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

In the matter of 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

SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT is made this 31ST day of October, 2003, by and between the Food and Drug Administration ("FDA") Center for Devices and Radiological Health ("CDRH" or the "Petitioner"), the LaHaye Center for Advanced Eye Care of Lafayette, d/b/a LaHaye Total Eye Care ("LaHaye Center"), and Dr. Leon C. LaHaye ("LaHaye") (collectively, "Respondents").

WHEREAS, in or about 1995, Respondents constructed an excimer-laser system (the "laser") in order to provide laser assisted in-situ keratomileusis ("LASIK") to patients of Respondents', and thereafter used the laser to provide LASIK without a Pre-Market Application or an Investigational Device Exemption ("IDE") approved by the Food and Drug Administration ("FDA") for the laser;

WHEREAS, in or about 1997, Respondents made an application to FDA for an IDE for the laser;

WHEREAS, pursuant to Respondents' application for an IDE, FDA did grant an Investigational Device Exemption ("Respondents' IDE") for the laser;

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WHEREAS, Respondents' IDE authorized Respondents to provide LASIK to a specified number of subjects, for specified medical conditions, subject to statutory and regulatory requirements governing IDEs, including, but not limited to, various record keeping and reporting requirements;

WHEREAS, CDRH filed an amended administrative complaint for civil money penalties against Respondents, alleging that Respondents violated Sections 301(q)(1) and (q)(2) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 331(q)(1) and (q)(2), by failing to comply with the requirements prescribed under 21 U.S.C. § 360j(g) and the accompanying regulations set forth at 21 C.F.R. Part 812. These alleged violations included the following:

a. using the laser to treat a greater number of subjects than were authorized by Respondents' IDE, 21 C.F.R. § 812.110(a);

b. using the laser to treat medical conditions beyond those authorized by Respondents' IDE, 21 C.F.R. § 812.110(b);

c. in Respondents' capacity as a study sponsor, changing an investigational plan prior to obtaining FDA approval, 21 C.F.R. § 812.35; and

d. failing to keep complete and accurate records of use of the laser, and submitting IDE progress reports that were incomplete, inaccurate, and, in certain respects, false or misleading, 21 C.F.R. §§ 812.140(a)(3) and 812.150;

WHEREAS, Respondents have denied and disputed Petitioner's allegations and/or that either or both Respondents' use of the laser outside of the terms and conditions of Respondents' IDE was unlawful;

WHEREAS, pursuant to FDA's request, Respondents ceased all use of the laser on or about March 14, 2001, and subsequently disassembled and otherwise destroyed the laser;

WHEREAS, FDA and Respondents have engaged in discussions directed to resolution of this civil money penalties action;

WHEREAS, these discussions have resulted in compromise and settlement, as set forth herein, and FDA and hereby agree to the following:

1. The Secretary of Health and Human Services has subject matter jurisdiction over this action pursuant to 21 U.S.C. § 333(f) and has delegated his functions to the Commissioner of Food and Drugs under 21 C.F.R. § 5.10(a). FDA has personal jurisdiction over Respondents pursuant to 21 U.S.C. § 333(f). Pursuant to 5 U.S.C. §§ 554 and 556, 21 U.S.C. § 333(f)(3)(A), and the implementing regulations at 21 C.F.R. Part 17, an administrative law judge appointed according to 5 U.S.C. § 3105 has the authority to conduct a civil money penalty hearing and assess a civil penalty.

2. In remedy of the alleged violations, Respondent LaHaye is assessed an agreed civil money penalty of $150,000. One-half of that amount shall be due and payable no later than 90 days from the date of entry of this Settlement Agreement. The balance shall be due and payable no later than 180 days from the date of entry of this Settlement Agreement.

3. In remedy of the alleged violations, Respondent LaHaye Center is assessed an agreed civil money penalty of $950,000. One-half of that amount shall be due and payable no later than 90 days from the date of entry of this Settlement Agreement. The balance shall be due and payable no later than 180 days from the date of entry of this Settlement Agreement.

4. All parties waive any right to a hearing under 21 U.S.C. § 333(f), and any other right that they may have to contest or appeal the imposition or amount of civil money penalties herein assessed.

5. In the event that either Respondent fails to make timely payments of any amounts specified in this Settlement Agreement, Petitioner may, at its option, declare either or both Respondents to be in default, and the full remaining unpaid balance owed by both Respondents shall become immediately due and payable without demand or other formality, judicial or otherwise, all of which are expressly waived by Respondents. Upon declaration of default, Petitioner shall give Respondent written notice thereof by United States Certified Mail, Return Receipt Requested, to Respondents' counsel at counsel's address set forth below. In the event that Petitioner declares either or both Respondents in default, interest shall accrue on all unpaid amounts at the rate of 15% *per annum*, compounded daily, from the date said notice is received.

In the event that payments are not timely, and Petitioner does not declare either or both Respondents to be in default, all late payments will be automatically subject to an interest charge of 15% *per annum*, compounded daily, commencing on the date payment is due. Petitioner may proceed against either or both Respondents for collection of any and all amounts owed by either Respondent including, but not limited to, any and all unpaid balance, late payments, and interest.

6. If FDA is required to take administrative or judicial action to enforce this Decree then Respondents shall be liable for FDA's costs of said action, including reasonable attorney fees therefor.

7. FDA and Respondents shall bear their own costs, including attorney fees, relating to the action underlying this Settlement Agreement.

8. Respondents shall bear their own cost for complying with this Settlement Agreement.

9. The Administrative Law Judge shall retain jurisdiction of this action until all of the payments addressed herein and including any interest, if accrued, are paid. Upon payment of the amounts in paragraphs 3, 4, and 6, if applicable, Petitioner shall cause to be filed a Joint Stipulation for Dismissal with Prejudice with the Administrative Law Judge.

10. This Settlement Agreement fully resolves and settles all claims in the Complaint against Respondent LaHaye, Respondent LaHaye Center, and its current and former directors, officers, employees, or agents, and all claims or actions by FDA related to the facts, circumstances, events, or violations alleged in the Complaint to the extent that such claims or

actions or potential claims or actions are based on facts, circumstances, events, or violations that predate the filing of the Complaint and that were known to Petitioner prior to the date of this Settlement Agreement.

IT IS SO ORDERED:

Dated this 13 day of November, 2003.

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