



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

December 9, 2011

Mr. C. David Richard, III
Assistant General Counsel
Texas Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

OR2011-18158

Dear Mr. Richards:

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# 438652 (DSHS Reference No. 1919407/2012).

The Texas Department of State Health Services (the "department") received a request for six categories of information pertaining to the sale of hearing aids in Texas, to Texas consumers, and/or by a specified vendor, from a specified date to the date of the request. You claim that a portion of the requested information is excepted from disclosure under section 552.101 of the Government Code.¹ We have considered your arguments and reviewed the Declaration of Shari J. Shambaugh, Director of the Compliance Branch in the Dallas District Office of the United States Food and Drug Administration (the "FDA").

You assert that the information at issue is deemed confidential by federal law and thus is excepted from required public disclosure under section 552.101 of the Government Code.² However, the FDA contends that the information at issue is not the department's information, but instead belongs to the FDA.

¹In a letter dated October 12, 2011, you informed our office that the department wished to withdraw its request for an opinion regarding the information submitted as Exhibits B, C, and D. Accordingly, this ruling does not address that information, or your arguments under sections 552.103, 552.107, and 552.111 of the Government Code.

²Section 552.101 of the Government Code excepts from disclosure "information considered to be confidential by law, either constitutional, statutory, or by judicial decision." Gov't Code § 552.101.

You inform us that the FDA provided “most if not all” the information at issue to department employees who have accepted commissions as FDA officers pursuant to federal law. *See* 21 U.S.C. § 372(a). Ms. Shambaugh states several department employees have signed Acceptance of Commission documents as officials of the Department of Health and Human Services (“DHHS”) and the FDA.³ In addition, Certificates of Commission for three department employees have been submitted. Ms. Shambaugh explains that these commissions include the ability to review and receive FDA records. You state that 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 [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, 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 state that the FDA considers the department’s commissioned officers to be serving in concurrent jurisdiction of the FDA and that any responsive documents remain the FDA’s property. Indeed, Ms. Shambaugh states in her Declaration that the information at issue consists of the FDA’s records. She explains that 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. Ms. Shambaugh also states that the request for information in this case should have been directed to the FDA rather than the department.

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 governmental officials commissioned pursuant to 21

³The FDA is a component of DHHS.

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.⁴ *Id.* § 20.2(a); *see generally id.* pt. 20 (regulations concerning public disclosure of FDA records).

You state that “most if not all” the 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 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 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, to the extent the FDA provided the information at issue 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. *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

⁴In particular, Ms. Shambaugh 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.

disclosure. Upon receipt of a request for the information, the FDA must make that determination in accordance with federal laws and regulations.⁵

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, toll free at (888) 672-6787.

Sincerely,



Michelle R. Garza
Assistant Attorney General
Open Records Division

MRG/em

Ref: ID# 438652

Enc. Submitted documents

c: Requestor
(w/o enclosures)

⁵Ms. Shambaugh states that some responsive documents may be available on the FDA's internet site without the need for a written request. Ms. Shambaugh also invites the requestor to submit his request to the following address:

Food and Drug Administration
Division of Freedom of Information (HFI-35)
12420 Parklawn Drive
Rockville, Maryland 20857