

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of :	)	
	)	ADMINISTRATIVE
	)	COMPLAINT FOR CIVIL
	)	MONEY PENALTIES
	)	
LAHAYE CENTER FOR ADVANCED	)	FDA Docket No. 02H-0443
EYE CARE OF LAFAYETTE,	)	
D/B/A LAHAYE TOTAL EYE CARE,	)	
	)	
A corporation, and	)	
	)	
LEON C. LAHAYE,	)	
	)	
An individual.	)	
	)	
	)	

**ORDER**

On July 18, 2003, Respondents LaHaye Center for Advanced Eye Care of Lafayette ("LaHaye Center") and Leon C. LaHaye ("Dr. LaHaye") (collectively "Respondents") submitted a Motion for Stipulated Confidentiality Order. The Motion is consented to by the FDA Complainant, Center for Devices and Radiological Health. Accordingly,

Respondents' Motion is **GRANTED**. And,

**IT IS ORDERED** that:

1. When used in this Order, the term Confidential may be used by Respondents to designate any documents or information contained therein which Respondents have reason to believe: (a) personally identifies a subject in a patient record; or (b) is trade secret or confidential commercial or confidential financial information within the meaning of the Federal Food, Drug, and Cosmetic Act ("Act") and applicable implementing regulations, the Trade Secrets Act and applicable implementing regulations, and controlling judicial decisions.

2. Respondents may designate any documents provided by them in connection with the present litigation that contain the categories of information described in Paragraph 1 as Confidential by labelling the document or information in accordance with Paragraph 10 of this

Order.

3. Any portion of any testimony given in this case that contains one or more of the categories of information described in Paragraph 1 may be designated as Confidential by promptly instructing the court reporter to so designate the testimony. Any testimony designated as Confidential shall be marked and treated in the same manner as documents marked Confidential.

4. Unless otherwise ordered by the Court, documents designated as Confidential shall be used solely for the prosecution and defense of: (a) this case; (b) any other litigation between the United States and Respondents; and (c) any other related action to enforce the Act (hereafter, collectively covered litigation), and shall be disclosed only to:

- a. The Court in this case or any appeal therefrom, or any court presiding over any covered litigation;
- b. Counsel of record for the parties in any covered litigation;
- c. Associates, secretaries, and paralegals of counsel of record for the parties who are assisting such counsel in any covered litigation;
- d. Employees of the FDA;
- e. Parties, witnesses, and deponents for whom Respondents have previously given consent to see the Confidential materials;
- f. Outside consultants and expert witnesses (whether or not designated as trial witnesses) employed or retained by the parties or counsel who shall have access to Confidential documents for services related to any covered litigation. Secretaries, clerical personnel, and other employees who assist in these services shall also have access to Confidential documents. Outside consultants and expert witnesses (and their secretaries, clerical personnel, and other employees) shall agree in writing on the form attached hereto as Exhibit A to abide by the terms of this Confidentiality Order before the disclosure to them of any documents or information designated as Confidential.

5. If Confidential testimony or documents are filed with the Court, they shall be filed under seal, shall be marked with reference to this Order (and any subsequent Order), and shall not be opened or viewed by anyone other than Court personnel, except upon order of the Court. The Court will direct the manner of filing of documents or testimony filed pursuant to this Paragraph.

6. Confidential documents or testimony may be disclosed at the trial of any covered litigation and offered in evidence at the trial of any covered litigation, or used in any hearing related to any covered litigation, subject to such provisions as the presiding Court may make, provided that nothing contained herein shall be deemed to waive any party's right to object to the admissibility of the documents or testimony.

7. Confidential documents or testimony shall not be used, directly or indirectly, by any person for any personal, business, commercial or competitive purpose, or for any purpose whatsoever other than the investigation, preparation, and trial of any covered litigation in accordance with the provisions of this Order.

8. No persons authorized under the terms of this Order to receive Confidential documents or testimony shall be granted access to any materials designated as Confidential until such persons have agreed to be bound by the terms of this Order. Each person who has access to Confidential documents or testimony shall, prior to having access, agree to the terms of the Order by signing a document in the form appended hereto as Exhibit A. Counsel of record shall be responsible for maintaining a record of all authorized persons to whom any Confidential documents or testimony are disclosed.

9. Nothing in this Order shall prevent any party from objecting to discovery which the party believes is improper.

10. Confidential documents or testimony shall be so designated by conspicuously stamping or marking the documents with the appropriate legend.

11. Respondents' designation of documents or testimony as Confidential shall not constitute a presumption or concession that the documents or testimony are confidential, and it shall remain Respondents' burden to establish that the documents or testimony are confidential. The FDA Complainant may contest Respondents' designation of any Confidential document or testimony. All documents and testimony designated as Confidential shall be maintained as such until the Court makes its determination.

12. The provisions of this Order shall be enforceable by the Court and the Court shall have continuing jurisdiction to enforce this Order after the conclusion of this action.

13. Subject to restrictions on the disclosure of information contained in the Act, the Freedom of Information Act (FOIA), and the Trade Secrets Act, and applicable regulations implementing those acts, nothing in this Order shall be construed to limit the FDA's authority or obligation to provide any documents, testimony, or other information received from Respondents in response to a valid legal request for such materials. By way of illustration, but not limitation, valid legal requests shall include requests under FOIA, *subpoenas* for documents, and authorized requests for information from the United States Congress and the General Accounting Office.

DATED this 21<sup>st</sup> day of July, 2003.

/s/ Daniel J. Davidson  
Daniel J. Davidson  
Administrative Law Judge

**EXHIBIT A**

The undersigned has read the Confidentiality Order entered in the matter captioned *In re LaHaye Center for Advanced Eye Care of Lafayette, d/b/a LaHaye Total Eye Care, et al.*, Docket Number 02H-0443, before the U.S. Food and Drug Administration, and agrees to abide by its terms.

Dated: \_\_\_\_\_

By: \_\_\_\_\_