# Risks Associated with Buying Contact Lenses from Low-Cost Internet Sites

Johnson & Johnson Vision Care, Inc. (JJVCI) receives many emails and calls about contact lens websites selling ACUVUE® products at extremely discounted prices. While JJVCI spends a significant amount of time and effort investigating these reports, this process is complicated by the fact that these sites are generally not US-based, and they purchase our products indirectly from non-authorized distributors, or "black market" suppliers, often under a different corporate name than the website.

This makes it difficult to find these unauthorized resellers and stop product distribution. These sites do not meet our supply chain standards, and our concerns about products sold through these channels include a lack of quality assurance and product expiration.

We are working to resolve this issue through activities such as the following:

- Cutting off their supply
- Removing their advertising of ACUVUE® Brand Contact Lens products on US Internet search engines
- Working with our Trademark Law and Brand Protection Teams
- Working with our international supply chain and affiliates

Although we cannot discuss details about our investigations of specific customers or unauthorized online resellers, we encourage you to contact us at <u>AcuvuePricePolicy@its.ini.com</u> with any concerns.

We also encourage you to explain to your patients the risks associated with purchasing contact lenses from a low-cost, unauthorized, online reseller.

### **Talking Points for Patients**

## 1. Why is it important to buy contacts from a site that requires prescription verification?

#### **Contact Lenses are Medical Devices and Require Prescriptions**

Contact lenses are classified by the FDA as Class II (daily wear) and Class III (extended wear) medical devices. Contacts undergo a review process to provide a reasonable assurance of safety and effectiveness to patients. Contacts require a valid prescription provided by a licensed eye doctor who conducts an eye exam to ensure the specific contact lens product fits appropriately on the eye. Each contact lens product has unique materials that are made for specific vision correction and eye health needs.

#### Contact Lens Sellers are Required by Law to Verify a Patient's Prescription at Time of Purchase

Contact lens sellers are required to follow a specific process for verifying a prescription provided by an eye care professional before selling contact lenses to customers, and may not represent by advertisement or sales presentation that contact lenses may be obtained without a prescription. This is a mandate of the Fairness to Contact Lens Consumers Act (FCLCA) passed by Congress in 2003, and this legislation authorized the FTC to develop and enforce the FCLCA legislative requirements, which resulted in the FTC's July 2004 Contact Lens Rule.

## 2. What are the eye health and safety risks associated with buying contact lenses from unauthorized, low-cost online resellers?

### Improper storage and handling may alter the performance of contact lenses, which, in turn, may create a health risk to patients.

Contact lenses purchased from unauthorized resellers have left the normal manufacturer supply chain, and may not be stored in conditions that meet our specifications. Additionally, the product packaging could be tampered with, such as opened boxes or contact lenses shipped outside of their boxes in loose bags. (See examples below)

**Example 1:** An online reseller sold contact lenses without asking for a copy of Rx or doctor's info for Rx verification. The contact lenses arrived outside of the manufacturer's box in a plastic bag.



**Example 2:** An online reseller sold contact lenses without asking for a copy of Rx or doctor's info for Rx verification. The lot number was destroyed on product packaging and covered by counterfeit label.



Original lot number destroyed and covered by a counterfeit label to hide identity of where product shipped.

#### Product authenticity and expiration cannot be controlled and may create a health risk to patients.

Contact lenses purchased from unauthorized resellers could be counterfeit or adulterated. Product not procured directly from the manufacturer or authorized distributors may come from many sources (e.g., major on-line auction sites, merchandise potentially stolen from facilities, or distressed merchandise) and the authenticity of the product may not be verified. Additionally, the manufacturer cannot ensure that contact lenses sold by unauthorized resellers are within their product expiration timeframe.

#### **Recall Limitations**

In the event of a product recall, Johnson & Johnson Vision Care, Inc. may not be able to effectively recall products purchased from unauthorized distributors. Patients may not be able to identify recalled products if the codes on product packaging have been tampered with or covered.