



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

February 4, 2008

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

OR2008-01599

Dear Mr. Dodson:

You ask whether certain information is subject to required public disclosure under the Public Information Act (the "PIA"), chapter 552 of the Government Code. Your request was assigned ID# 302027.

The Texas State Board of Pharmacy (the "board") received a request for any and all communications between the board and the United States Food and Drug Administration (the "FDA") pertaining in any way to Apothecure, Inc. You claim that the requested information is excepted from disclosure under section 552.101 of the Government Code. In addition, we have received and considered the Declaration of Mr. Reynaldo R. Rodriquez, Jr., Director of the Compliance Branch in the Dallas District Office of the FDA.

You assert that the information is deemed confidential by state and federal laws and thus is excepted from required public disclosure under section 552.101 of the PIA.¹ However, the FDA contends that the requested information is not the board's information, but instead belongs to the FDA.

You inform us that the FDA provided the information at issue to board employees who have accepted commissions as FDA officers. You also inform us that, pursuant to federal law, the United States Department of Health and Human Services ("DHHS") commissioned several

¹Section 552.101 excepts from required public disclosure information considered to be confidential law, either constitutional, statutory, or by judicial decision. See Gov't Code § 552.101.

board employees as FDA officers.² See 21 U.S.C. § 372(a). You have submitted for our review copies of several board employee commission acceptances. Mr. Rodriguez explains that these commissions include the ability to review and receive FDA records. The submitted acceptances, which are signed by the commissioning candidates, state that in accepting the commission, the candidate has read and understands 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 [DHHS], or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of sections 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, or 379e of this title concerning any method or process which as a trade secret is entitled to protection[.]

21 U.S.C. § 331(j). The acceptances go on to state that section 520(c) of the Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. ch. 9, prohibits the release of information exempt from disclosure under the Freedom of Information Act, 5 U.S.C. § 552(b)(4), that is obtained under section 513, 514, 515, 516, 518, 519, 704, or under section 520(f) or 520(g) of the FDC Act and the applicant understands that any non-public information he or she receives from the FDA, is protected from disclosure under federal law and that if the candidate makes any unauthorized disclosure of trade secret or confidential commercial information, the candidate is committing a criminal violation under section 331(j) of title 21 of the United States Code and section 1905 of title 18 of the United States Code. Thus, under the acceptances, the FDA records the candidate receives 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 candidate is subject to criminal penalties under federal law for the unauthorized release of confidential information.

You state that the FDA considers the board's commissioned officers to be standing in the shoes of the FDA and that any responsive documents remain the FDA's property. Indeed, Mr. Rodriguez states in his Declaration that the requested information consists of the FDA's records. He explains that 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. Mr. Rodriguez also states that the request for information in this case should have been directed to the FDA rather than the board.

The 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).

²The FDA is a component of the DHHS.

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 governmental 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 that 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).³

You state that the responsive documents were 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 the [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 we have seen, 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 whom you state 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, because you state that the FDA provided the information at issue to board employees who have accepted commissions as FDA officers who are subject to the same restrictions on disclosure as other FDA employees and because the FDA considers the

³In particular, Mr. Rodriguez states that the requested records contain non-public information that may be protected from disclosure by the deliberative process and open investigatory privileges, as well as protected personal information, trade secret, and confidential commercial information. *See* 20 C.F.R. §§ 20.61-.64.

requested 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 requested information is a decision for the FDA. See *Christensen v. Harris County*, 529 U.S. 576, 588 (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 requested information 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.⁴

This letter ruling is limited to the particular records 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 records or any other circumstances.

This ruling triggers important deadlines regarding the rights and responsibilities of the governmental body and of the requestor. For example, governmental bodies are prohibited from asking the attorney general to reconsider this ruling. Gov't Code § 552.301(f). If the governmental body wants to challenge this ruling, the governmental body must file suit in Travis County within 30 calendar days. *Id.* § 552.324(b). In order to get the full benefit of such a challenge, the governmental body must file suit within 10 calendar days. *Id.* § 552.353(b)(3), (c). If the governmental body does not appeal this ruling and the governmental body does not comply with it, then both the requestor and the attorney general have the right to file suit against the governmental body to enforce this ruling. *Id.* § 552.321(a).

If this ruling requires the governmental body to release all or part of the requested information, the governmental body is responsible for taking the next step. Based on the statute, the attorney general expects that, upon receiving this ruling, the governmental body will either release the public records promptly pursuant to section 552.221(a) of the Government Code or file a lawsuit challenging this ruling pursuant to section 552.324 of the Government Code. If the governmental body fails to do one of these things, then the requestor should report that failure to the attorney general's Open Government Hotline, toll free, at (877) 673-6839. The requestor may also file a complaint with the district or county attorney. *Id.* § 552.3215(e).

⁴Mr. Rodriguez states that some responsive documents may be available on the FDA's internet site without the need for a written request. Mr. Rodriguez also invites the requestor to submit his request to the following address:

Food and Drug Administration
Office of Management Programs
Division of Freedom Information (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857

If this ruling requires or permits the governmental body to withhold all or some of the requested information, the requestor can challenge that decision by suing the governmental body. *Id.* § 552.321(a); *Texas Dep't of Pub. Safety v. Gilbreath*, 842 S.W.2d 408, 411 (Tex. App.—Austin 1992, no writ).

Please remember that under the Act the release of information triggers certain procedures for costs and charges to the requestor. If records are released in compliance with this ruling, be sure that all charges for the information are at or below the legal amounts. Questions or complaints about over-charging must be directed to Hadassah Schloss at the Office of the Attorney General at (512) 475-2497.

If the governmental body, the requestor, or any other person has questions, or comments about this ruling, they may contact our office. Although there is no statutory deadline for contacting us, the attorney general prefers to receive any comments within 10 calendar days of the date of this ruling.

Sincerely,



Kay Hastings
Assistant Attorney General
Open Records Division

KH/sdk

Ref: ID# 302027-07

c: Mr. Timothy Micah Dortch
Cooper Scully
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