



ATTORNEY GENERAL OF TEXAS  
GREG ABBOTT

July 14, 2014

Ms. Laura Pfefferle  
Acting Deputy General Counsel  
Texas Department of State Health Services  
P.O. Box 149347  
Austin, Texas 78714-9347

OR2014-12084

Dear Ms. Pfefferle:

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# 529003 (DSHS OR File No. 22909/2014).

The Texas Department of State Health Services (the "department") received a request for information pertaining to a specified complaint. You state the department has provided or will provide some information to the requestor. You claim the remaining requested information is excepted from disclosure under section 552.101 of the Government Code. We have considered the exception you claim.

You assert some of the requested information is confidential by federal law and thus is excepted from required public disclosure under section 552.101 of the Government Code. Section 552.101 excepts from disclosure "information considered to be confidential by law, either constitutional, statutory, or by judicial decision." Gov't Code § 552.101. In this instance, we understand the information at issue is not the department's information, but instead belongs to the United States Food and Drug Administration (the "FDA").

You inform us the requested information includes confidential information the FDA provided to department employees who have accepted commissions as FDA officers pursuant to federal law. *See* 21 U.S.C. § 372(a). You state any information acquired from the FDA is confidential pursuant to section 331(j) of title 21 of the United States Code, which prohibits

[t]he using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the [United States Department of Health and Human Services ("DHHS")], or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under

authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection[.]

21 U.S.C. § 331(j). Accordingly, we understand the FDA records the commissioned employees receive are subject to federal law, including the Freedom of Information Act, 5 U.S.C. § 552, which applies only to federal agencies and not state agencies, and the employee is subject to criminal penalties under federal law for the unauthorized release of confidential information.

You indicate that the FDA considers the department's commissioned officers to be serving in concurrent jurisdiction of the FDA and that the information at issue remains the FDA's property. We understand the information at issue consists of records belonging to the FDA, and department employees have access to the records at issue only in their capacities as commissioned FDA officers and not in their capacities as state officers or employees.

The Food, Drug, and Cosmetic Act ("FDC Act") grants DHHS the authority to conduct examinations and investigations by commissioning employees of any state as officers of DHHS. *See* 21 U.S.C. § 372(a)(1)(A). With regard to the disclosure of confidential information by these commissioned officers, section 20.84 of title 21 of the Code of Federal Regulations provides as follows:

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

21 C.F.R. § 20.84; *see also id.* § 20.88 (stating state or local governmental officer commissioned by FDA pursuant to 21 U.S.C. § 372(a) shall have same status with respect to disclosure of FDA records as any special government employee). Furthermore, section 20.2(a) of title 21 of the Code of Federal Regulations states any request for records of the FDA shall be handled pursuant to FDA procedures and requires compliance with the FDA rules governing public disclosure. *Id.* § 20.2(a). *See generally id.* pt. 20 (regulations concerning public disclosure of FDA records).

The department states the requested information at issue was sent to or received by the commissioned officers from the FDA solely pursuant to their commissions. Under section 372(a) of the FDC Act, "[t]he Secretary [of DHHS] is authorized to conduct examinations and investigations . . . through any . . . employee of any State . . . duly commissioned by the Secretary as an officer of [DHHS]." 21 U.S.C. § 372(a). When an examination or investigation is conducted by an investigator as a commissioned officer of

DHHS (or a component of DHHS, in this case, the FDA), it follows that the information gathered pursuant to such an examination is a record of DHHS, the commissioning agency. In other words, the records of such investigation are the records of the agency that authorized the investigation. As noted above, FDA regulation requires commissioned officers to comply with the same federal laws and regulations with respect to disclosure of FDA records in the same way as any other FDA employee. *See* 20 C.F.R § 20.84. In light of DHHS's authority to commission as FDA officers the department employees who maintain the information at issue here, and after consideration of the relevant regulations on disclosure of FDA records by commissioned officers, we do not believe the FDA's position that the records of the commissioned officers require treatment as FDA records is unreasonable.

Therefore, to the extent the FDA provided the information at issue to department employees who have accepted commissions as FDA officers and who are subject to the same restrictions on disclosure as other FDA employees, and to the extent the FDA considers the information held by these commissioned employees to be the records of the FDA, we conclude for purposes of responding to a request for information from a member of the public, the decision to release or withhold the information at issue is a decision for the FDA. *See Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (agency interpretations in formats such as opinion letter are entitled to respect under decision in *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), if persuasive). Thus, neither the department nor this office may determine the extent to which the information at issue is subject to required public disclosure. Upon receipt of a request for the information, the FDA must make that determination in accordance with federal laws and regulations.

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.texasattorneygeneral.gov/open/orl\\_ruling\\_info.shtml](http://www.texasattorneygeneral.gov/open/orl_ruling_info.shtml), 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 may be directed to the Office of the Attorney General, toll free, at (888) 672-6787.

Sincerely,



Britni Fabian  
Assistant Attorney General  
Open Records Division

BF/tch

Ref: ID# 529003

c: Requestor