



Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

[CPSC Docket No. CPSC-2012-0005]

Requirements for Child-Resistant Packaging: Products Containing Specified Imidazolines Equivalent to 0.08 Milligrams or More; Extension of Stay of Enforcement

AGENCY: Consumer Product Safety Commission.

ACTION: Extension of stay of enforcement.

SUMMARY: This document announces the Commission's decision to extend the conditional stay of enforcement of special packaging requirements for over-the-counter and prescription products containing the equivalent of 0.08 milligrams or more of a specified imidazoline (tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline) in a single package. Firms that meet the conditions of the stay have until June 10, 2015 to comply with the special packaging requirements.

DATES: The stay of enforcement of special packaging requirements for specified imidazoline products expires on June 10, 2015.

FOR FURTHER INFORMATION CONTACT: Carol Afflerbach, Senior Compliance Officer, Division of Regulatory Enforcement, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7529; e-mail: cafflerbach@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 10, 2012 (77 FR 73294), the Commission issued a rule requiring special packaging (also called child-resistant or CR packaging) for any over-the-counter or prescription products containing the equivalent of 0.08 milligrams or more of a specified imidazoline (tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline) in a single package. 16 CFR 1700.14(a)(3). The rule included an effective date of 1 year after publication of the rule in the *Federal Register* (making the effective date December 10, 2013); however, in consideration of concerns raised in comments on the proposed rule, the Commission allowed manufacturers of imidazoline products subject to the rule to avail themselves of a 1-year conditional stay of enforcement (77 FR 73300). Firms meeting the conditions for the stay of enforcement would have until December 10, 2014 to comply with the rule. The final rule preamble set forth the conditions that a firm would need to satisfy to obtain the 1-year conditional stay of enforcement:

- Provide notice to the Commission of intent to receive the benefit of the conditional stay of enforcement, which includes a detailed timeline setting forth the steps necessary for the firm to produce CR packaging for its products and a range of time anticipated for completion of each step; and
- Submit quarterly status reports during the 1-year stay of enforcement for each affected product, providing the following information:
 - proposed packaging specifications;
 - estimated initial production date;

- progress made and/or steps completed during the quarterly reporting period; and
- reports of any incidents or exposures involving the firm's imidazoline-containing products subject to the rule.

Id.

Eleven manufacturers of imidazoline products covered by the rule and one contract packager timely notified the Commission of their intent to avail themselves of the 1-year conditional stay of enforcement; to date, these manufacturers and the packager have met the reporting requirements of the conditional stay. The 1-year conditional stay is due to expire on December 10, 2014.

II. Requests for Extension of the Conditional Stay of Enforcement

Twelve companies provided timely notice and met the conditions for the 1-year conditional stay of enforcement. Eight of these 12 firms have notified the Commission that they likely will not be able to comply with the requirements of the rule by December 10, 2014 for certain of their imidazoline products; for that reason these firms are seeking an extension of the conditional stay. Four of the 12 firms expect to have their products in compliant packaging before the expiration of the conditional stay.

Five additional manufacturers of imidazoline products covered by the rule that did not provide timely notice of their intent to avail themselves of the conditional stay have contacted the Commission regarding the stay of enforcement. These firms are not covered by the 1-year conditional stay of enforcement, and therefore not eligible for the 6-month extension of the conditional stay.

The 17 firms that have contacted the Commission regarding the conditional stay of enforcement account for a substantial share of the imidazoline products on the market subject to the rule.

A. Manufacturers of Ophthalmic-Use Products Covered by the Stay of Enforcement

Five firms that manufacture imidazoline-containing products intended for ophthalmic use timely notified the Office of Compliance and Field Operations (Compliance) of their intent to avail themselves of the 1-year conditional stay of enforcement. These five firms produce 35 different eye drop products. One of these firms expects to meet the CR packaging requirements for its products before the expiration of the 1-year conditional stay. The other four firms have notified the Commission that they require additional time to meet the CR packaging requirements for their products.

The four firms that manufacture imidazoline products for ophthalmic use have provided detailed explanations of the difficulties encountered in developing or obtaining CR packaging for their products, such as:

- multiple prototype packages failing the child-resistant and senior-friendly test requirements when produced for testing purposes;
- prototype packages passing the child-resistant and senior-friendly test requirements, but then failing the test requirements when mass-produced;
- mass production problems encountered by a third party contract packager;
- inability to obtain sufficient quantities of special packaging to permit timely mass production of imidazoline products in CR packaging; and
- intent to conduct final protocol testing of packaging supplied by third party

package suppliers before beginning distribution of ophthalmic imidazoline products.

B. Manufacturers of Nasal Products Covered by the Stay of Enforcement

Imidazoline-containing products that are intended to relieve nasal congestion use either a squeeze-to-spray or metered-pump-to spray delivery system. Seven manufacturers of nasal products provided timely notice to the Commission of their intent to avail themselves of the conditional stay of enforcement and have satisfied the other conditions of the stay. These seven firms include one contract packager that supplies products for 28 different distributors/private labelers, who, in turn, supply products to retailers who sell store brand nasal products. These seven firms manufacture 156 different nasal decongestant products—118 products are packaged in a squeeze-spray bottle, and 38 are packaged in pump-spray bottles. Four of these seven firms do not expect to be able to produce compliant products by December 10, 2014.

The firms that manufacture imidazoline products for nasal use have provided detailed explanations of the difficulties encountered in developing or obtaining CR packaging for their products, such as:

- mass production problems encountered by a third party contract packager;
- possible incompatibility of manufacturing lines with the mass production of new package designs;
- intent to conduct final protocol testing of packaging supplied by third party package suppliers before beginning distribution of nasal imidazoline products;
- inability to obtain sufficient quantities of special packaging to permit

timely mass production of imidazoline products in CR packaging.

III. Incident and Injury Data

As discussed more extensively in the *Federal Register* notice for the final rule, CPSC staff reviewed several sources for information on adverse health effects from ingestion of imidazolines. One source reviewed by CPSC staff is the National Electronic Injury Surveillance System (NEISS).¹ Another incident data source reviewed in connection with the final rule is the Children and Poisoning (CAP) system maintained by the CPSC's Directorate for Health Sciences. The CAP is a subset of NEISS records containing additional information obtained through NEISS involving children under 5 years old.²

The final rule noted that an analysis of the CAP database revealed a total of 198 emergency-room treated injuries associated with household products containing imidazolines involving children under 5 years old from January 1, 1997 to December 31, 2011—an average of 13 cases per year.

CPSC staff searched the CAP database for incidents involving household products that typically contain imidazolines and children under 5 years old for the period from December 2012 (when the final rule for imidazolines was published) through September 8, 2014, to update the injury and incident data discussed in the final rule. This search revealed 79 cases involving decongestants/nose drops, nose sprays, nose drops, and naphazoline eye drops. These cases were reviewed for incidents involving imidazolines

¹ NEISS is a statistically valid injury surveillance and follow-back database that the Commission maintains of consumer product-related injuries occurring in the United States. Injury data are gathered from the emergency departments (ED) of 96 hospitals selected as a probability sample of all 5,000+ U.S. hospitals with emergency departments.

² CAP includes data on each pediatric poisoning, chemical burn, or ingestion case reported from a NEISS hospital, as well as data on some ingestions that could lead to poisoning.

used in nose drops, nose sprays and eye drops, and 17 cases were identified—13 involving eye drops, and four involving nasal drops or spray. One of these cases involved a 3-year old female who ingested eye drops and was hospitalized. The remaining patients were treated and released, except for one child who left the emergency room without being seen by medical personnel. Fifteen of the 17 cases occurred during the 12-month period from December 2012 to December 2013, the one year period prior to the effective date of the rule. Two cases occurred during the most recent 9-month period during which the stay of enforcement was in effect. Neither of the two most recent cases resulted in the hospitalization of the child. Moreover, the narratives describing these two cases did not provide sufficient information to determine whether the incident products were in CR packaging, or whether the circumstances of the incident suggest that CR packaging would likely have prevented the ingestion.

CPSC staff also searched the Consumer Product Safety Risk Management System (CPSRMS) for reports of incidents received by the Commission involving household products containing imidazolines. The search was conducted on September 9, 2014, and included all incidents for which reports had been received from December 2012 to September 9, 2014. One report involving eye drops that was received arose from an investigation of one of the 17 NEISS cases mentioned above. No other reports involving eye drops, nasal sprays, or nasal drops were received during this time period.

IV. Extension of Stay of Enforcement

Twelve firms that manufacture and/or package imidazoline-containing products covered by the final rule provided timely notice to the Commission of their intent to avail themselves of the conditional stay of enforcement authorized in the final rule. These

firms have also met the other conditions of the stay, *i.e.*, providing quarterly status reports during the 1-year stay of enforcement that include the information specified in the final rule. As discussed above, eight of these firms have advised CPSC staff that they likely will be unable to package some of their imidazoline products in CR packaging by the date that the current conditional stay of enforcement is set to expire. Four of the five firms that manufacture ophthalmic products and that have met the requirements to participate in the stay have advised staff that the firms need additional time to produce their products in CR packaging. Four of seven firms that manufacture nasal products and that have met the requirements to participate in the stay have advised staff that the firms need additional time to produce either squeeze spray or metered pump spray bottles for their imidazoline products.

A review of injury data reveals a significant reduction in NEISS cases since the effective date of the final rule. Although there was an average of approximately 13 NEISS cases of imidazoline ingestions by children under 5 years of age, per year, from January 1997 to December 2013, two cases were found for the most recent 9-month period. Furthermore, there have been no CPSRMS reports of incidents involving household products containing imidazolines since publication of the final rule.

The Commission finds that the circumstances described above warrant an extension of the conditional stay of enforcement. All but one of the eight firms covered by the conditional stay of enforcement that have requested additional time to comply with the rule have advised Compliance staff that their products will comply with the rule by May 2015 at the latest. Therefore, we have determined that the duration of the extension of the conditional stay of enforcement will be 6 months from the date of the expiration of

the conditional stay, or June 10, 2015. The stay will apply only to firms that are subject to the current conditional stay of enforcement and that continue to meet the reporting conditions set forth in the final rule preamble as explained above.

One firm covered by the stay of enforcement has told Compliance staff that the firm's products will not comply with the final rule by May 2015. The Office of Compliance will consider requests for an additional temporary extension of the stay of enforcement on a case-by-case basis, if a firm covered by the extended stay of enforcement anticipates difficulties meeting the June 10, 2015 date. A request for time beyond June 10, 2015 must be submitted to the Office of Compliance before the expiration of the extended conditional stay of enforcement. The request must specify the period of time needed to produce CR packaging, explain the reasons why additional time is needed, and provide a timeline or schedule outlining the steps the firm will take to comply with the final rule.

Dated: November 14, 2014

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

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