

**TITLE 22**                    **EXAMINING BOARDS**  
**PART 15**                    **TEXAS STATE BOARD OF PHARMACY**  
**CHAPTER 291**            **PHARMACIES**  
**SUBCHAPTER B**        **COMMUNITY PHARMACY (CLASS A)**

**§291.33**            **Operational Standards**

XXX

(c) Prescription dispensing and delivery.

XXX

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

XXX



September 5, 2014

This is in response to your request about certain performance characteristics of the Centor product line.

Products listed below comply with the Pharmacopeia requirements for "tight container" and "light resistant" containers. Specification for water vapor permeation and light transmission are established in the United States Pharmacopeia USP and the National Formulary NF. Legal recognition of the United States Pharmacopeia and the National Formulary is given at Section 201 of the Federal Food, Drug, and Cosmetic Act.

- L vial series - All sizes Screw-Loc Clear Vu® vials and closures, both CRC and NCRC
- 1-Clic series – All sizes 1-Clic Clear Vu® vials and closures, both CRC and NCRC
- RX Oval – All sizes RX Ovals and closures, both CRC and NCRC
- Ointment Jars – All sizes Ointment Jars and closures
- Repack Bottles – 75cc, 120cc, 200cc

All sizes of Screw-Loc®, 1-Clic® vials and RX Ovals when fitted with child resistant closures, comply with the "child resistant" and "adult use" effectiveness requirements of 16 CFR Part 1700.20 under The Poison Prevention Act of 1970 as amended July 21, 1995 (Federal Register Vol. 60 No. 140).

Resins used to manufacture all sizes of Centor products are free of any rubber products and are latex free.

Regulatory requirements for the resin used in the manufacture of these products and legal basis for their use in food applications are established in FDA regulation 21 CFR 177.1520. The resin used complies with all specifications and requirements stipulated in the applicable sections of this regulation.

Please note, Centor Inc. reserves the right to use interchangeable resins or equivalent that complies with the requirements in 21 CFR 177.1520.

Should you need further assistance, please call me at (330)893-2451, extension 215.

Sincerely,

David Borter  
Quality Assurance Manager  
Centor Inc.

This facility is ISO 9001:2008 certified and we follow current Good Manufacturing Practices.

**Centor Inc.**  
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**RULE ADOPTIONS**

**LAW AND PUBLIC SAFETY  
DIVISION OF CONSUMER AFFAIRS  
BOARD OF PHARMACY**

47 N.J.R. 120(a)

**Adopted Amendment: N.J.A.C. 13:39-5.8**

**Minimum Standards for Container Integrity**

Proposed: June 16, 2014, at 46 N.J.R. 1413(a).

Adopted: September 24, 2014, by the State Board of Pharmacy, Thomas F.X. Bender, President.

Filed: November 21, 2014, as R.2015 d.001, **without change**.

Authority: N.J.S.A. 45:14-47 and 48.

Effective Date: January 5, 2015.

Expiration Date: May 17, 2017.

**Summary of Public Comment and Agency Response:**

The official comment period ended on August 15, 2014. **The Board of Pharmacy (Board) received no comments on the notice of proposal.**

**Federal Standards Statement**

A Federal standards analysis is not required because the adopted amendment does not exceed, but rather references the standard and requirements set forth in the United States Pharmacopoeia/National Formulary (USP), which may be viewed as establishing and setting forth Federally enforceable standards and requirements for container integrity.

Full text of the adoption follows:

**SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS**

13:39-5.8 Minimum equipment and supplies; cleanliness

(a) All prescription areas shall contain the following minimum equipment and supplies, which shall be stored, so as to be readily accessible:

1.-10. (No change.)

11. Two Drug Utilization Review Council Placards and the 29th edition of the list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," incorporated herein by reference, as amended and supplemented. The Orange Book can be obtained by contacting the Superintendent of Documents, Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954, (202) 512-1800 or toll free (866) 512-1800, and is available on-line at <http://www.fda.gov/cder/orange/default.htm> and at <http://www.fda.gov/cder/ob/default.htm>;

12. Assorted stock of prescription containers and child safety closures or caps that meet the standards on light resistance, tightness, and water vapor permeation of Chapter 661 and moisture permeability of Chapter 671 of the United States Pharmacopoeia/National Formulary, 2014 edition, which are both incorporated herein by reference, as amended and supplemented, and are available for purchase at the United States Pharmacopoeia/National Formulary website at [www.usp.org](http://www.usp.org); and

13. (No change.)

(b)-(c) (No change.)