



Office of the Attorney General
State of Texas

DAN MORALES
ATTORNEY GENERAL

March 15, 1996

Mr. John T. Richards
Assistant General Counsel
Supervising Attorney, Litigation Section
Texas Department of Health
1100 West 49th Street
Austin, Texas 78756-3199

OR96-0338

Dear Mr. Richards:

You have asked whether certain information is subject to required public disclosure under chapter 552 of the Government Code. Your request was assigned ID# 37583.

The Texas Department of Health (the "department") received a request for:

- (1) audiotape recordings made by the U.S. Food and Drug Administration ("FDA") inspectors during the October 31-November 6, 1995 inspection of the facilities of Electromedical Products International, Inc. ("EPI")
- (2) photographs taken by FDA inspectors during the inspection
- (3) complaints that formed the basis for the inspection
- (4) a copy of the investigatory report or the other reports prepared during and following the inspection
- (5) copies of forms 482 and 483 relating to the inspection
- (6) copies of diaries of the inspectors present at the inspection

(7) copies of interagency memoranda and other records that include factual findings, conclusions of law, and recommendations for action in reference to EPI

You state that the 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.¹ You state that the inspection reports are submitted to the FDA. You also state that the FDA has informed the department that the reports and any information obtained from the EPI inspection 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.² Open Records Decision No. 561 (1990).

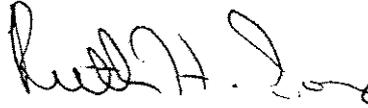
We are resolving this matter with an informal letter ruling rather than with a published open records decision. This ruling is limited to the particular records at issue under the facts presented to us in this request and should not be relied upon as a previous

¹It is not clear in what capacity these employees reviewed the responsive documents. If the documents were reviewed only in the employees' capacity as federal officers, it is not apparent that the department actually had access to the documents. Open Records Decision No. 561 (1990) at 9 (governmental body is not required to obtain information it does not have to comply with an open records request).

²We note that you may wish to seek guidance from the FDA concerning public access to these records under federal law.

determination regarding any other records. If you have questions about this ruling, please contact our office.

Yours very truly,



Ruth H. Soucy
Assistant Attorney General
Open Records Division

RHS/ch

Ref.: ID# 37583

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(w/o enclosures)