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UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

COMMISSIONERS: Timothy J. Muris, Chairman

Sheila F. Anthony Mozelle W. Thompson

Orson Swindle Thomas B. Leary

In the Matter of) DOCKET NO. C-4083)

LCA-VISION, INC. d\b\a LASIKPLUS,)
a corporation.) DECISION AND ORDER)

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorneys, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of

public comments, and having duly considered the comment received from an interested party pursuant to section 2.34 of its Rules, now in further conformity with the procedure prescribed in section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

- 1. Respondent LCA-Vision, Inc. ("LCA"), is a Delaware corporation with its principal office or place of business at 7840 Montgomery Road, Cincinnati, Ohio 45236. LCA provides refractive surgery services under the name Lasik *Plus*.
- 2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

- 1. Unless otherwise specified, "respondent" shall mean LCA-Vision, Inc., a corporation, its successors and assigns and its officers, agents, representatives, and employees.
- 2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- 3. "Refractive surgery services" shall mean any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.
- 4. "Device," shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- 5. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, or sale of LASIK surgery services or any other refractive surgery services, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such services:

- A. Eliminate the need for glasses and contacts for life;
- B. Pose significantly less risk to patients' eye health than wearing glasses or contacts; or
- C. Eliminate the risk of glare and haloing,

unless, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale, or sale, of any LASIK surgery services or any other refractive surgery services, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, efficacy, or safety of any such services, unless, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

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Nothing in this order shall prohibit respondent from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, managers, employees, agents, and representatives having responsibilities for developing, contracting for, and/or approving marketing campaigns, marketing materials, advertisements, or claims, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that respondent and its successors and assigns shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

VIII.

This order will terminate on July 8, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; <u>provided</u>, <u>however</u>, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

<u>Provided, further</u>, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark Secretary

ISSUED: July 8, 2003

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