



January 8, 2002

Mr. Michael Greenberg
Assistant General Counsel
Texas Department of Health
1100 West 49th Street
Austin, Texas 78756-3199

OR2002-0126

Dear Mr. Greenberg:

You ask whether certain information is subject to required public disclosure under chapter 552 of the Government Code. Your request was assigned ID# 157079.

The Texas Department of Health (the "department") received a request for all documents received or generated by or on behalf of the state since January 1, 1995, regarding Sulzer Orthopedics, Inc., Sulzer Intermedics, Inc., Intermedics, Sulzer Carbomedics, Sulzer Medica USA, Inc., or Sulzer Medica, Ltd. You claim that some of the requested information is exempted from disclosure under section 552.101 of the Government Code. You advise that you are releasing the remaining requested information to the requestor. We have considered the exception you claim and reviewed the submitted information.

We first note that subsections 552.301(a) and (b) provide:

(a) A governmental body that receives a written request for information that it wishes to withhold from public disclosure and that it considers to be within one of the [act's] exceptions . . . must ask for a decision from the attorney general about whether the information is within that exception if there has not been a previous determination about whether the information falls within one of the exceptions.

(b) The governmental body must ask for the attorney general's decision and state the exceptions that apply within a reasonable time but not later than the 10th business day after the date of receiving the written request.

The department received the request for information on July 25, 2001, and delivered the request for a ruling on October 29, 2001. Therefore, you have failed to request a decision within the ten business-day period mandated by section 552.301(a) of the Government Code. Because the request for a decision was not timely received, the requested information is presumed to be public information. Gov't Code § 552.302.

In order to overcome the presumption that the requested information is public, a governmental body must provide compelling reasons why the information should not be disclosed. *Id.*; *Hancock v. State Bd. of Ins.*, 797 S.W.2d 379, 381 (Tex. App.--Austin 1990, no writ); *see* Open Records Decision No. 630 (1994). Compelling reasons exist when the information is made confidential by law or affects the interest of a third party. Open Records Decision No. 630 at 3 (1994). The application of section 552.101 is such a compelling reason.

You claim that the highlighted portions of the submitted information are confidential under section 552.101. Section 552.101 of the Government Code excepts "information considered to be confidential by law, either constitutional, statutory, or by judicial decision." This section encompasses information protected by other statutes. You inform this office that the United States Food and Drug Administration (FDA) contracts with the department to conduct inspections under authority of federal law, and the inspections are conducted by department employees who are commissioned officers of the FDA. You state that the inspection reports created by the department are then submitted to the FDA. The FDA has informed the department that the highlighted information is confidential pursuant to 5 USC 552(b)(4) and 21 CFR 20.61(c), concerning commercial and trade secret information, and 5 USC 552(b)(6) and 21 CFR 20.111(c)(3), concerning private information. These federal laws provide for confidentiality of certain information under the federal Freedom of Information Act. On this basis, we conclude that the information at issue is excepted from disclosure under section 552.101 of the Government Code, as the FDA in this case deems it to be confidential under federal law. *See generally* Open Records Decision No. 561 (1990) (when information in the possession of a federal agency is "deemed confidential" by federal law, such confidentiality is not destroyed by the sharing of the information with a governmental body in Texas). Therefore, the highlighted information in the submitted materials must be withheld from the requestor. The remaining information in the submitted materials must be released to the requestor.

You also state that the FDA has informed the department that the reports and any information obtained from the Sulzer 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:

Any Food and Drug Administration records 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), 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.

You assert that these federal provisions also prohibit this office from reviewing any documents that may be responsive to this request. Since you have not provided this office the documents at issue for review, we are unable to make any determination regarding such documents. We note that if the information at issue is actually made confidential under federal law, it is also excepted from disclosure under chapter 552 of the Government Code.¹

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 appeal by filing suit in Travis County within 30 calendar days. *Id.* § 552.324(b). In order to get the full benefit of such an appeal, 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, within 10 calendar days of this ruling, the governmental body will do one of the following three things: 1) release the public records; 2) notify the requestor of the exact day, time, and place that copies of the records will be provided or that the records can be inspected; or 3) notify the requestor of the governmental body's intent to challenge this letter ruling in court. If the governmental body fails to do one

¹We note that you may wish to seek guidance from the FDA concerning public access to these records under federal law.

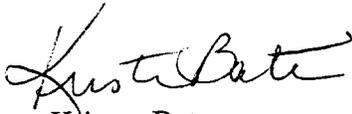
of these three things within 10 calendar days of this ruling, then the requestor should report that failure to the attorney general's Open Government Hotline, toll free, at 877/673-6839. The requestor may also file a complaint with the district or county attorney. *Id.* § 552.3215(e).

If this ruling requires or permits the governmental body to withhold all or some of the requested information, the requestor can appeal that decision by suing the governmental body. *Id.* § 552.321(a); *Texas Department of Public 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 Texas Building and Procurement Commission 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,



Kristen Bates
Assistant Attorney General
Open Records Division

KAB/seg

Ref: ID# 157079

Enc. Submitted documents

c: Ms. Amy Schatz
Austin American-Statesman
305 South Congress Avenue
Austin, Texas 78704
(w/o enclosures)