



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

January 15, 2008

Mr. Michael Greenberg
Assistant General Counsel
Texas Department of State Health Services
1100 West 49th Street
Austin, Texas 78756

OR2008-00738

Dear Mr. Greenberg:

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# 299696.

The Texas Department of State Health Services (the "department") received a request for information regarding Neuro Resource Group, Inc. You state that you have released some information to the requestor, but claim that the remaining requested information is excepted from disclosure pursuant to federal law.¹ We have considered your arguments.

You state that the United States Food and Drug Administration (FDA) contracts with the department to conduct inspections under authority of federal law and that the inspections are conducted by department employees who are commissioned officers of the FDA. You inform this office that the inspection reports created by the department are then submitted to the FDA. You assert that the FDA has informed the department that the reports and any information obtained from the inspections are confidential pursuant to 21 U.S.C. § 301 and 21 U.S.C. § 331(j). These provisions provide that the Federal Food, Drug, and Cosmetic Act prohibits the disclosure of certain confidential information, such as trade secrets acquired in an official capacity. You also refer to section 20.85, title 21, of the Code of Federal Regulations, which states:

¹Although you initially raised section 552.101 of the Government Code, you have not submitted arguments explaining how this exception applies to the requested information. Therefore, we presume that you have withdrawn this exception. See Gov't Code § 552.301, 302.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited by 21 U.S.C. § 331(j), 21 U.S.C. § 360(j)(c), 42 U.S.C. § 263g(d) and 42 U.S.C. § 263i(e) may be released only as provided by those sections. Any disclosure under this section shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.

21 C.F.R. § 20.85. You assert that these federal provisions also prohibit this office from reviewing any documents that may be responsive to this request. Because you have not provided this office the documents at issue for review, we are unable to make any determination regarding such documents.

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).

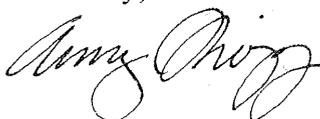
If this ruling requires the governmental body to release all or part of the requested information, the governmental body is responsible for taking the next step. Based on the statute, the attorney general expects that, upon receiving this ruling, the governmental body will either release the public records 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).

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,



Amy L.S. Shipp
Assistant Attorney General
Open Records Division

ALS/mcf

Ref: ID# 299696

No enclsoures

c: Mr. Michael J. Berens
The Seattle Times
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(w/o enclosures)