

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

Plaintiff,

v.

**JOKESHOP USA, LLC, a Massachusetts
Limited Liability Corporation, also doing
business as Vampfangs and Glowmark
Novelties, and**

**SCOTT SMILEGE-FERRAGAMO, also
doing business as Vampfangs and Glowmark
Novelties, individually, and in his official
capacity as managing member of JOKESHOP
USA, LLC,**

Defendants.

**CONSENT DECREE AND ORDER FOR
CIVIL PENALTIES,
PERMANENT INJUNCTION, AND
OTHER RELIEF**

WHEREAS, Plaintiff, the United States of America, has commenced this action by filing the Complaint herein; Defendants have waived service of the Summons and Complaint; the parties have been represented by the attorneys whose names appear hereafter; and the parties have agreed to settlement of this action upon the following terms and conditions, without adjudication of any issue of fact or law;

THEREFORE, on the joint motion of Plaintiff and Defendants, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

FINDINGS

1. This Court has jurisdiction of the subject matter and of the parties pursuant to 28 U.S.C. §§ 1331, 1337(a), 1345, and 1355, and 15 U.S.C. §§ 45(m)(1)(A), 53(b), 56(a), and 57b.
2. Venue is proper as to all parties in the District of Massachusetts under 28 U.S.C. §§ 1391(b)-(d) and 15 U.S.C. § 53(b).
3. The activities of Defendants are in or affecting commerce as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
4. The Complaint states a claim upon which relief may be granted against Defendants under Sections 9(a) and 9(b) of the Fairness to Contact Lens Consumers Act ("FCLCA"), 15 U.S.C. §§ 7608(a) and (b), and Sections 5(a)(1), 5(m)(1)(A), 13(b), 16(a), and 19(a)(1) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a)(1), 45(m)(1)(A), 53(b), 56(a), and 57b(a)(1).
5. Defendants have entered into this Consent Decree and Order for Civil Penalty, Permanent Injunction, and Other Relief ("Order") freely and without coercion. Defendants further acknowledge that they have read the provisions of this Order and are prepared to abide by them.
6. Plaintiff and Defendants hereby waive all rights to appeal or otherwise challenge or contest the validity of this Order.
7. Plaintiff and Defendants stipulate and agree that the entry of this Order shall constitute a full, complete, and final settlement of this action.

8. Defendants have agreed that this Order does not entitle Defendants to seek or to obtain attorneys' fees as a prevailing party under the Equal Access to Justice Act, 28 U.S.C. § 2412, and Defendants further waive any rights to attorneys' fees that may arise under said provision of law.

9. Entry of this Order is in the public interest.

DEFINITIONS

10. "Individual Defendant" means Scott Smiledge-Ferragamo.

11. "Corporate Defendant" means Jokeshop USA, LLC, also doing business as Vampfangs and Glowmark Novelties, and its successors and assigns, including, but not limited to Vampfangs/321FX Studios, LLC.

12. "Defendants" means the Individual Defendant and the Corporate Defendant, individually, collectively, or in any combination.

13. "Rule" means the Federal Trade Commission's Contact Lens Rule, 16 C.F.R. Part 315.

14. The term "contact lens" means any contact lens for which State or Federal law requires a prescription.

15. The term "contact lens prescription" means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

- A. The name of the patient;
- B. The date of the examination;

- C. The issue date and expiration date of prescription;
- D. The name, postal address, telephone number, and facsimile telephone number of prescriber;
- E. The power, material, or manufacturer or both of the prescribed contact lens;
- F. The base curve or appropriate designation of the prescribed contact lens;
- G. The diameter, when appropriate, of the prescribed contact lens; and
- H. In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of the equivalent brand name.

16. "Contact lens fitting" means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include:

- A. An examination to determine the lens specifications;
- B. Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and
- C. Medically necessary follow-up examinations.

17. "Private label contact lenses" means contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.

18. "Direct communication" means completed communication by telephone, facsimile, or electronic mail.

19. "Prescriber" means, with respect to contact lens prescriptions, an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the United States Food and Drug Administration. "Other person," for purposes of this definition, includes a dispensing optician who is permitted under State law to issue prescriptions and who is authorized or permitted under State law to perform contact lens fitting services.

20. "Net proceeds" means any sum remaining after any payment to third parties of reasonably and customary fees and commissions.

INJUNCTION

21. Defendants, their successors and assigns, and their officers, agents, representatives, and employees, and all persons in active concert or participation with any one of them, who receive actual notice of this Order by personal service or otherwise, are hereby enjoined, directly or through any corporation, subsidiary, division, website, or other device, from selling contact lenses to a consumer without a contact lens prescription for that consumer that is either:

- A. Presented to Defendants by the consumer or prescriber directly or by facsimile; or
- B. Verified by direct communication with the prescriber.

22. Defendants, their successors and assigns, and their officers, agents, representatives, and employees, and all persons in active concert or participation with any one of them, who receive actual notice of this Order by personal service or otherwise, are hereby enjoined, directly or through any corporation, subsidiary, division, website, or other device, from failing to maintain the following:

- A. For prescriptions presented to Defendants as described in Paragraph 21.A. of this Order the prescription itself, or the facsimile version thereof (including an email containing a digital image of the prescription); and
- B. For verification requests made by Defendants as described in Paragraph 21.B. of this Order:
 - 1. If the communication occurs via facsimile or email, a copy of the verification request, including the information provided to the prescriber regarding the consumer, and confirmation of the completed transmission thereof, including a record of the date and time the request was made.
 - 2. If the communication occurs via telephone, a log (a) describing the information provided to the prescriber; (b) setting forth the date and time the request was made; (c) indicating how the call was completed; and (d) listing the names of the individuals who participated in the calls.

C. For communications from the prescriber, including prescription verifications:

1. If the communication occurs via facsimile or email, a copy of the communication and a record of the time and date it was received;
2. If the communication occurs via telephone, a log describing the information communicated, the date and time that the information was received, and the name of the individuals who participated in the call.

23. Defendants, their successors and assigns, and their officers, agents, representatives, and employees, and all persons in active concert or participation with any one of them, who receive actual notice of this Order by personal service or otherwise, are hereby enjoined, directly or through any corporation, subsidiary, division, website, or other device, from violating any provision of the Contact Lens Rule, 16 C.F.R. Part 315, and as the Rule may hereafter be amended. A copy of the Rule is attached hereto as Attachment A and incorporated herein as if fully set forth verbatim.

CIVIL PENALTY

24. Defendants shall pay to Plaintiff a civil penalty, pursuant to Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. § 45(m)(1)(A), in the amount of two hundred thousand dollars (\$200,000), which payment shall be suspended except for fifty thousand dollars (\$50,000), and the net proceeds, if any, from the sale of one automobile, as described below in Paragraph 26.A. of this Order, subject to the provisions of the section of this Order entitled "RIGHT TO

REOPEN.” Defendants are jointly and severally responsible for payment of the civil penalty.

25. Prior to or concurrently with Defendants’ execution of this Order, Defendants shall turn over fifty thousand dollars (\$50,000) to their attorney, who shall hold the entire sum for no purpose other than payment to the Treasurer of the United States after entry of this Order by the Court. Within five (5) days of receipt of notice of the entry of this Order, Defendants’ attorney shall transfer the sum of fifty thousand dollars (\$50,000) in the form of a wire transfer or certified cashier’s check made payable to the Treasurer of the United States. The check and/or written confirmation of the wire transfer shall be delivered in accordance with procedures specified by the Office of Consumer Litigation, Civil Division, U.S. Department of Justice, Washington, D.C. 20530.

26. The payment and the transfer of any net proceeds from the sale of the identified automobile shall be made as follows:

- A. Defendants agree to relinquish all rights, title, and interest in the 2009 Mercedes C300, Vehicle Identification Number WDDGF81X09F207348, owned by Individual Defendant. Upon entry of this Order, Defendants shall immediately retain an auction company or other company, designated by a representative of the FTC, and direct the company to take all necessary steps to sell said 2009 Mercedes C300 at a public auction; or, alternatively, at the FTC representative’s designation, Defendants shall sell all of their rights, title, and interest in the vehicle to such designated company. Defendants shall take all reasonable and necessary steps to

assist in the sale of the 2009 Mercedes C300; and

B. Within ten (10) business days of the transfer of any interests in said 2009 Mercedes C300:

1. Defendants shall turn over the full amount of the net proceeds from the sale, auction, foreclosure, or other transfer of the 2009 Mercedes C300, to their attorney, who shall hold the entire sum for no purpose other than payment to the Treasurer of the United States. Within five (5) days of the receipt of such funds, Defendants' attorney shall transfer the full amount in the form of a wire transfer or certified cashier's check made payable to the Treasurer of the United States. The check and/or written confirmation of the wire transfer shall be delivered in accordance with procedures specified by the Office of Consumer Litigation, Civil Division, U.S. Department of Justice, Washington, D.C. 20530; and
2. Defendants shall provide counsel for the FTC with: (1) proof of such transfers, including the amounts paid by the purchaser for said 2009 Mercedes C300, (2) proof of the payment of any outstanding liens on the vehicle, and (3) proof of all payments by Defendants of any fees, commissions, closing costs, and any other charges or other payments.

27. Defendants relinquish all dominion, control, and title to the funds paid to the fullest extent permitted by law. Defendants shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise.

28. Defendants agree that the facts as alleged in the Complaint filed in this action shall be taken as true, without further proof, in any subsequent civil litigation filed by or on behalf of the Commission to enforce its rights to any payment or money judgment pursuant to this Order.

29. Defendants agree that the judgment represents a civil penalty owed to the United States Government, is not compensation for actual pecuniary loss, and, therefore, as to Individual Defendant, it is not subject to discharge under the Bankruptcy Code pursuant to 11 U.S.C. § 523(a)(7).

30. In accordance with 31 U.S.C. § 7701, Defendants are hereby required, unless they have already done so, to furnish to the Federal Trade Commission ("FTC" or "Commission") their taxpayer identifying numbers (social security number or employer identification number), which shall be used for purposes of collecting and reporting on any delinquent amount arising out of their relationship with the government.

31. In the event of default on the payment required to be made under this Paragraph, the entire unpaid civil penalty, together with interest computed under 28 U.S.C. § 1961 (accrued from the date of default until the date of payment) shall be immediately due and payable.

32. Defendants shall cooperate fully with Plaintiff and the Commission and their agents in all attempts to collect the amount due pursuant to this Paragraph if Defendants fail to pay fully the amount due at the time specified herein. In such an event, Defendants agree to

provide Plaintiff and the Commission with their federal and state tax returns for the preceding two (2) years, and to complete new standard-form financial disclosure forms fully and accurately within ten (10) business days of receiving a request from Plaintiff or the Commission to do so. Defendants further authorize Plaintiff and the Commission to verify all information provided on their financial disclosure forms with all appropriate third parties, including, but not limited to, financial institutions.

RIGHT TO REOPEN

33. IT IS FURTHER ORDERED that

- A. The Commission's agreement to this Order is expressly premised upon the truthfulness, accuracy, and completeness of the individual and business financial statements submitted to the Commission by the Defendants and signed and dated January 4, 2011 and the additional information submitted to the Commission and signed and dated on January 6, 2011. Defendants stipulate that all of the materials that Defendants submitted are truthful, accurate, and complete. These documents contain material information upon which the Commission relied in negotiating and agreeing to the terms of this Order.
- B. If, upon motion by the Commission, a Court determines that Defendants made a material misrepresentation or omitted material information concerning Defendants financial conditions, then the Court shall lift the suspension described in the section of this Order entitled "CIVIL

PENALTY” and reinstate the full civil penalty against Defendants and for Plaintiff in the amount of two hundred thousand dollars (\$200,000) less any amount already paid by or on behalf of Defendants to Plaintiff, provided, however, that in all other respects this Order shall remain in full force and effect unless otherwise ordered by the Court; and provided, further, that proceedings instituted under this provision would be in addition to, and not in lieu of, any other civil or criminal remedies as may be provided by law, including but not limited to contempt proceedings, or any other proceedings that the Commission may initiate to enforce this Order.

COMPLIANCE MONITORING

34. IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order:

- A. Within ten (10) days of receipt of written notice from a representative of the Commission, Defendants each shall submit additional written reports, which are true and accurate and sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and provide entry during normal business hours to any business location in each Defendants’ possession or direct or indirect control to inspect the business operation;**

- B. In addition, the Commission is authorized to use all other lawful means, including, but not limited to:
1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, 45 and 69;
 2. having its representatives pose as consumers and suppliers to Defendants, their employees, or any other entity managed or controlled in whole or in part by any Defendant, without the necessity of identification or prior notice; and
- C. Defendants shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

Provided however, that nothing in this Order shall limit the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49 and 57b-1, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

COMPLIANCE REPORTING

35. **IT IS FURTHER ORDERED** that, in order that compliance with the provisions of this Order be monitored:

A. For a period of five (5) years from the date of entry of this Order,

1. Individual Defendant shall notify the Commission of the following:

- a. Any changes in such Defendant's residence, mailing addresses, and telephone numbers, within ten (10) days of the date of such change;
- b. Any changes in such Defendant's employment status (including self-employment), and any change in his ownership of any business entity within ten (10) days of the date of such change. Such notice shall include the name and address of each business that such Defendant is affiliated with, employed by, creates or forms, or performs services for; a detailed description of the nature of the business; and a detailed description of such Defendant's duties and responsibilities in connection with the business or employment; and
- c. Any changes in such Defendant's name or use of any aliases or fictitious names within ten (10) days of such change;

2. Defendants shall notify the Commission of any changes in structure of any Corporate Defendant, or any business entity that any Defendant directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this Order, including, but not limited to: incorporation or other organization; a dissolution, assignment, sale, merger, or other action; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; or a change in the business name or address, at least thirty (30) days prior to such change, *provided that*, with respect to any such change in the business entity about which a Defendant learns less than thirty (30) days prior to the date such action is to take place, such Defendant shall notify the Commission as soon as it is practicable after obtaining such knowledge.
- B. One hundred eighty (180) days after the date of entry of this Order and annually thereafter for a period of five (5) years, Defendants each shall provide a written report to the FTC, which is true and accurate and sworn to under penalty of perjury, setting forth in detail the manner and form in which they have complied and are complying with this Order. This report shall include, but not be limited to:

1. **For Individual Defendant:**
 - a. **Such Defendant's then-current residence address, mailing addresses, and telephone numbers;**
 - b. **Such Defendant's then-current employment status (including self-employment), including the name, addresses, and telephone numbers of each business that such Defendant is affiliated with, employed by, or performs services for; a detailed description of the nature of the business; and a detailed description of such Defendant's duties and responsibilities in connection with the business or employment; and**
 - c. **Any other changes required to be reported under Subsection A of this Section.**
2. **For all Defendants:**
 - a. **A copy of each acknowledgment of receipt of this Order and the Compliance Guides entitled, *The Contact Lens Rule: A Guide for Prescribers and Sellers and Complying with the Contact Lens Rule* (collectively, the "Compliance Guides"), attached hereto as Attachments B and C, obtained pursuant to the Section titled "Distribution of this Order,"**

- b. Any other changes required to be reported under Subsection A of this Section;
- c. A statement describing in detail the process for obtaining copies of contact lens prescriptions for orders obtained through all sales channels, including, but not limited to, telephone sales and Internet sales;
- d. A statement describing the process for verifying contact lens prescriptions for orders obtained through all sales channels, including, but not limited to, telephone sales and Internet sales;
- e. A sample copy of each different type of communication used to request prescription information from consumers, including, but not limited to, any online form, email message, telephone script, web page, or screen;
- f. A sample copy of each different type of communication used to submit verification requests to prescribers, including, but not limited to, any fax form, email message, or telephone script;
- g. A statement describing Defendants' procedure for maintaining the records required by the Rule, including, but not limited to, contact lens prescriptions directly presented

to Defendants, prescription verification requests submitted to prescribers, and direct communications received from prescribers; and

- h. A list of persons or employees who are responsible for collecting and maintaining compliance-related information.
- C. Each Defendant shall notify the Commission of the filing of a bankruptcy petition by such Defendant within fifteen (15) days of filing.
- D. For the purposes of this Order, Defendants shall, unless otherwise directed by the Commission's authorized representatives, send by overnight courier (not the U.S. Postal Service) all reports and notifications to the Commission that are required by this Order to:

Associate Director for Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
RE: U.S. v. Jokeshop USA, LLC

Provided that, in lieu of overnight courier, Defendants may send such reports or notifications by first-class mail, but only if Defendants contemporaneously send an electronic version of such report or notification to the Commission at DEbrief@ftc.gov.

- E. For purposes of compliance reporting and monitoring required by this Order, the Commission is authorized to communicate directly with each Defendant.

RECORDKEEPING

36. **IT IS FURTHER ORDERED** that for a period of eight (8) years from the date of entry of this Order, Corporate Defendant and Individual Defendant, for any business entity for which they, individually or collectively, are the majority owner or directly or indirectly control, are hereby restrained and enjoined from failing to create and retain the following records:

- A. Accounting records that reflect the cost of goods or services sold, revenues generated, and the disbursement of such revenues;
- B. Personnel records accurately reflecting: the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;
- C. Customer files containing the names, addresses, phone numbers, dollar amounts paid, quantity of items or services purchased, and description of items or services purchased, to the extent such information is obtained in the ordinary course of business;
- D. Complaints and refund requests (whether received directly or indirectly, such as through a third party,) and any responses to those complaints or requests;
- E. Copies of all sales scripts, training materials, advertisements, or other marketing materials for contact lenses; and

- F. All records and documents necessary to demonstrate full compliance with each provision of this Order, including but not limited to, a sample copy of every different type of communication used to request prescription information from consumers or to submit verification requests to prescribers, copies of acknowledgments of receipt of this Order required by the Sections titled "Distribution of Order" and "Acknowledgment of Receipt of Order" and all reports submitted to the FTC pursuant to the Section titled "Compliance Reporting." Electronic copies shall include all text and graphic files, audio scripts, and other computer files used to present information to consumers and/or prescribers.

DISTRIBUTION OF ORDER

37. **IT IS FURTHER ORDERED** that, for a period of five (5) years from the date of entry of this Order, Defendants shall deliver copies of this Order as directed below:

- A. Corporate Defendant: Corporate Defendant shall deliver a copy of this Order and the Compliance Guides to (1) all of its principals, officers, directors, and managers; (2) all of its employees, agents, and representatives who engage in conduct related to the subject matter of this Order; and (3) any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Order upon such Defendant. For new personnel, delivery shall occur

prior to them assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting," delivery shall be at least ten (10) days prior to the change in structure.

- B. Individual Defendant as control person: For any business that an Individual Defendant controls, directly or indirectly, or in which such Defendant has a majority ownership interest, such Defendant shall deliver a copy of this Order and the Compliance Guides to (1) all principals, officers, directors, and managers of that business; (2) all employees, agents, and representatives of that business who engage in conduct related to the subject matter of this Order; and (3) any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting." For current personnel, delivery shall be within five (5) days of service of this Order upon such Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities. For any business entity resulting from any change in structure set forth in Subsection A.2 of the Section titled "Compliance Reporting," delivery shall be at least ten (10) days prior to the change in structure.
- C. Individual Defendant as employee or non-control person: For any business where Individual Defendant is not a controlling person of a business but

otherwise engages in conduct related to the subject matter of this Order, such Defendant shall deliver a copy of this Order and the Compliance Guides to all principals and managers of such business before engaging in such conduct.

- D. Defendants shall secure a signed and dated statement acknowledging receipt of this Order and the Compliance Guides, within thirty (30) days of delivery, from all persons receiving a copy of this Order and the Compliance Guides pursuant to this section, and shall maintain these statements in accordance with the Section of this Order entitled "Recordkeeping."

ACKNOWLEDGMENT OF RECEIPT OF ORDER BY DEFENDANTS

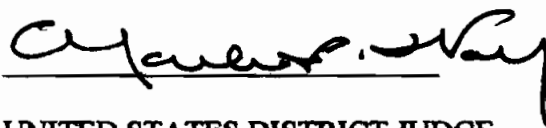
38. **IT IS FURTHER ORDERED** that each Defendant, within five (5) business days of receipt of this Order as entered by the Court, shall submit to the Commission a truthful, sworn statement acknowledging receipt of this Order.

RETENTION OF JURISDICTION

39. **IT IS FURTHER ORDERED** that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

JUDGMENT IS THEREFORE ENTERED pursuant to all the terms and conditions recited above.

Dated this 28th Day of November, 2011

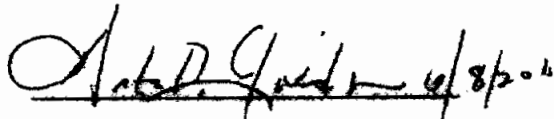
A handwritten signature in black ink, appearing to read "C. J. ...", is written over a horizontal line.

UNITED STATES DISTRICT JUDGE

FOR THE UNITED STATES OF AMERICA:

TONY WEST
Assistant Attorney General
Civil Division
U.S. DEPARTMENT OF JUSTICE

CARMEN M. ORTIZ
United States Attorney
District of Massachusetts




Anton Giedt 4/8/11

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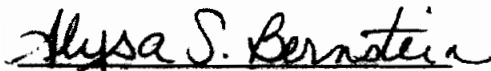
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FOR THE FEDERAL TRADE COMMISSION:



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(202) 325-3259 (facsimile)

FOR THE DEFENDANTS:



SCOTT SMILEDGE-FERRAGAMO,

also doing business as Vampfangs and Glowmark

Novelties, individually, and in his official

capacity as managing member of

JOKESHOP USA, LLC



Peter J. Lawton, Esq.

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Woburn, MA 01801

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(781) 933-2824 (facsimile)

ATTACHMENT A

315.7 Content of advertisements and other representations.

315.8 Prohibition of certain waivers.

315.9 Enforcement.

315.10 Severability.

315.11 Effect on state and local laws.

AUTHORITY: Pub. L. 106-184, secs. 1-12; 117 Stat. 2834 (15 U.S.C. 7801-7810).

SOURCE: 69 FR 49008, July 2, 2004, unless otherwise noted.

§ 315.1 Scope of regulations in this part.

This part, which shall be called the "Contact Lens Rule," implements the Fairness to Contact Lens Consumers Act, codified at 15 U.S.C. 7801-7810, which requires that rules be issued to address the release, verification, and sale of contact lens prescriptions. This part specifically governs contact lens prescriptions and related issues. Part 456 of Title 16 governs the availability of eyeglass prescriptions and related issues (the Ophthalmic Practice Rules (Eyeglass Rule)).

§ 315.2 Definitions.

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

Business hour means an hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. "Business hour" also may include, at the seller's option, a prescriber's regular business hours on Saturdays, provided that the seller has actual knowledge of these hours. "Business hour" shall be determined based on the time zone of the prescriber.

"Eight (8) business hours" shall be calculated from the time the prescriber receives the prescription verification information from the seller, and shall conclude when eight (8) business hours have elapsed. For verification requests received by a prescriber during non-business hours, the calculation of "eight (8) business hours" shall begin at 9 a.m. on the next weekday that is not a Federal holiday or, if applicable, on Saturday at the beginning of the prescriber's actual business hours.

Commission means the Federal Trade Commission.

Contact lens means any contact lens for which State or Federal law requires a prescription.

Contact lens fitting means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and each term may include:

(1) An examination to determine lens specifications;

(2) Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and

(3) Medically necessary follow-up examinations.

Contact lens prescription means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

(1) The name of the patient;

(2) The date of examination;

(3) The issue date and expiration date of prescription;

(4) The name, postal address, telephone number, and facsimile telephone number of prescriber;

(5) The power, material or manufacturer or both of the prescribed contact lens;

(6) The base curve or appropriate designation of the prescribed contact lens;

(7) The diameter, when appropriate, of the prescribed contact lens; and

(8) In the case of a private-label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.

Direct communication means completed communication by telephone, facsimile, or electronic mail.

Issue date means the date on which the patient receives a copy of the prescription at the completion of a contact lens fitting.

Ophthalmic goods are contact lenses, eyeglasses, or any component of eyeglasses.

Ophthalmic services are the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.

Prescriber means, with respect to contact lens prescriptions, an ophthalmol-

PART 315—CONTACT LENS RULE

Sec.

315.1 Scope of regulations in this part.

315.2 Definitions.

315.3 Availability of contact lens prescriptions to patients.

315.4 Limits on requiring immediate payment.

315.5 Prescriber verification.

315.6 Expiration of contact lens prescriptions.

ogist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration. "Other person," for purposes of this definition, includes a dispensing optician who is permitted under State law to issue prescriptions and who is authorized or permitted under State law to perform contact lens fitting services.

Private label contact lenses mean contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.

§15.3 Availability of contact lens prescriptions to patients.

(a) *In general.* When a prescriber completes a contact lens fitting, the prescriber:

(1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and

(2) Shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.

(b) *Limitations.* A prescriber may not:

(1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;

(2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or

(3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1) or (a)(2) of this section.

§15.4 Limits on requiring immediate payment.

A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.

§15.5 Prescriber verification.

(a) *Prescription requirement.* A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is:

(1) Presented to the seller by the patient or prescriber directly or by facsimile; or

(2) Verified by direct communication.

(b) *Information for verification.* When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information through direct communication:

(1) The patient's full name and address;

(2) The contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate;

(3) The quantity of lenses ordered;

(4) The date of patient request;

(5) The date and time of verification request;

(6) The name of a contact person at the seller's company, including facsimile and telephone numbers; and

(7) If the seller opts to include the prescriber's regular business hours on Saturdays as "business hours" for purposes of paragraph (c)(3) of this section, a clear statement of the prescriber's regular Saturday business hours.

(c) *Verification events.* A prescription is verified under paragraph (a)(2) of this section only if one of the following occurs:

(1) The prescriber confirms the prescription is accurate by direct communication with the seller;

(2) The prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; or

(3) The prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section. During these eight (8) business hours, the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request.

(d) *Invalid prescription.* If a prescriber informs a seller before the deadline under paragraph (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified under paragraph (c)(2) of this section.

(e) *No alteration of prescription.* A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, a seller may substitute for private label contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(f) *Recordkeeping requirement—verification requests.* A seller shall maintain a record of all direct communications referred to in paragraph (a) of this section. Such record shall consist of the following:

(1) For prescriptions presented to the seller: the prescription itself, or the facsimile version thereof (including an email containing a digital image of the prescription), that was presented to the seller by the patient or prescriber.

(2) For verification requests by the seller:

(i) If the communication occurs via facsimile or e-mail, a copy of the verification request, including the information provided to the prescriber pursuant to paragraph (b) of this section, and confirmation of the completed transmission thereof, including a record of the date and time the request was made;

(ii) If the communication occurs via telephone, a log;

(A) Describing the information provided pursuant to paragraph (b) of this section.

(B) Setting forth the date and time the request was made.

(C) Indicating how the call was completed, and

(D) Listing the names of the individuals who participated in the call.

(3) For communications from the prescriber, including prescription verifications:

(i) If the communication occurs via facsimile or e-mail, a copy of the communication and a record of the time and date it was received;

(ii) If the communication occurs via telephone, a log describing the information communicated, the date and time that the information was received, and the names of the individuals who participated in the call.

(4) The records required to be maintained under this section shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(g) *Recordkeeping requirement—Saturday business hours.* A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for verification specified in §315.5(c)(3) shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

§315.6 Expiration of contact lens prescriptions.

(a) *In general.* A contact lens prescription shall expire:

(1) On the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;

(2) Not less than one year after the issue date of the prescription if such State law specifies no date or specifies a date that is less than one year after the issue date of the prescription; or

(3) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

(b) *Special rules for prescriptions of less than one year.* (1) If a prescription expires in less than one year, the specific reasons for the medical judgment referred to in paragraph (a)(3) of this section shall be documented in the patient's medical record with sufficient detail to allow for review by a qualified professional in the field.

(2) The documentation described in the paragraph above shall be maintained for a period of not less than three years, and it must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(3) No prescriber shall include an expiration date on a prescription that is less than the period of time that he or she recommends for a reexamination of the patient that is medically necessary.

§315.7 Content of advertisements and other representations.

Any person who engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

§315.8 Prohibition of certain waivers.

A prescriber may not place on a prescription, or require the patient to sign, or deliver to the patient, a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.

§315.9 Enforcement.

Any violation of this Rule shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices,

and the Commission will enforce this Rule in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 et seq.

§315.10 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

§315.11 Effect on state and local laws.

(a) State and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are preempted.

(b) Any other State or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency.

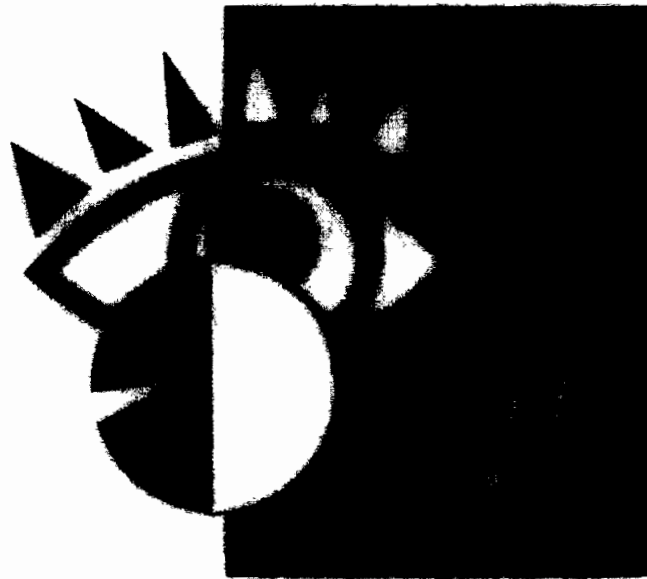
ATTACHMENT B

BUSINESS

Federal Trade Commission

www.ftc.gov

The Contact Lens Rule: A Guide for Prescribers and Sellers



The Fairness to Contact Lens Consumers Act increases consumers' ability to shop around when buying contact lenses. The Act gives consumers certain rights, imposes duties on contact lens prescribers and sellers, and requires the Federal Trade Commission (FTC) to develop and enforce implementing rules. The FTC issued the Contact Lens Rule in July 2004 to spell out the Act's requirements.

The Contact Lens Rule requires prescribers to give patients a copy of their contact lens prescriptions at the end of a contact lens fitting, even if the patient doesn't ask for it. A patient who wants to buy contact lenses from another seller then may give the prescription to that seller. If a consumer doesn't give his prescription to that seller, the seller must verify the prescription before selling the lenses.

The verification process works like this: the consumer provides prescription information to the seller, who then submits it to the prescriber in a verification request. The prescriber has eight-business-hours to respond. If the prescriber does not respond within the required time, the prescription is verified automatically, and the seller may provide contact lenses to the consumer.

FOR PRESCRIBERS

According to the Rule, “prescriber” refers to anyone permitted under state law to issue prescriptions for contact lenses — including ophthalmologists, optometrists, and licensed opticians who also are permitted under state law to fit contact lenses (sometimes called “dispensing opticians”).

Prescribers must:

- give a copy of the contact lens prescription to the patient at the end of the contact lens fitting — even if the patient doesn’t ask for it.
- provide or verify the contact lens prescription to anyone who is designated to act on behalf of the patient, including contact lens sellers.

In any response to a verification request, prescribers must correct any inaccuracy in the prescription, inform the seller if it’s expired and specify the reason if it’s invalid.

Prescribers cannot require patients to:

- buy contact lenses
- pay additional fees or
- sign a waiver or release in exchange for a copy of the contact lens prescription.

Prescribers may require a patient to pay for the eye exam, fitting and evaluation before giving the patient a copy of the contact lens prescription, but only if the prescriber also requires immediate payment from patients whose eye exams reveal no need for glasses, contact lenses,

or other corrective eye care products. Proof of valid insurance coverage counts as payment for purposes of this requirement.

Prescribers cannot disclaim liability or responsibility for the accuracy of an eye examination.

Prescription expiration

The Rule allows prescribers to set prescription expiration dates — one year or more from the date the prescription is issued to a patient. If applicable state law requires a specific expiration period that is longer than one year, however, the prescriber must follow that law.

A prescriber may set an expiration date of earlier than one year *only if* that date is based on the prescriber’s medical judgment about the patient’s eye health. In these cases, the prescriber must document the medical reason for the shorter expiration date with enough detail to allow for review by a qualified medical professional, and maintain the records for at least three years.

FOR SELLERS

Sellers may provide contact lenses only in accordance with a valid prescription that is directly presented to the seller or verified with the prescriber. That means sellers may provide contact lenses when the consumer presents his prescription in person, by fax, or by email if the prescription has been scanned and attached to the email. The consumer also can authorize the seller to verify his prescription via “direct communication” with the prescriber. (See next page, “What is direct communication?”.)

Verification

When verifying a contact lens prescription, sellers must provide the following information to the prescriber using direct communication:

- patient’s full name and address
- contact lens power, manufacturer, base curve

or appropriate designation, and diameter when appropriate

- quantity of lenses ordered
- date of patient order
- date and time of verification request
- a contact person for the seller, including name, fax and phone numbers and
- a clear statement of the prescriber's regular Saturday business hours if the seller is counting those hours as "business hours" under the Rule.

Under the Rule, a prescription is verified if the prescriber:

- confirms its accuracy to the seller via direct communication
- informs the seller that the prescription is inaccurate and provides accurate information to the seller via direct communication or
- fails to communicate with the seller within "eight-business-hours" of receiving a complete verification request. During the "eight-business-hour" period, the seller must give the prescriber a reasonable opportunity to get in touch with the seller about the verification request.

Record-keeping

Sellers must maintain prescriptions presented to them, prescription verification requests, and prescriber responses to the verification requests. The Rule also requires sellers who count a prescriber's Saturday business hours to maintain a record of what those hours are and how the seller learned of them. Sellers must maintain these records for at least three years.

The Fine Print

What practices are not allowed?

Sellers must not:

- fill a contact lens prescription unless the seller has either received a copy of the prescription or verified the prescription as required by the Rule
- fill a contact lens prescription if the prescriber tells them by direct communication within "eight-business-hours" after receiving

the complete verification request that the prescription is inaccurate, expired, or otherwise invalid

- alter contact lens prescriptions. If the prescription specifies private label contact lenses, however, sellers may substitute "identical" contact lenses made by the same manufacturer and sold under a different name
- represent that consumers can get contact lenses without a prescription.

What's a business hour?

Prescriptions are verified automatically if the prescriber doesn't respond to the seller's verification request within "eight-business-hours." A business hour is defined as one hour between 9 a.m. and 5 p.m., Monday through Friday, excluding federal holidays, in the prescriber's time zone. If a seller determines that a particular prescriber has regular Saturday business hours, the seller also may count those Saturday hours as business hours under the Rule.

How is the "eight-business-hour" verification period calculated?

When calculating "eight-business-hours," begin the verification period the first business hour after the prescriber receives a complete verification request and end it eight-business-hours later. For example, if the prescriber receives a request at 10 a.m. Monday, the prescriber must respond by 10 a.m. Tuesday. If there's no response, the seller can provide the contact lenses at 10:01 a.m. Tuesday. If the verification request is received at 10 p.m. Monday, the response would be due by 5 p.m. Tuesday. If there's no response, the seller can provide the lenses at 5:01 p.m. Tuesday.

What is direct communication?

"Direct communication" is a completed communication by telephone, facsimile or electronic mail.

Direct communication by telephone requires reaching and speaking to the intended

recipient, or leaving a voice message on the telephone answering machine of the intended recipient.

Direct communication by facsimile or electronic mail requires that the intended recipient actually receive the facsimile or electronic mail message.

For more details about compliance, see "Q&A: The Contact Lens Rule and the Eyeglass Rule" at www.ftc.gov.

The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop and avoid them. To file a complaint or get free information on consumer issues, visit www.ftc.gov or call toll-free, 1-877-FTC-HELP (1-877-382-4357);

TTY: 1-866-653-4261. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

Your Opportunity to Comment

The National Small Business Ombudsman and 10 Regional Fairness Boards collect comments from small businesses about federal compliance and enforcement activities. Each year, the Ombudsman evaluates the conduct of these activities and rates each agency's responsiveness to small businesses. Small businesses can comment to the Ombudsman without fear of reprisal. To comment, call toll-free 1-888-REGFAIR (1-888-734-3247) or go to www.sba.gov/ombudsman.

Federal Trade Commission

www.ftc.gov

Federal Trade Commission
Bureau of Consumer Protection
Office of Consumer and Business Education

October 2004

ATTACHMENT C

BUSINESS

Federal Trade Commission

For Your Convenience




Complying with the Contact Lens Rule

INTRODUCTION

The Federal Trade Commission enforces both the Contact Lens Rule and the Eyeglass Rule. These Rules require that eye care providers give their customers copies of their prescriptions: Contact lens prescriptions must be given to the customers once the lens fitting is complete; eyeglass prescriptions must be given to customers at the end of the eye exam. Here are questions and answers to help eye care providers comply with the Contact Lens Rule.

1. Who — and What — the Rule Covers

- **I'm an optician. Am I considered a "prescriber" under the Contact Lens Rule?**
Under the Contact Lens Rule, opticians are prescribers if state law permits them to fit contact lenses and to issue prescriptions. Sometimes opticians are called "dispensing opticians."
- **I'm a prescriber. What if I verify a prescription and then something is wrong with the contact lenses the consumer bought from another seller? Am I liable?**
The Fairness to Contact Lens Consumers Act and the Contact Lens Rule don't impose liability on a prescriber for problems with contact lenses sold by someone else. Traditionally, state law determines the liability.
- **I'm a prescriber. If I don't act on a verification request, the prescription is verified passively. The consumer gets the contacts from another seller. Am I liable if something is wrong with the contact lenses?**
Neither the Act nor the Rule imposes liability on a prescriber for problems with contact lenses. State law determines who would be liable if problems arise.
- **I'm a prescriber. What if I'm unable to verify my patient's prescription during the "eight business hours" period, and later learn that the prescription was inaccurate, expired, or invalid? Am I required to contact the seller?**
Neither the Act nor the Rule addresses this situation. However, it would be in your patient's best interest to contact the seller and the patient to alert them to a possible error in the prescription.
- **Does the Contact Lens Rule apply to contact lens sellers located beyond U.S. borders?**
The Contact Lens Rule applies to all sellers who provide contact lenses to consumers who live in the U.S.

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- **Does the Contact Lens Rule apply to non-corrective “cosmetic” or “decorative” contact lenses?**
Both contact lenses that correct users’ vision and decorative, cosmetic, or plano lenses require a valid contact lens prescription.

2. The Prescription

- **When am I required to give my patients their contact lens prescriptions?**
You must give your patients a copy of their contact lens prescription when the lens fitting is complete. Some patients may require follow-up visits after the initial exam before their contact lens fitting is complete. All follow-up exams must be medically necessary, and eye care providers should use sound professional judgment — based on appropriate and objective standards of care — to make that call.
- **What if my patient asks for a copy of the contact lens prescription before the lens fitting is complete?**
The Act and the Rule do not require that you provide the contact lens prescription to the patient before the fitting is complete. If you are prepared to sell your patients contact lenses, however, you cannot refuse to give them a copy of their prescription on the grounds that their fitting isn’t complete. If you’re willing to sell them the lenses, that means their fitting is complete, and you must give them a copy of the prescription.
- **In my state, a contact lens prescription expires two years after it’s written. Does the Contact Lens Rule change that?**
No. If state law specifies an expiration date of one year or more from the prescription’s issue date, the prescription expires on that date. But if state law specifies an expiration date of less than one year from the prescription’s issue date, the expiration date is determined by the Rule. Under the Rule, a prescription expires one year from its issue date, unless there’s a legitimate medical reason for setting a shorter expiration date.
- **In my state, the law says I have to provide contact lens prescriptions to patients only if they ask for them. But the Contact Lens Rule says I have to provide the prescriptions regardless. Which law applies?**
The Contact Lens Rule applies. You must give your patients their contact lens prescription at the completion of the contact lens fitting, whether the patient asks for it or not.
- **As an eye care provider, can I charge a patient for trial lenses or require a patient to buy them?**
You may, but only if the trial lenses are necessary to complete the fitting process. This is sometimes the case with some “specialty” or custom-made lenses. You may not require a patient to buy contact lenses — such as a six-month supply of disposable lenses — as a condition of giving them a copy of their prescription.
- **I’m a contact lens seller. Can I substitute one brand of contact lenses for another brand under the Rule?**
You can substitute one brand of contact lenses for another if:
 - the prescription specifies private label lenses, and
 - the substitute lenses are identical to the prescribed lenses.

Example: TekViz, Inc. manufactures and sells contact lenses under both the “TekViz” brand and the “Dr.

Jones" brand. If the prescription specifies "Dr. Jones" brand lenses, the seller may substitute "TekViz" brand lenses. The seller may not substitute non-identical lenses manufactured by TekViz, Inc., or lenses manufactured by another company.

- **The Contact Lens Rule says prescribers must provide or verify contact lens prescription information "as directed" by a third party designated by a patient. But according to HIPAA (Health Insurance Portability and Accountability Act of 1996), don't I have to get written authorization from a patient before providing or verifying his contact lens prescription to a seller?**

No. HIPAA permits covered entities to use or disclose protected health information without patient authorization if the use or disclosure is for "treatment" or "required by law." Providing, confirming, correcting, or verifying a contact lens prescription to a seller designated by the patient constitutes treatment or is required by the Act and the Rule.

- **As the eye care provider, may I include a specific number of refills on a contact lens prescription?**

The Contact Lens Rule doesn't require or prohibit you from including refill quantities on contact lens prescriptions. Follow your state law if it requires — or prohibits — such information. Note that the Rule does not allow you to use refill quantities to shorten a prescription expiration period to less than a year, unless there are legitimate medical reasons.

3. Record-keeping Requirements for Sellers

- **As a contact lens seller, I've called a lot of eye care providers to find out whether they have Saturday business hours. What records do I keep to show I have "actual knowledge" of their Saturday business hours?**

As a seller, you must keep a record of the eye care provider's regular Saturday hours and how you know those are the hours. If you call eye care providers to learn their actual business hours, keep your notes from those calls for record-keeping purposes. You must include Saturday business hours on a verification request if you want to include those hours in the "eight business hour" verification period.

- **Can my verification request form state that I assume that all prescribers' offices have Saturday business hours unless the prescriber's office tells me otherwise?**

No. A seller may count a prescriber's Saturday business hours as part of the "eight business hour" verification period only if the seller knows that the prescriber has Saturday business hours. Assuming that a prescriber has Saturday business hours unless the prescriber tells you otherwise does not constitute actual knowledge for purposes of the Rule.

- **As a seller, can I depend on information a customer gives me about an eye care provider's Saturday business hours?**

Depending on the circumstances, information you get from a customer may be acceptable under the Rule. For example, if a customer gives you the prescriber's business card, which states that the office is open from 9 a.m. to 3 p.m. on Saturdays, you may rely on it. Remember to document that this information is the basis for your determination.

- **What if the customer tells me, "I think my eye doctor's office is open from 9 a.m. to 5 p.m. on Saturdays"?**

Don't rely on a customer's statement alone as a basis for your actual knowledge of a prescriber's regular Saturday hours. Verify an eye care provider's Saturday hours some other way.

4. **“Eight business hours” for Verification**

- **I’m a prescriber. How much time do I have to verify a prescription?**

The Act and the Rule give prescribers “eight business hours” to verify a prescription regardless of when the prescriber receives a properly completed verification request. “Eight business hours” is not the same as “eight hours.”

A “business hour” is an hour during the period from 9 a.m. to 5 p.m., Monday through Friday (excluding federal holidays), plus hours on Saturday that the seller actually knows the prescriber is regularly open for business. Business hours are calculated based on the prescriber’s time zone.

- **How is the “eight business hour” period calculated if the seller’s verification request is received during business hours?**

If you receive the verification request during business hours, the “eight business hour” period starts when the prescriber receives the request from the seller and ends when “eight business hours” have elapsed.

For example, say the verification request is received at 4 p.m. on Monday. The “eight business hour” period begins at 4 p.m. on Monday and ends at 4 p.m. on Tuesday. If the eye care provider doesn’t respond, the seller can ship at 4:01 p.m. on Tuesday.

But say the verification request is received at 11 a.m. on Friday. The seller has documented actual knowledge that the eye care provider’s office is regularly open from 10 a.m. to 4 p.m. on Saturday. In this case, the “eight business hour” period would begin at 11 a.m. on Friday and end at noon on Saturday. If the eye care provider doesn’t respond, the seller can ship at 12:01 p.m. on Saturday.

What if you get a verification request at 11 a.m. on Friday, but the eye care provider’s office isn’t regularly open Saturdays? The “eight business hour” period begins at 11 a.m. on Friday and ends at 11 a.m. on Monday. If the eye care provider doesn’t respond, the seller can ship at 11:01 a.m. on Monday.

Or suppose you get a verification request at 2 p.m. on Monday, July 3. The “eight business hour” period begins at 2 p.m. on Monday and ends at 2 p.m. on Wednesday, because Tuesday is July 4, a federal holiday. If the eye care provider doesn’t respond, the seller can ship at 2:01 p.m. on Wednesday.

- **How is the “eight business hour” period calculated if the seller’s verification request is received outside business hours?**

If the verification request is received outside of business hours, the “eight business hour” period starts at 9 a.m. the next weekday that isn’t a federal holiday (or on Saturday, if appropriate). It ends “eight business hours” later.

For example, say the verification request is received at 7 p.m. on Tuesday. The “eight business hour” period begins at 9 a.m. on Wednesday and ends at 5 p.m. the same day. If the eye care provider doesn’t respond, the seller can ship at 5:01 p.m. on Wednesday.

Or, the verification request is received at 2 p.m. on Saturday. The eye care provider’s office isn’t open Saturdays, and Monday is July 4. In this case, the “eight business hour” period begins at 9 a.m. on Tuesday and ends at 5 p.m. on Tuesday. If the eye care provider doesn’t respond, the seller can ship at 5:01 p.m. on Tuesday.

5. Direct Communication

- **When is a direct communication “completed” under the Contact Lens Rule?**

A direct communication is completed when the recipient gets all the required information. For example, direct communication by telephone requires reaching and speaking with the intended recipient, or leaving a clear voice message, including all the required information, on the recipient’s telephone answering machine. Similarly, a direct communication by fax or email is completed when the intended recipient receives the fax or email message.

- **How do I know that a direct communication by fax or email has been completed?**

A fax confirmation sheet showing that a fax was transmitted is sufficient to conclude that the communication is completed.

Confirmation that an email was sent generally is sufficient to conclude that it was received. Of course, if the sender has reason to believe that an email message was not transmitted instantly (such as an electronic notice stating that the email could not be sent), the communication is not considered completed until it is successfully transmitted to the recipient’s account.

- **I’m a seller who uses the telephone for direct communication with eye care providers. Do I have to keep a written log of all communications, or can I store this information electronically?**

The Rule allows you to store the required information electronically, and the information can be made available for review by the Commission, if necessary.

6. Automated Telephone Systems

- **My company sells contact lenses to consumers. Can I use an automated telephone system to send a verification request to an eye care provider?**

The Act expressly authorizes sellers to send verification requests by telephone, including automated telephone systems, as long as the requests comply with the Rule. That is, the verification request must provide all the information required, and sellers must wait “eight business hours” before selling contact lenses to the consumer.

A request delivered by an automated telephone system doesn’t comply with the Rule if: it isn’t delivered in a volume and cadence that a reasonable person can understand; it contains incomplete verification information; or it requires the prescriber’s office to provide an immediate response.

- **When I respond to a verification request, I’d like to get some confirmation — a call, email or fax — indicating that the seller received my response. Does the Rule require that?**

Neither the Act nor the Rule requires sellers to provide confirmation to prescribers, although they may choose to do so.

- **My calls to the seller are answered by an automated response system or by their contact person’s voicemail. Does the Rule require sellers to have a person available to respond to my calls?**

The Rule requires sellers to provide “a reasonable opportunity” for prescribers to communicate with them, but it doesn’t require them to have a person available to respond to calls. Nevertheless, sellers may choose to have someone available. If you have left a response on a seller’s verification response line indicating that the prescription has expired or is otherwise invalid, the seller is not permitted to ship the lenses.

- I've received a seller's verification request via an automated telephone message but I can't understand it. What can I do?

Automated telephone verification messages must be delivered in a volume and cadence that a reasonable person can understand. If you are unable to hear or understand an automated verification request, FTC staff attorneys encourage you to contact the seller directly. If you cannot contact the seller, file a complaint with the FTC at ftc.gov.

- Sometimes I can't get my calls or faxes through to the sellers. What can I do?

If some attempts to contact the seller are unsuccessful, try other methods of communication. For example, if your fax transmission fails, try contacting the seller via telephone or email. If you cannot contact the seller, file a complaint with the FTC at ftc.gov. Document your attempts; details make complaints more helpful.

7. Filing a Complaint with the FTC

You can file a complaint with the FTC online or by phone. To file a complaint online, visit ftc.gov, click "File a Complaint," and enter your information into the form. At the section entitled, "Subject of Your Complaint," click on "Health." In the final section, "Explain Your Problem," include as many details as possible. Click "Submit Complaint" to complete the process.

To file a complaint by phone, call 1-877-FTC-HELP (1-877-382-4357); TTY: 1-866-653-4261. A counselor will record your information and enter it directly into the agency's complaint database.

The complaint should include specific details, for example, the date and time your call was made or the reason the call you received wasn't understandable. Prescribers with evidence, such as an audiotape of a call or the recording left on an answering machine, should keep the evidence because it may be very helpful.

While the FTC doesn't resolve individual complaints, your complaints help the agency investigate Rule violations and may lead to enforcement action.

The FTC works for the consumer to prevent fraudulent, deceptive and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint or to get free information on consumer issues, visit ftc.gov or call toll-free, 1-877-FTC-HELP (1-877-382-4357); TTY: 1-866-653-4261. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

YOUR OPPORTUNITY TO COMMENT

The National Small Business Ombudsman and 10 Regional Fairness Boards collect comments from small businesses about federal compliance and enforcement activities. Each year, the Ombudsman evaluates the conduct of these activities and rates each agency's responsiveness to small businesses. Small businesses can comment to the Ombudsman without fear of reprisal. To comment, call toll-free 1-888-REGFAIR (1-888-734-3247) or go to www.sba.gov/ombudsman.

