



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

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BALLOT VOTE SHEET

Date: October 30, 2014

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Patricia H. Adkins, Executive Director

FROM : Patricia M. Pollitzer, Assistant General Counsel

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

BALLOT VOTE Due: November 6, 2014

Attached is a draft *Federal Register* notice announcing a 6-month extension of the current conditional stay of enforcement of the rule (16 C.F.R. § 1700.14(a)(33)) requiring child-resistant packaging for products containing the equivalent of 0.08 milligrams or more of a specified imidazoline in a single package. The Office of Compliance and Field Operations (Compliance) recommends that the Commission:

- grant a 6-month extension for the conditional stay of enforcement; and
- authorize Compliance to provide additional temporary stays beyond the 6-month extension on a case-by-case basis.

Please indicate your vote on the following options for an extension of the conditional stay of enforcement:

A. Six-Month Extension of Stay

- I. Approve publication in the *Federal Register* of the attached document announcing a 6-month extension to the conditional stay of enforcement of the rule (16 C.F.R. §1700.14(a)(33)) requiring child-resistant packaging for products containing the equivalent of 0.08 milligrams or more of a specified imidazoline in a single package, as drafted.

(Signature)

(Date)

- II. Approve publication in the *Federal Register* of the attached document announcing a 6-month extension to the conditional stay of enforcement of the rule (16 C.F.R. § 1700.14(a)(33)) requiring child-resistant packaging for products containing the equivalent of 0.08 milligrams or more of a specified imidazoline in a single package, with changes. (Please specify.)

(Signature)

(Date)

- III. Do not approve publication of the attached draft notice in the *Federal Register*.

(Signature)

(Date)

- IV. Take other action. (Please specify.)

(Signature)

(Date)

B. Authorization for Compliance to Grant Additional Temporary Stays

- I. Approve authority for Compliance to grant additional temporary stays of enforcement beyond the 6-month extension on a case-by-case basis.

(Signature)

(Date)

- II. Do not approve authority for Compliance to grant additional temporary stays of enforcement beyond the 6-month extension on a case-by-case basis.

(Signature)

(Date)

- III. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice of Extension of Stay of Enforcement

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 notice 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 May 10, 2015 to comply with the special packaging requirements.

DATES: The stay of enforcement of special packaging requirements for specified imidazoline products expires on May 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, 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 73924, 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;

- o progress made and/or steps completed during the quarterly reporting period; and
- o 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 May 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 May 10, 2015 date. A request for time beyond May 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: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

This document has been electronically
approved and signed.

Memorandum

Date: October 30, 2014

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Patricia H. Adkins, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations
Marc J. Schoem, Deputy Director, EXC
Mary Toro, Director, Regulatory Enforcement Division, EXC

FROM: John Boja, Ph.D., Lead Compliance Officer and Carol Afflerbach, Senior
Compliance Officer, Regulatory Enforcement Division, EXC

SUBJECT: Extension of Conditional Stay of Enforcement for Special Packaging
Requirements for Products Containing the Equivalent of 0.08 mg of a Specified
Imidazoline

This memorandum provides the recommendation of the Office of Compliance and Field Operations (Compliance) regarding an extension of the 1-year conditional stay of enforcement of the child-resistant (CR) packaging requirements for products containing the equivalent of 0.08 mg or more of a specified imidazoline (16 C.F.R. § 1700.14(a)(33)). Products subject to the rule include ophthalmic products designed to cause vasoconstriction of the blood vessel in the eye and thus reduce the "redness" that can occur, and nasal decongestant products that work by constricting the blood vessels in nasal tissue, thus reducing congestion, which contain as the active ingredient tetrahydrozoline, naphazoline, oxymetazoline or xylometazoline.

Background:

The Commission authorized the publication of a notice of proposed rulemaking (NPR) to require special (child-resistant and senior-friendly) packaging for any over-the-counter or prescription product containing the equivalent of 0.08 mg or more of a specified imidazoline in a single package. 77 Fed. Reg. 3546 (January 25, 2012). The NPR proposed an effective date of 1 year after publication of the final rule in the *Federal Register*.

We received two comments that addressed the proposed 1-year effective date. One commenter agreed with the 1-year effective date and requested that the Commission consider a stay of enforcement for a period of 1 year after the effective date of the rule. Another commenter stated that 2 years from the date of publication of the final rule would be needed for manufacturers of covered products to comply with the rule. This commenter provided a timeline for bringing these products into compliance, which included estimates of the time necessary for the development, testing, and approval stages of the process. Based on a review and analysis of the information submitted by the commenters and in consultation with independent sources, staff recommended

that a conditional 1-year stay of enforcement was warranted. The Commission issued a rule requiring special packaging for over-the-counter or prescription products containing 0.08 milligrams or more of a specified imidazoline with a 1-year effective date. 77 Fed. Reg. 73294 (December 10, 2012). In the *Federal Register* notice, the Commission announced an additional 1-year conditional stay of enforcement for firms that:

1. provide notice to the Commission of their intent to receive the benefit of the conditional stay of enforcement before the effective date of the rule, 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
2. submit quarterly status reports during the 1-year stay of enforcement period for each affected product, providing the following information:
 - a. proposed packaging specifications;
 - b. estimated initial production date;
 - c. progress made and/or steps completed during the quarterly reporting period; and
 - d. reports of any incidents or exposures involving the firm's imidazoline-containing products subject to the rule.

77 Fed. Reg. at 73300. Companies meeting the requirements of and participating in the stay of enforcement currently have until December 10, 2014 to comply with the rule.

Issue:

Actions Necessary to Produce Compliant Packaging

Eleven manufacturers and one contract packager notified the Commission of their intent to avail themselves of the 1-year conditional stay of enforcement, and each of these twelve entities has met the requirements of the conditional stay. Each manufacturer participating in the conditional stay of enforcement has stated that there are no current off-the-shelf ¹ child-resistant packaging options available for the ophthalmic or nasal imidazoline products the company manufactures that are subject to the regulatory requirements. In the absence of off-the-shelf packages, firms must select packaging suppliers, design packaging, create the molds and tooling for the package, and finally, conduct protocol testing on candidate packages according to the method provided in 16 C.F.R. § 1700.20 to ensure compliance with the special packaging requirements at 16 C.F.R. § 1700.15.

Manufacturers of any package that does not pass the child and adult test requirements must restart the process and create a new design(s), molds, and thereafter, conduct protocol testing. Once a package design passes the initial testing phase, production molds suitable for high-speed or mass production are created, and final packaging samples are produced. Final protocol testing

¹ Off-the-shelf packages are package designs that meet the special packing requirements of 16 C.F.R. § 1700.15 and are currently in commercial production or that are available and could be scaled-up immediately for commercial production.

is repeated on the production samples. A failure at this point would necessitate redesign of the package and/or tooling. In addition, approval by the U.S. Food and Drug Administration (FDA) may be required if these products are considered to be New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) products. FDA approval takes minimum of 30 days, which could further delay the firm's timeline to have its products commercially available in special packaging.

Market Information

In the briefing package accompanying the final rule requiring special packaging for imidazoline-containing products, staff of the Directorate for Economic Analysis (EC) stated that more than 60 products manufactured by approximately 45 companies would be affected by this rule. At that time, EC believed that statement was a reasonable estimate of the number of imidazoline-containing products in the market that contained the specified imidazolines and thus would be affected by the rule. However, in light of more current data, Compliance staff now believes that many of these products are actually private label products and that the actual manufacturing and packaging of consumer imidazoline-containing products subject to the rule is concentrated in fewer firms than the prior estimate indicated. These firms represent a large number of private labeled product.

According to information received by Compliance, it appears that one manufacturer, a contract packager, manufactures the products for a substantial number of the companies that offer private label imidazoline products. Based on the information Compliance has received from industry, 12 companies (the 11 national brand suppliers and the contract packager), plus five companies that did not meet the deadline to apply for the conditional stay of enforcement, appear to account for a very substantial share of consumer imidazoline products on the market that are subject to the packaging requirements of the rule.

Manufacturers' Difficulties Meeting the December 2014 Deadline

Several firms currently under the stay of enforcement have contacted Compliance staff and have also indicated in their quarterly reports that they have encountered unexpected difficulties with package design and implementation, which will result in their inability to meet the December 2014 deadline for complying with the CR packaging requirements for certain imidazoline-containing products. Five firms that manufacture imidazoline-containing products intended to relieve ocular redness that are affected by the rule are participating in the 1-year conditional stay of enforcement. These five firms produce 35 different products intended for ophthalmic use. Only one of the five firms reports that it may be able to produce compliant products by December 2014. Products intended to relieve nasal congestion that contain imidazolines use either a squeeze-to-spray or pump-to-spray delivery system. Seven manufacturers of imidazoline-containing nasal products affected by the rule are participating in the 1-year conditional stay of enforcement and have contacted staff about their difficulty meeting the December 10, 2014 date. Three of the seven firms report that they may be able to produce compliant products by December 2014. However, any unexpected difficulties could result in their inability to meet the deadline. One of the manufacturers is a contract packager who supplies product that is covered by the rule for 28 different firms. Many of the 28 firms, in turn, supply

product to various private labelers, *e.g.*, assorted drug or grocery store brands. These seven manufacturers of nasal products manufacture 156 different products that contain the specifically-identified imidazolines covered by the rule.

Recently, five additional manufacturers of imidazoline-containing products that are subject to the rule contacted the CPSC, asking to be added to the conditional stay of enforcement that is in effect. These manufacturers did not notify the Commission of their intent to avail themselves of the conditional stay of enforcement by the deadline and thus have not submitted the requisite timeline and reports, among other things. As a result, these five manufacturers did not qualify for the conditional stay of enforcement. In addition, each has been advised that they may be in violation of the applicable special packaging requirements. Each of these five firms has indicated that they have been working to meet the December 10, 2014 deadline. However, two of these firms have stated that they will require additional time beyond December 10, 2014.²

Ophthalmic Products

Compliance staff has received information that manufacturers of ophthalmic drops that are subject to the special packaging requirements are encountering the following problems that are affecting the companies' ability to meet the December 10, 2014 deadline.

- Special packaging for ophthalmic drops that consists of the bottle, the cap, and the dropper tip has only recently been produced in quantity. This type of combination package is provided in a non-sterile state. Thus, imidazoline manufacturers who intend to use this type of packaging must modify existing bottling equipment to accommodate the new special packaging and sterilize the packages before filling them. This may also require additional time to obtain approval from the FDA, which takes minimum of 30 days.
- In accordance with the CPSIA, manufacturers subject to any PPPA regulation must provide a general certificate of compliance (GCC). Although manufacturers can rely on protocol testing conducted by the package manufacturer as the basis for the GCC, some imidazoline product manufacturers have stated they intend to conduct final protocol testing themselves before they distribute their products. This will take additional time.
- Manufacturers have encountered problems going from design of special packaging to actual production, *e.g.*, a special packaging design that passes protocol testing and meets the test requirements as an initial package design does not meet those requirements when produced at high speed. The manufacturer then must modify its packaging, and possibly the production line equipment as well, and repeat the protocol testing.

² The five firms that did not notify the Commission of their intent to avail themselves of the conditional stay of enforcement by the deadline are not currently covered by the conditional stay of enforcement. Therefore, any of these firms currently selling covered imidazoline products in non-CR packaging are in violation of the rule. Compliance will review these cases and undertake appropriate enforcement actions. The five firms are separated from the product discussion below.

- Some manufacturers use a third party supplier of special packaging. Unexpected manufacturing problems experienced by third party suppliers have delayed the ability of some imidazoline product manufacturers to meet the December 10, 2014 deadline.

Nasal Products

Compliance has received information that manufacturers of nasal products subject to the special packaging requirements are encountering the following problems that are affecting the companies' ability to meet the December 10, 2014 deadline.

- For some firms, although compliant packaging may be available in December 2014, firms will then need to order the packages and check that modifications they have made to manufacturing lines are compatible with the new packages. Independent protocol testing will also take additional time.
- Manufacturers that use third party suppliers of special packaging have the same problems mentioned above that ophthalmic drop manufacturers are facing.

Information Provided by Trade Association

In addition to receiving information from product and packaging manufacturers, Compliance staff received a letter dated August 21, 2014 from the Consumer Healthcare Products Association (CHPA), which represents many of the regulated manufacturers. CHPA believes that only one of its nine members that produce imidazoline-containing products subject to the rule will be able to meet the December 10, 2014 deadline. We believe that many of these firms have also contacted Compliance. CHPA expressed concern that a failure to grant additional time to their members could result in a shortage of imidazoline-containing nasal and ophthalmic products subject to the packaging rule, to the detriment of consumers.³ CHPA had commented on the proposed rule, highlighting the need for additional time beyond the 1 year effective date and the 1 year conditional stay of enforcement for products subject to an NDA or an ANDA, particularly because some packaging changes would require approval by the FDA. In CHPA's comment to the NPR, CHPA also stated that a number of its member companies estimated that producing compliant packaging would take more than 2 years. For that reason, in its comment to the proposed rule, CHPA requested that the CPSC expressly permit manufacturers to petition for longer stays of enforcement, as needed, and request additional temporary stays until such time as an enforcement stay is no longer appropriate. The CHPA estimate about time needed to comply with the rule's packaging requirements is borne out by the information included in the quarterly reports submitted by CHPA members, which show that additional time will be required.

³ In a teleconference with CPSC staff on June 6, 2014, FDA staff expressed concern about the possibility that these products may not be available to consumers if the stay is not extended beyond the current expiration date of December 10, 2014. FDA staff also requested a list of contacts for the manufacturers under the conditional stay of enforcement that were having difficulties meeting the deadline for special packaging.

Incidents of Ingestion

From December 1, 2013 to September 9, 2014, during which the conditional stay was in effect, there have been two reports of incidents of ingestion of an imidazoline-containing product affected by the rule by children under 5 years of age included in the National Electronic Injury Surveillance System (NEISS). However, we cannot identify the specific imidazoline(s) involved, and whether the products would have been affected by the rule. Both children were treated and released. It is unclear from the information available whether the children opened the bottle and whether special packaging would have prevented the incidents. CPSC staff also reviewed the Consumer Product Safety Risk Management System and found no ingestion incidents between December 1, 2013 and the present, which involved eye drops or nose sprays.

In addition, one requirement of the conditional stay of enforcement is that firms currently under the stay must submit quarterly reports informing the Commission of any incidents reported to them during the stay. The firms have reported receiving notice of the following incident information:

Ocular Products

Since the effective date of the rule, there have been four incidents of ingestions of imidazoline-containing ocular products for which the age of the child is unknown. In addition, during that period, there have been three ingestion incidents described as non-serious that involved children under 5 years of age. The specific imidazoline involved in these ingestion incidents, and thus whether the rule would apply to the product, is unknown. In one of the three non-serious incidents, it is unclear whether the child ingested any of the substance because the incident report only stated that the child put the bottle in his mouth. Likewise, it is unclear from the information available whether any of the incidents involved a child opening the bottle, or if special packing would have prevented the incidents.

Nasal Products

There were six reports of ingestion of imidazoline-containing nasal products subject to the rule involving children under 5 years of age since the effective date of the rule. One report stated that the child had only sucked on the lid, and it was unknown whether any exposure to the drug occurred. The specific imidazoline involved in these ingestion incidents, and thus whether the rule would apply to the product, is unknown. All six incidents were considered non-serious, and it was unclear from the information available whether any of the incidents involved a child opening the bottle or if special packing would have prevented the incidents.

Commission Options:

1. The Commission can take no action and allow the conditional stay of enforcement to expire on December 10, 2014. This action may result in a possible shortage of products containing tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline used as ocular vasoconstrictors or nasal decongestants available to consumers; or
2. The Commission can extend the conditional stay of enforcement for firms that have qualified for the stay of enforcement, met the conditions, including the quarterly reporting requirements, and are under the current stay of enforcement and which notified the Commission of their intent to avail themselves of the conditional stay by the December 10, 2013 deadline. The stay of enforcement would be extended under the same conditions as the initial stay, for a period of time the Commission deems appropriate, *e.g.*, 6 months, 1 year; or
3. The Commission can authorize the Office of Compliance to grant additional temporary stays of enforcement upon expiration of the 1-year conditional stay for firms that notified the Commission of their intent to avail themselves of the conditional stay by the December 10, 2013 deadline and which are currently covered by the conditional stay and that demonstrate a need for additional time. The firms would need to provide Compliance staff with a timeline or schedule outlining the steps the firms will take to bring CR packaging to commercial use for their imidazoline-containing products; or
4. The Commission can grant an additional 6-month conditional stay of enforcement under the same conditions as the initial stay and authorize the Office of Compliance to grant additional temporary stays on a case-by-case basis to manufacturers that notified the Commission of their intent to avail themselves of the conditional stay by the December 10, 2013 deadline and which are covered by the initial conditional stay of enforcement. The firms would have to demonstrate a need for additional time and provide the Office of Compliance with a timeline or schedule outlining the steps they will take to bring CR packaging to commercial use for their imidazoline-containing products.

Compliance Staff Recommendation:

The Office of Compliance recommends that the Commission grant a 6-month extension to the conditional stay of enforcement that already is in effect for 12 firms and authorize the Office of Compliance to grant additional temporary stays beyond 6 months on a case-by-case basis to firms in compliance with the extended conditional stay of enforcement that individually request and demonstrate a need for a temporary stay of enforcement. This extension would only be available to firms that notified the Commission of their intent to avail themselves of the conditional stay by the December 10, 2013 deadline and that are covered by the initial stay under the same conditions as the initial stay.

This recommendation is based on the fact that Compliance staff believes most of the manufacturers of imidazoline-containing products will be compliant within the 6 month additional time frame. Extending the stay for 6 months rather than a longer period of time such

as 1 year will mean that compliant products will be available on the market sooner. This will provide greater safety to consumers.

Staff is aware, however, of at least one firm that is unlikely to meet a May 10, 2015 extension date. Providing a 6 month extension and giving Compliance the authority to provide additional time on a case-by-case basis will mean that most imidazoline-containing ophthalmic and nasal products subject to the special packaging requirements should be in CR packaging by May 2016 and will give Compliance the flexibility to deal with the few remaining non-compliant firms as appropriate based on the firms' efforts to come into compliance. Firms that need an additional temporary stay would have to:

- submit a request before the extended conditional stay of enforcement expires,
- request an additional temporary stay of enforcement for a specific period of time,
- provide the reasons why additional time is needed to produce CR packaging, and
- provide a timeline or schedule outlining the steps the firm will take to comply with the final rule.

Compliance staff believes the recommendation that the Commission extend the stay of enforcement for 6 months and give Compliance the authority to allow additional temporary stays on a case-by-case basis is reasonable based on the following:

1. The firms that have availed themselves of the conditional 1-year stay of enforcement have adhered to the conditions set forth in the stay and have demonstrated to Compliance staff the firms' continued efforts to meet the deadline. These firms have initiated open dialogues with staff regarding the unanticipated delays in the design and production of special packaging for their products.
2. Each firm covered by the conditional stay and requesting additional time has provided supporting documentation that, in staff's opinion, demonstrates each firm's diligence in meeting the deadlines. Difficulties encountered by these firms in obtaining packages that pass the child-resistant and senior-friendly testing requirements and in implementing the requirements were not reasonably foreseeable and not under the control of the regulated firms; *e.g.*, difficulties that the contract packagers experienced delays resulting from obtaining automation equipment from foreign suppliers. Staff considers requests for additional time such as these requests to be reasonable.
3. It is important to have continuity in the availability of products containing tetrahydrozoline, naphazoline, oxymetazoline, and xylometazoline that are designed to cause vasoconstriction of the blood vessels in the eye and thus reduce the "redness" that can occur, and nasal decongestant products that work by constricting the blood vessels in nasal tissue, thus reducing congestion.

Only four of the 12 firms that are participating in the 1-year conditional stay of enforcement anticipate that their products will comply with the special packaging requirements by December 10, 2014. The firms that are not likely to have compliant products on the market by December 10, 2014 make up a significant portion of imidazoline-containing ophthalmic and nasal products.

Only one of five firms that manufacture ophthalmic drops and is participating in the stay of enforcement has indicated that its products will comply with the CR requirement by December 2014. Seven manufacturers (six manufacturers and one contract packager) of nasal products have indicated they will have complying products by December 2014. Because some of these firms supply products to private labelers, a significant number of products will not be in compliance by December 2014. Without extending the stay, these products will be in violation of the CR packaging rule. If companies pull their non-compliant products from retail shelves, a shortage of imidazoline-containing ophthalmic and nasal product could result.