

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

In the matter of)
)
)
)
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.)
_____)

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MOTION FOR STIPULATED CONFIDENTIALITY ORDER

Respondents LaHaye Center for Advanced Eye Care of Lafayette (“LaHaye Center”) and Leon C. LaHaye (“Dr. LaHaye”) (collectively “Respondents”), by and through their undersigned counsel and pursuant to 21 C.F.R. §§ 17.23 and 17.32, hereby respectfully move this Court for an Order adopting the parties’ stipulated confidentiality agreement, attached hereto. Counsel for the Food and Drug Administration (“Complainant”), Mr. Steven D. Silverman, has consented to this motion. In support, Respondents state the following:

1. Complainants filed their First Requests for Production on May 1, 2003.
2. Certain responsive documents contain identifiable patient information, or information that Respondents believe is trade secret or otherwise confidential commercial or confidential financial information.
3. The stipulated confidentiality agreement attached hereto will allow the parties to proceed with discovery in an efficient and timely manner.

Accordingly, Respondents request that this Court grant the proposed stipulated confidentiality order, attached hereto, in order to allow the parties to proceed with discovery.

DATED: July 18, 2003.

Respectfully submitted,



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Henry Chajet
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July 18, 2003

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

)	
In the matter of)	
)	PROTECTIVE ORDER
)	
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.)	
)	

STIPULATED CONFIDENTIALITY ORDER

Upon consideration of Respondents LaHaye Center for Advanced Eye Care of Lafayette's and Leon C. LaHaye's Consent Motion for Stipulated Confidentiality Order, it is this ____ day of July, 2003, it is hereby ORDERED that Respondents' Motion is GRANTED

SO ORDERED:

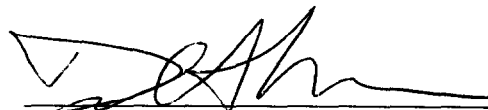
Daniel J. Davidson
Administrative Law Judge

Dated: _____

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 18th day of July, 2003, I caused to be placed in the United States mail (first class mail, postage prepaid) a copy of Respondents LaHaye Center's and Dr. Leon C. LaHaye's Motion for Protective Order to be sent to the following:

Steven D. Silverman
U.S. Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857

A handwritten signature in black ink, appearing to read "S. Silverman", is written over a horizontal line.

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

In the matter of)	
)	
)	
LAHAYE CENTER FOR ADVANCED)	FDA Docket No. <u>02H-0443</u>
EYE CARE OF LAFAYETTE,)	
D/B/A LAHAYE TOTAL EYE CARE,)	
)	
a corporation,)	
)	
and)	
)	
LEON C. LAHAYE,)	
)	
an individual.)	
_____)	

DRAFT STIPULATED CONFIDENTIALITY ORDER

It is stipulated and agreed by the parties to this action through the undersigned counsel that:

1. When used in this Order, the term Confidential may be used by the LaHaye Center for Advanced Eye Care of Lafayette, d/b/a LaHaye Total Eye Care (ALaHaye Center), and Leon C. LaHaye (collectively, 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 labeling 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 United States Food and Drug Administration (AFDA);
- 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. FDA 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.

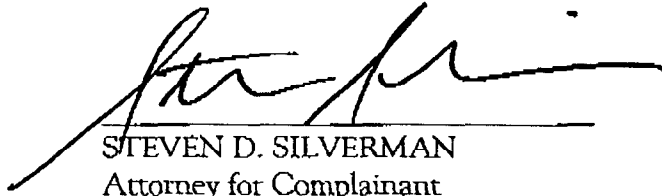
12. The provisions of this Order shall be enforceable by the Court and the Court shall have continuing jurisdiction to enforce this Order after the conclusion of this action.

13. Subject to restrictions on the disclosure of information contained in the Act, the Freedom of Information Act (AFOIA), and the Trade Secrets Act, and applicable regulations implementing those acts, nothing in this Order shall be construed to limit 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: July __, 2003

Respectfully submitted,



STEVEN D. SILVERMAN
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(301) 827-6474



DANIEL A. KRACOV
Attorney for Respondents
PATTON BOGGS LLP
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(202) 457-5623

SO ORDERED:

DANIEL J. DAVIDSON
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

Dated: July 18, 2003

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: _____