



ATTORNEY GENERAL OF TEXAS  
GREG ABBOTT

December 9, 2011

Mr. Reg Hargrove  
Assistant Attorney General  
Public Information Coordinator  
General Counsel Division  
Office of the Attorney General  
P.O. Box 12548  
Austin, Texas 78711-2548

OR2011-18173

Dear Mr. Hargrove:

You ask whether certain information is subject to required public disclosure under chapter 552 of the Government Code. Your request was assigned ID# 438443 (PIR No. 11-31759).

The Office of the Attorney General (the "OAG") received a request for information regarding the OAG's, Texas Department of State Health Services', and United States Food and Drug Administration's (the "FDA") communications pertaining to the sale of hearing aids in Texas and in particular Wal-Mart's sales. The OAG asserts the information is deemed confidential by federal laws as it is the FDA's exclusive property, not the OAG's, and public information requests should be directed to the FDA. We have considered the OAG's arguments and have also received and considered the Declaration of Ms. Shari J. Shambaugh, Director of the Compliance Branch in the Dallas District Office of the FDA, who also asserts the requested information belongs to the FDA.

The OAG informs us that, pursuant to federal law, the United States Department of Health and Human Services (the "DHHS") commissioned two assistant attorneys general as FDA officers.<sup>1</sup> See 21 U.S.C. § 372(a) (DHHS Secretary is authorized to conduct examinations

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<sup>1</sup>The FDA is a component of the DHHS.

and investigations through any employee of any state duly commissioned by the Secretary as an officer of DHHS). The OAG submitted for our review copies of their commission acceptances. Ms. Shambaugh explains these commissions include the ability to review and receive FDA records. The acceptance states in accepting the commission, the employee 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 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). The acceptance further states section 520(c) of the Food, Drug, and Cosmetic Act (the “FDC Act”), 21 U.S.C. ch. 9, prohibits the release of information exempt from disclosure under the Freedom of Information Act (the “FOIA”), 5 U.S.C. § 552, that is obtained under section 513, 514, 515, 516, 518, 519, 704, or under section 520(f) or 520(g) of the FDC Act. The employee acknowledges that any non-public information she receives from the FDA is protected from disclosure under federal law, and if the employee makes any unauthorized disclosure of trade secret or confidential commercial information, the employee 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, pursuant to the acceptance, the FDA records the employee receives are subject to federal law, including the FOIA, 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.

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 [FDA] 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 [FDA]. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other [FDA] employee.

21 C.F.R. § 20.84; *see also id.* § 20.88 (stating state 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 the 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 OAG explains the FDA provided the information at issue to the assistant attorneys general who have accepted commissions as FDA officers. The FDA Director considers the OAG's commissioned officers to be standing in the FDA's shoes and states the requested information consists of the FDA's records. She explains the OAG employees have access to the records at issue only in their capacities as commissioned FDA officers and not in their capacities as state employees. Ms. Shambaugh also states the request for information in this case should have been directed to the FDA rather than the OAG. In light of the DHHS's authority to commission as FDA officers the OAG 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, because the FDA provided the information at issue to OAG employees who are commissioned FDA officers subject to the same restrictions on disclosure as other FDA employees and because the FDA considers the 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, 587 (2000) (agency interpretations in formats such as opinion letters are entitled to respect under decision in *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), if persuasive). Thus, this office may not 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.<sup>2</sup>

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](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

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<sup>2</sup>Ms. Shambaugh states some responsive documents may be available on the FDA's internet site without the need for a written request and invites the requestor to submit her request to the following address: Food and Drug Administration, Division of Freedom Information (HFI-35), 12420 Parklawn Drive, Rockville, Maryland 20857.

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,

A handwritten signature in black ink, appearing to read "Yen-Ha Le". The signature is fluid and cursive, with a large initial "Y" and a distinct "L" at the end.

Yen-Ha Le  
Assistant Attorney General  
Open Records Division

YHL/sdk

Ref: ID# 438443

c: Requestor