



ATTORNEY GENERAL OF TEXAS  
GREG ABBOTT

March 19, 2014

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

OR2014-04627

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# 516939 (DSHS OR File: 22470/2013).

The Department of State Health Services (the "department") received a request for all documents pertaining to complaints, as well as orders and communications issued by the department, regarding three entities and four named individuals relating to alpha lipoic acid, alleged injuries of a named individual, and alleged injury or death of another named individual. You state the department has provided or will provide some of the responsive information to the requestor with e-mail addresses subject to section 552.137 of the Government Code redacted pursuant to Open Records Decision No. 684 (2009).<sup>1</sup> You claim that the submitted information is excepted from disclosure under section 552.101 of the Government Code. We have considered the exception you claim and reviewed the submitted representative sample of information.<sup>2</sup> We have also considered comments from the Texas State Board of Pharmacy (the "board"). See Gov't Code § 552.304 (interested party may submit comments stating why information should or should not be released).

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<sup>1</sup>Open Records Decision No. 684 is a previous determination to all governmental bodies authorizing them to withhold certain categories of information without the necessity of requesting an attorney general decision, including an e-mail address of a member of the public under section 552.137 of the Government Code.

<sup>2</sup>We assume the "representative sample" of records submitted to this office is truly representative of the requested records as a whole. See Open Records Decision Nos. 499 (1988), 497 (1988). This open records letter does not reach, and therefore does not authorize the withholding of, any other requested records to the extent those records contain substantially different types of information than that submitted to this office.

Initially, you inform us some of the submitted information was the subject of a previous request for information, in response to which this office issued Open Records Letter No. 2013-08563 (2013). We have no indication the law, facts, or circumstances on which Open Records Letter No. 2013-08563 was based have changed. Accordingly, with regard to the requested information that is identical to the information previously requested and ruled upon by this office in the prior ruling, we conclude the department may continue to rely on Open Records Letter No. 2013-08563 as a previous determination and withhold or release the previously ruled upon information in accordance with that ruling. *See* Open Records Decision No. 673 (2001) (so long as law, facts, and circumstances on which prior ruling was based have not changed, first type of previous determination exists where requested information is precisely same information as was addressed in prior attorney general ruling, ruling is addressed to same governmental body, and ruling concludes information is or is not excepted from disclosure). To the extent the information at issue is not encompassed by the previous ruling, we will address the arguments against disclosure.

Next, we note, and you acknowledge, the department has not complied with the procedural requirements of section 552.301 of the Governmental Code in requesting this ruling. *See* Gov't Code § 552.301(b), (e). Pursuant to section 552.302 of the Government Code, a governmental body's failure to comply with the procedural requirements of section 552.301 results in the legal presumption that the information is public and must be released, unless the governmental body demonstrates a compelling reason to withhold the information to overcome this presumption. *See id.* § 552.302; *Simmons v. Kuzmich*, 166 S.W.3d 342 (Tex. App.—Fort Worth 2005, no pet.); *Hancock v. State Bd. of Ins.*, 797 S.W.2d 379, 381-82 (Tex. App.—Austin 1990, no writ) (governmental body must make compelling demonstration to overcome presumption of openness pursuant to statutory predecessor to section 552.302); *see also* Open Records Decision No. 319 (1982). This office has held that a compelling reason exists to withhold information when the information is confidential by law or affects third party interests. *See* Open Records Decision No. 150 (1977). Because section 552.101 of the Government Code can provide a compelling reason to withhold information, we will consider your arguments regarding this exception.

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 that some of 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 some of the requested information 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.

Section 552.101 of the Government Code also encompasses information made confidential by section 565.055 of the Occupations Code. Section 565.055 provides:

- (a) The board or the board’s authorized representative may investigate and gather evidence concerning any alleged violation of this subtitle or a board rule.
  
- (b) Information or material compiled by the board in connection with an investigation, including an investigative file of the board, is confidential and not subject to:

- (1) disclosure under Chapter 552, Government Code; or

(2) any means of legal compulsion for release, including disclosure, discovery, or subpoena, to anyone other than the board or a board employee or board agent involved in discipline of a license holder.

(c) Notwithstanding Subsection (b), information or material compiled by the board in connection with an investigation may be disclosed:

(1) during any proceeding conducted by the State Office of Administrative Hearings, to the board, or a panel of the board, or in a subsequent trial or appeal of a board action or order;

(2) to a person providing a service to the board, including an expert witness, investigator, or employee of an entity that contracts with the board, related to a disciplinary proceeding against an applicant or license holder, or a subsequent trial or appeal, if the information is necessary for preparation for, or a presentation in, the proceeding;

(3) to an entity in another jurisdiction that:

(A) licenses or disciplines pharmacists or pharmacies;

or

(B) registers or disciplines pharmacy technicians or pharmacy technician trainees;

(4) to a pharmaceutical or pharmacy peer review committee as described under Chapter 564;

(5) to a law enforcement agency;

(6) to a person engaged in bona fide research, if all information identifying a specific individual has been deleted; or

(7) to an entity that administers a board-approved pharmacy technician certification examination.

Occ. Code § 565.055. You state the board and the department conducted a joint investigation related to the prescription drug manufacturer and compounding pharmacy referenced in the instant request. You further state the information at issue was compiled by the board in connection with the investigation. The board also contends that information held by the department regarding the investigation that was received from the board is confidential. You do not inform us the requestor is entitled to this information pursuant to section 565.055(c). Therefore, based on these representations and our review, we find

the submitted information is confidential under section 565.055(b) and must be withheld under section 552.101 of the Government Code.<sup>3</sup> See Open Records Decision No. 474 at 2-3 (1987) (construing predecessor statute).

In summary, with regard to the requested information that is identical to the information previously requested and ruled upon by this office in the prior ruling, we conclude the department may continue to rely on Open Records Letter No. 2013-08563 as a previous determination and withhold or release the previously ruled upon information in accordance with that ruling. To the extent the FDA provided the information you have identified to department employees who have accepted commissions as FDA officers 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 that 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. The department must withhold the submitted information under section 552.101 of the Government Code in conjunction with section 565.055(b) of the Occupations Code.

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,



Sarah Casterline  
Assistant Attorney General  
Open Records Division

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<sup>3</sup>As our ruling is dispositive, we need not address your remaining argument against disclosure.

Ref: ID# 516939

Enc. Submitted documents

c: Requestor  
(w/o enclosures)

Ms. Gay Dodson, R.Ph.  
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Texas State Board of Pharmacy  
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(w/o enclosures)