA commissioned officers, which is confidential under section 20.64 of title 21 of the Code of Federal Regulations. *See* 21 C.F.R. § 20.64 (stating certain records compiled for law enforcement purposes may be withheld from public disclosure). Sections 301 and 331(j) of title 21 of the United States Code provide that the Federal Food, Drug, and Cosmetic Act prohibits the disclosure of certain confidential information, such as trade secrets acquired in

an official capacity. You also refer to section 20.88, title 21, of the Code of Federal Regulations, which states in relevant part

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

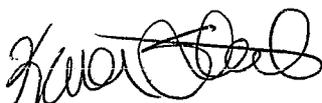
(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

21 C.F.R. § 20.88(c). You assert that because this office is not commissioned by the FDA, section 20.88(c) prohibits you from disclosing the requested investigatory records to this office. Thus, because you have not provided this office with the documents at issue, we are unable to make any determination regarding such documents.

This letter ruling is limited to the particular information at issue in this request and limited to the facts as presented to us; therefore, this ruling must not be relied upon as a previous determination regarding any other information or any other circumstances.

This ruling triggers important deadlines regarding the rights and responsibilities of the governmental body and of the requestor. For more information concerning those rights and responsibilities, please visit our website at http://www.oag.state.tx.us/open/index_orl.php, or call the Office of the Attorney General's Open Government Hotline, toll free, at (877) 673-6839. Questions concerning the allowable charges for providing public information under the Act must be directed to the Cost Rules Administrator of the Office of the Attorney General at (512) 475-2497.

Sincerely,



Karen E. Stack
Assistant Attorney General
Open Records Division

KES/cc

Ref: ID# 348742

Enc. Submitted documents

c: Requestor
(w/o enclosures)