

Part I of the order prohibits claims that LASIK surgery services or any other refractive surgery services: (1) Eliminate the need for glasses and contacts for life; (2) eliminate the need for reading glasses; or (3) eliminate the need for bifocals, unless the claims are substantiated by competent and reliable scientific evidence. "Refractive surgery services" are defined as any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.

Part II of the order requires that future claims about the benefits, performance, efficacy, or safety of any refractive surgery service be substantiated by competent and reliable scientific evidence.

Part III of the order prohibits LVI from misrepresenting: (1) That consumers will receive a free consultation that determines their candidacy for LASIK or any other refractive surgery services; (2) the cost to consumers to have their candidacy for refractive surgery services determined; or (3) the information consumers will receive during a consultation for refractive surgery services.

Part IV of the order permits device claims approved by the FDA under any new medical device application.

Parts V and VI of the order require LVI to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, and provide copies of the order to certain of its personnel.

Part VII of the order requires the corporate respondent to notify the Commission of changes in corporate structure.

Part VIII of the order requires the individual respondents to notify the Commission of their employment status in the eye care industry.

Part IX of the order requires LVI to file compliance reports with the Commission, and Part X provides that the order will terminate after 20 years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

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FEDERAL TRADE COMMISSION

[File No. 022 3098]

LCA-Vision, Inc. d/b/a LasikPlus; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before April 25, 2003.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: consentagreement@ftc.gov, as prescribed below.

FOR FURTHER INFORMATION CONTACT: Matthew Daynard, FTC, Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-3291.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission's rules of practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 26, 2003), on the World Wide Web, at "<http://www.ftc.gov/os/2003/03/index.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW.,

Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled "confidential." Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to e-mail messages directed to the following e-mail box: consentagreement@ftc.gov. Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's rules of practice, 16 CFR 4.9(b)(6)(ii).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from LCA-Vision, Inc. d/b/a LasikPlus ("LCA").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves allegedly misleading representations about LASIK (laser assisted in situ keratomileusis) refractive surgery services designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye), thereby reducing patients' dependence on eyeglasses and contact lenses.

According to the FTC complaint, LCA failed to have substantiation for the claims that its LASIK surgery services: (1) Eliminate the need for glasses and contacts for life; and (2) pose significantly less risk to patients' eye health than wearing glasses or contacts. Among other reasons, LASIK surgery does not eliminate most peoples' need for reading glasses, and the relative risks of LASIK surgery and wearing contact lenses over time are not readily comparable. The complaint further alleges that LCA did not have substantiation for its claim that its LASIK surgery services eliminate the risk of glare and haloing, a starburst effect around lights at night, that can be caused by the LASIK procedure.

The proposed consent order contains provisions designed to prevent LCA

from engaging in similar acts and practices in the future.

Part I of the order prohibits claims that LASIK surgery services or any other refractive surgery services: (1) Eliminate the need for glasses and contacts for life; (2) pose significantly less risk to patients' eye health than wearing glasses or contacts; or (3) eliminate the risk of glare and halving, unless the claims are substantiated by competent and reliable scientific evidence. "Refractive surgery services" are defined as any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.

Part II of the order requires that future claims about the benefits, performance, efficacy, or safety of any refractive surgery service be substantiated by competent and reliable scientific evidence.

Part III of the order permits device claims approved by the FDA under any new medical device application.

Parts IV, V, VI, and VII of the order require LCA to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part VIII provides that the

order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03-7930 Filed 4-1-03; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

Interagency Committee for Medical Records (ICMR); Automation of Medical Standard Form 88

AGENCY: Office of Communications,
GSA.

ACTION: Guideline on automating
medical standard forms.

BACKGROUND: The Interagency Committee on Medical Records (ICMR) is aware of numerous activities using computer-generated medical forms, many of which are not mirror-like images of the genuine paper Standard/Optional form. With GSA's approval to ICMR eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed

and granted an exception. The committee proposes to set required fields standards and that activities developing computer-generated versions adhere to the required fields but not necessarily to the image. The ICMR plans to review medical Standard/Optional forms which are commonly used and/or commonly computer-generated. We will identify those fields which are required, those (if any) which are optional, and the required format (if necessary). Activities may not add or delete data elements that would change the meaning of the form. This would require written approval from the ICMR. Using the process by which overprints are approved for paper Standard/Optional forms, activities may add other data entry elements to those required by the committee. With this decision, activities at the local or headquarters level should be able to develop electronic versions which meet the committee's requirements. This guideline controls the "image" or required fields but not the actual data entered into the field.

SUMMARY: With GSA's approval, the Interagency Committee of Medical Records (ICMR) eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed and granted any exception. The following fields must appear on the electronic version of the following form:

ELECTRONIC ELEMENTS FOR SF 88

Item	Placement*
Report of Medical Examination	Top of form. Bottom right corner of form.
Standard Form 88 (Rev. 8/2001) (Form ID)	
Data Entry Fields:	
1. Date of Exam	
2. Last Name	
2. First Name	
2. Middle Name	
3. Identification Number	
4. Grade of Position	
4. Component of Position	
5. Home Address (Number, street or RFD, city or town, state and ZIP code)	
6. Emergency Contact (Name)	
6. Emergency Contact (address)	
7. Date of Birth	
8. Age	
9. Sex—Female (Checkbox)	
9. Sex—Male (Checkbox)	
10. Relationship of Contact	
11. Place of Birth	
12. Agency	
13. Organization Unit	
14a. Total Years Government Service—Military	
14b. Total Years Government Service—Civilian	
15. Name of Examining Facility or Examiner	
15. Address of Examining Facility or Examiner	
16. Rating or Specialty of Examiner	
17. Purpose of Examination	
18. Clinical Evaluation—Check each item in appropriate columns; enter "NE" if not evaluated	Above below listed items
a. Head, Face, Neck and Scalp—Normal (Checkbox)	