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 EYE CARE OF LAFAYETTE, D/B/A LAHAYE TOTAL EYE CARE, a corporation, and LEON C. LAHAYE, an individual.	FDA Docket No. 02H-0443

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RESPONDENTS' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS

Respondents LaHaye Center for Advanced Eye Care of Lafayette ("LaHaye Center") and Leon C. LaHaye ("Dr. LaHaye") (collectively "Respondents"), pursuant to 21 C.F.R. § 17.23, hereby request that the Food and Drug Administration ("FDA" or "Complainant") produce for inspection and copying the following documents in FDA's possession, custody, or control on or before August 28, 2003, at the offices of Patton Boggs LLP, 2550 M St. N.W., Washington, D.C. 20037.

Definitions

A. The term "communication" means any transmittal of information (in the form of facts, ideas, inquiries or otherwise).

B. The term "document" is defined to be synonymous in meaning and equal in scope to the usage of this term in 21 C.F.R. § 17.23. A draft or non-identical copy is a separate document within the meaning of this term.

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C. The terms "concerning" and "regarding" mean relating to, referring to, describing, evidencing or constituting.

D. The term "relating to" means concerning, referring to, describing, evidencing or constituting.

E. The term "identify," when referring to a person, means to give, to the extent known, the person's full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment. Once a person has been identified in accordance with this provision, only the name of that person need be listed in response to subsequent discovery requesting the identification of that person.

F. The term "identify," when referring to a document, means to give, to the extent known, the (i) type of document; (ii) general subject matter; (iii) date of the document; and (iv) author(s), addressee(s) and recipient(s).

G. The term "party" means the Complainant and Respondent as well as the party's full or abbreviated name or a pronoun referring to a party.

H. The term "person" means any natural person or any business, legal or governmental entity or association.

I. The term "you" means the Complainant.

Instructions

Respondent seeks the production of documents and things to the full extent provided by the 21 C.F.R. § 17.23, and this request shall be interpreted so as to make your responses inclusive rather than exclusive. All responsive documents in your possession, custody or control should be produced.

A. In the event that a copy of any document sought by this request is not identical to any other copy thereof by reason of marginal notations or otherwise, each such non-identical copy is deemed to be a separate document and is to be produced.

B. All documents should be produced, as closely as possible, in the manner and order in which they are kept. Specifically, each set of responsive documents held by Complainant or agent thereof should be identified as being from that particular person's or office's files. Further, all file folders, dividers and other containers for such documents should be copied so that Respondent may understand who keeps the documents produced, where they are kept and how they are organized.

C. If your response to any of the requests below is that no responsive documents exist, state that no such documents exist rather than leave the request unanswered. If responsive documents exist but are not available to you, state to the best of your knowledge where the documents are located, including the name, address and telephone number of the custodian. If responsive documents no longer exist because they have been destroyed or cannot be located, identify each such document and describe the circumstances under which it was destroyed or lost.

D. If a response to any request below cannot be made in full, produce all available documents. If you object to only part of any request below, produce all documents responsive to that portion of the request to which you do not object.

E. If you assert either privilege or immunity as a ground for not producing a responsive document, please describe the bases for such assertion, provide a list identifying each document or thing as to which you assert a privilege or immunity. If you object to or refuse to produce any document or thing responsive to any part of any request below on grounds other than privilege or immunity, please describe the grounds separately, fully and with particularity.

F. The fact that investigation is continuing or that discovery is not complete shall not be used as an excuse for failure to respond to each request below as fully as possible.

G. The terms "and" and "or" shall be construed disjunctively or conjunctively as necessary to bring within the scope of a request all responses that might otherwise be construed to be outside of its scope.

H. The singular form of any word shall be deemed to include the plural and vice versa. The neuter form of a pronoun shall be deemed to include the masculine and feminine forms of the pronoun and vice versa. The use of any tense of any verb shall be considered to include all other tenses of the verb. Each request below shall be construed so as to furnish the most complete and inclusive answer.

I. If you believe that any word or phrase in a request below is ambiguous, or if you do not understand any word or phrase below, identify the ambiguity or source of confusion and explain the definition or understanding that you relied upon in responding.

J. Each request below shall be deemed continuing so as to require the responding party to supplement its production of documents and things if, at any time prior to termination of this case, the responding party discovers additional or different documents and things that render any response to any request below incomplete. Such supplemental productions are to be served as soon as reasonably possible after the document or thing becomes available to the responding party or its counsel, but in no case later than 10 days after any such document or thing is obtained.

Documents and Things Requested

1. All documents concerning or regarding FDA's allegation that Respondents have, or any individual respondent has, violated 21 U.S.C. §§ 331(q)(1)(2) and the regulations implementing 21 U.S.C. § 360j(g).

2. All documents concerning or regarding Complainant's allegations at 12a-d of the Complaint.

3. All documents concerning or regarding any analysis of this civil money penalties action per the Civil Money Penalty Policy Draft Guidance document released by the Center for Devices and Radiological Health on June 8, 1999, including the appended SMDA Civil Money Penalty Decision Tree and Civil Money Penalty Fee Matrix.

4. All documents concerning or regarding any analysis of this civil penalties action per the FDA's Regulatory Procedures Manual.

5. All documents concerning or regarding or in any way referencing or referring to either or both Respondents.

6. All documents concerning or regarding or in any way referencing or referring to communications between either or both Respondents and FDA and/or any FDA employee.

7. All documents concerning or regarding or in any way referencing or referring to any decision by FDA to contact Respondents' patients.

8. All documents concerning or regarding or in any way referencing or referring to any communications between FDA and employees or former employees of Respondents'.

9. All investigator notes, internal memoranda, and other documents not previously produced (including documents in FDA District Offices) concerning or regarding FDA inspection of LaHaye Center for Advanced Eye Care of Lafayette.

10. All documents concerning or regarding Respondents' IDE submissions.

11. All documents concerning or regarding any communications (including correspondence, conversations, or meetings) between FDA personnel and third parties (including Respondents) regarding the use or regulation of Respondents' excimer laser system.

12. All documents concerning or regarding any notice given by FDA personnel to Respondents regarding FDA's views of the legality of use or the regulation of excimer laser systems. Such documents include, but are not limited to, those concerning or regarding any warning letters,

untitled letters, FDA-483s, establishment inspection reports, administrative actions, discussions between FDA personnel and responsible individuals for Respondents, verbal notifications from FDA personnel to Respondents (e.g., in meetings or telephone conversations confirmed in writing), or written or oral advisory communication issued by FDA personnel.

13. All documents concerning or regarding FDA regulation of ophthalmic excimer lasers.

14. All documents concerning or regarding FDA approval of LASIK devices.

15. All documents concerning or regarding any communications (including correspondence, conversations, or meetings) between FDA, including any FDA employees, and Respondent(s).

16. All documents regarding a discussion on or about September 12, 1997, between FDA and Respondent(s).

17. All advertisements, patient brochures, descriptive videos or other "promotional" materials, or copies thereof, in the possession of FDA regarding Respondents' excimer laser.

18. Any documents concerning or regarding communications within FDA's possession between Respondent(s) and other physicians.

19. Any and all documents provided to FDA by Respondent(s) during inspections of Respondent(s) clinic.

20. All documents concerning or regarding any communications between individuals who received treatment with an unapproved ophthalmic excimer laser (for which an IDE was submitted to FDA or for which an IDE was not submitted to FDA).

21. All documents concerning or regarding any communications (including correspondence, conversations, or meetings) between FDA personnel and third parties (including Respondents) regarding the use or regulation of excimer laser systems not approved by the FDA (including those for which an Investigational Device Exemption ("IDE") application was submitted to FDA and those for which an IDE was not submitted to FDA).

22. All documents concerning or regarding any notice given by FDA personnel to persons using unapproved excimer laser systems (for which an IDE was submitted to FDA or for which an IDE was not submitted to FDA) regarding FDA's views of the legality of use or the regulation of excimer laser systems. Such documents include, but are not limited to, those concerning or regarding any warning letters, untitled letters, FDA-483s, establishment inspection reports, administrative actions, discussions between FDA personnel and responsible individuals for the persons using the excimer laser systems, verbal notifications from FDA personnel to responsible individuals for the persons using the excimer laser systems (e.g., in meetings or telephone conversations confirmed in writing), or written or oral advisory communication issued by FDA personnel.

23. All documents concerning or regarding expert reports, studies, or analyses of unapproved excimer laser systems (for which an IDE was submitted to FDA or for which an IDE was not submitted to FDA).

24. All documents concerning or regarding communications between FDA and Summit Technologies or FDA and Visx regarding third party uses of unapproved excimer lasers.

25. All documents concerning or regarding investigations involving, or enforcement actions against, ophthalmic laser service providers other than Respondents.

26. All documents concerning or regarding the use of approved ophthalmic excimer lasers prior to May 1998 for the treatment of myopia beyond the then-approved labeled uses. Such documents include, but are not limited to, those concerning or regarding any guidances, guidelines, policies, standards, transcripts or other recordings of speeches or public presentations or statements by FDA personnel, correspondence between FDA and third parties, or memoranda of conversations or meetings between FDA personnel and third parties.

27. All documents concerning or regarding the use of unapproved ophthalmic excimer lasers (for which an IDE was submitted to FDA or for which an IDE was not submitted to FDA). Such documents include, but are not limited to, those concerning or regarding any guidances, guidelines, policies, standards, transcripts or other recordings of speeches or public presentations or statements by FDA personnel, correspondence between FDA and third parties, or memoranda of conversations or meetings between FDA personnel and third parties.

28. Meeting minutes and all documents concerning or regarding or in any way referencing or referring to a meeting on or about November 15, 1996 between FDA and users of excimer lasers.

29. Meeting minutes and all documents concerning or regarding or in any way referencing or referring to a meeting on or about January 15, 1997 between FDA and users of excimer lasers.

30. All documents concerning or regarding any reports of patients injured or otherwise adversely affected as a result of the use of unapproved ophthalmic excimer lasers (for which an IDE was submitted to FDA or for which an IDE was not submitted to FDA).

31. All documents concerning or regarding FDA implementation of 21 U.S.C. 360j(b) with regard to custom devices.

32. All documents concerning or regarding FDA's position with regard to the practice of medicine for medical devices.

33. All documents concerning or regarding factors relevant to mitigation, in accordance with 21 C.F.R. § 17.34.

34. All documents concerning or regarding development, implementation, or application of the Civil Money Penalty Policy Draft Guidance document released by the Center for Devices and Radiological Health on June 8, 1999, including the appended SMDA Civil Money Penalty Decision Tree and Civil Money Penalty Fee Matrix.

35. All documents consisting of, concerning or regarding any comments to the Civil Money Penalty Policy Draft Guidance document released by the Center for Devices and Radiological Health on June 8, 1999, including the appended SMDA Civil Money Penalty Decision Tree and Civil Money Penalty Fee Matrix.

36. All documents concerning or regarding the development, implementation, or application of the Civil Money Penalty Policy Draft Guidance released by the Center for Devices and Radiological Health on April 7, 1994.

37. All documents concerning or regarding FDA's response, dated June 7, 1996 and signed by Sharon Smith Holston, Deputy Commissioner for External Affairs, to questions submitted by the House Commerce Subcommittee on Oversight and Investigations on April 12, 1996 regarding FDA's authority to impose civil money penalties against medical device manufacturers.

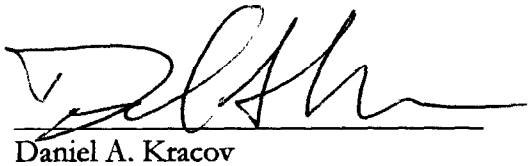
38. All documents concerning or regarding the development, implementation, or application of the Civil Money Penalties subchapter of Chapter 5 of FDA's Regulatory Procedures Manual.

39. All documents concerning or regarding instances in which FDA has either sought or obtained civil money penalties pursuant to Section 303(f) of the Food, Drug, and Cosmetic Act.

40. All documents concerning or regarding FDA enforcement actions against a person for violations of 21 U.S.C. §§ 331(q)(1) or (2) and/or the regulations implementing 21 U.S.C. § 360j(g).

41. All documents otherwise pertinent to, bearing on, or which FDA intends to offer as evidence in the referenced civil penalty action.

Respectfully submitted,



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July 29, 2003

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 29th day of July 2003, I caused to be placed in the United States mail (first class mail, postage prepaid) a copy of Respondents' First Request for Production of Documents to be sent to the following:

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