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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,	)	FDA Docket No. 02H-0443
	)	
a corporation,	)	
	)	
and	)	
	)	
LEON C. LAHAYE,	)	
	)	
an individual.	)	

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**RESPONDENTS' MOTION FOR LEAVE TO AMEND THEIR ANSWER**

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. § 17.9(d) and 17.32, hereby respectfully move this Court for an Order granting permission to amend their Answer to the Complaint filed in the above-captioned action.

Respondents herein incorporate by reference their responses to the separately numbered paragraphs of the above-referenced Administrative Complaint as provided in their earlier Answer, and, in response to the United States' Motion to Amend its Complaint, seek leave to amend their Answer as follows:

12c. The amended reference in Paragraph 12c. to 21 C.F.R. § 812.35 is a conclusion of law that does not require a response.

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12d. The reference in Paragraph 12d. to 21 C.F.R. § 812.140(a)(3) is a conclusion of law that does not require a response.

In addition, Respondents move for leave to amend their Answer to include the following affirmative defense:

**Fifth Affirmative Defense**

Inasmuch as the Administrative Law Judge in this matter is precluded under 21 C.F.R. § 17.19(c) from invalidating the statutes and regulations which form the basis for this case, and given that Respondents are thereby denied the right to a full and fair defense and to Due Process of Law, the proceedings constitute a violation of Respondents' Constitutional rights.

A memorandum in support of this motion and a proposed order are filed herewith for this Court's consideration.

Respectfully submitted,



Daniel A. Kracov  
Henry Chajet  
Attorneys for Respondents  
PATTON BOGGS LLP  
2550 M Street, NW  
Washington, DC 20037-1350  
(202) 457-5623  
(202) 457-6315 - facsimile

Charles Boudreaux, Jr.  
Joseph Lemoine  
ONEBANE, BERNARD, TORIAN,  
MCNAMARA & ABELL P.C.  
Versailles Center, Suite 600  
102 Versailles Boulevard  
Lafayette, LA 70501  
(337) 237-2660  
(337) 266-1232 – facsimile

June 16, 2003



**CERTIFICATE OF SERVICE**

I hereby certify under penalty of perjury that on this \_\_\_\_ day of June, 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 Leave to Amend Their Answer, Memorandum in Support thereof, and Proposed 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", written over a horizontal line.