January 28, 2015

Ms. Gay Dodson
Executive Director/Secretary
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-3943

OR2015-01677

Dear Ms. Dodson:

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#551693.

The Texas State Board of Pharmacy (the "board") received a request for information related to a specified recall from Specialty Compounding, L.L.C.[1] You state the board is releasing some information to the requestor. You claim the submitted information is excepted from disclosure under sections 552.101, 552.107, and 552.111 of the Government Code. We have considered the exceptions you claim and reviewed the submitted information.

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

[1]We note the requestor seeks some information beyond the date of the request. It is implicit in several provisions of the Act that the Act applies only to information already in existence. *See* Gov't Code §§ 552.002, .021, .227, .351. The Act does not require a governmental body to prepare new information in response to a request. *See* Attorney General Opinion H-90 (1973); *see also* Open Records Decision Nos. 572 at 1 (1990), 555 at 1-2 (1990), 452 at 2-3 (1986), 87 (1975). Consequently, a governmental body is not required to comply with a standing request to supply information prepared in the future. *See* Attorney General Opinion JM-48 at 2 (1983); *see also* Open Records Decision Nos. 476 at 1 (1987), 465 at 1 (1987). Thus, the only information encompassed by the present request consists of information the board maintained or had a right of access to as of the date it received the request.

instance, we understand the information at issue is not the board'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 board 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 board'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 board 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 board 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 board 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 board 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 board 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 information at issue was compiled by the board in connection with an investigation. 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 information you have indicated is confidential

under section 565.055(b) and must be withheld under section 552.101 of the Government Code.[2] *See* Open Records Decision No. 474 at 2-3 (1987) (construing predecessor statute).

Section 552.101 of the Government Code also encompasses information made confidential by section 569.004 of the Occupations Code. Section 569.004 provides, in relevant part:

> (a) Information submitted to the board under this subchapter and the fact that the information has been submitted to the board may not be:
>
> > (1) offered in evidence or used in any manner in the trial of a suit described in this subchapter; or
> >
> > (2) used in any manner to determine the eligibility or credentialing of a pharmacy to participate in a health insurance plan defined by the Insurance Code.
>
> (b) Information submitted under this subchapter is confidential and is not subject to disclosure under Chapter 552, Government Code.

Occ. Code § 569.004(a)-(b). Section 569.001 of the Occupations Code requires insurers to report information described in section 569.002 of the Occupations Code to the board. *See id.* §§ 569.001 (duty to report to the board certain information related to notice of claim letters and complaints filed regarding pharmaceutical care or services in certain circumstances), .002 (delineating information to be reported under section 569.001). You state the information you have indicated was provided to the board pursuant to section 569.001 of the Occupations Code. Thus, because the information at issue was submitted to the board as required by section 569.001, we find it is confidential under section 569.004(b) of the Occupations Code. Accordingly, the board must withhold the information you have indicated under section 552.101 of the Government Code in conjunction with section 569.004(b) of the Occupations Code.

In summary, to the extent the FDA provided the information you have identified to board 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 board must withhold the information you have indicated under section 552.101 of the Government Code in conjunction with section 565.055(b) and section 569.004(b) of the Occupations Code. The board must release the remaining information.

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[2]As our ruling is dispositive, we need not address your remaining arguments against disclosure of this information.

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, 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

Britni Fabian
Assistant Attorney General
Open Records Division

BF/bhf

Ref: ID# 551693

Enc. Submitted documents

c: Requestor
(w/o enclosures)