

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE-10, Benchmark Survey of U.S. Direct Investment Abroad—2014, contained herein, whether or not they are contacted by BEA. Also, a person, or their agent, that is contacted by BEA about reporting in this survey, either by sending them a report form or by written inquiry, must respond in writing pursuant this section. This may be accomplished by:

(1) Certifying in writing, by the due date of the survey, to the fact that the person had no direct investment within the purview of the reporting requirements of the BE-10 survey;

(2) Completing and returning the “BE-10 Claim for Not Filing” by the due date of the survey; or

(3) Filing the properly completed BE-10 report (comprising Form BE-10A and Form(s) BE-10B, BE-10C, and/or BE-10D) by May 29, 2015, or June 30, 2015, as required.

(b) *Who must report.* (1) A BE-10 report is required of any U.S. person that had a foreign affiliate—that is, that had direct or indirect ownership or control of at least 10 percent of the voting stock of an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise, including a branch—at any time during the U.S. person’s 2014 fiscal year.

(2) If the U.S. person had no foreign affiliates during its 2014 fiscal year, a “BE-10 Claim for Not Filing” must be filed by the due date of the survey; no other forms in the survey are required. If the U.S. person had any foreign affiliates during its 2014 fiscal year, a BE-10 report is required and the U.S. person is a U.S. Reporter in this survey.

(3) Reports are required even if the foreign business enterprise was established, acquired, seized, liquidated, sold, expropriated, or inactivated during the U.S. person’s 2014 fiscal year.

(4) The amount and type of data required to be reported vary according to the size of the U.S. Reporters or foreign affiliates, and, for foreign affiliates, whether they are majority-owned or minority-owned by U.S. direct investors. For purposes of the BE-10 survey, a “majority-owned” foreign affiliate is one in which the combined direct and indirect ownership interest of all U.S. parents of the foreign affiliate exceeds 50 percent; all other affiliates are referred to as “minority-owned” affiliates.

(c) *Forms to be filed.* (1) Form BE-10A must be completed by a U.S. Reporter. If the U.S. Reporter is a corporation,

Form BE-10A is required to cover the fully consolidated U.S. domestic business enterprise. It must also file Form(s) BE-10B, C, and/or D for its foreign affiliates, whether held directly or indirectly.

(2) Form BE-10B must be filed for each majority-owned foreign affiliate for which any of the following three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than \$80 million (positive or negative) at any time during the affiliate’s 2014 fiscal year.

(3) Form BE-10C must be filed:

(i) For each majority-owned foreign affiliate for which any one of the three items listed in paragraph (c)(2) of this section was greater than \$25 million but for which none of these items was greater than \$80 million (positive or negative), at any time during the affiliate’s 2014 fiscal year, and

(ii) For each minority-owned foreign affiliate for which any one of the three items listed in (c)(2) of this section was greater than \$25 million (positive or negative), at any time during the affiliate’s 2014 fiscal year.

(4) Form BE-10D must be filed for majority- or minority-owned foreign affiliates for which none of the three items listed in paragraph (c)(2) of this section was greater than \$25 million (positive or negative) at any time during the affiliate’s 2014 fiscal year. Form BE-10D is a schedule; a U.S. Reporter would submit one or more pages of the form depending on the number of affiliates that are required to be filed on this form.

(d) *Due date.* A fully completed and certified BE-10 report comprising Form BE-10A and Form(s) BE-10B, C, and/or D (as required) is due to be filed with BEA not later than May 29, 2015, for those U.S. Reporters filing fewer than 50, and June 30, 2015, for those U.S. Reporters filing 50 or more, foreign affiliate Forms BE-10B, C, and/or D. If the U.S. person had no foreign affiliates during its 2014 fiscal year, it must file a BE-10 Claim for Not Filing by May 29, 2015.

[FR Doc. 2014–27421 Filed 11–19–14; 8:45 am]

BILLING CODE 3510–06–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; email: [cafflerbach@cpsc.gov](mailto: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).<sup>1</sup> 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.<sup>2</sup>

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

<sup>1</sup> 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.

<sup>2</sup> 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.

(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 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.

[FR Doc. 2014-27378 Filed 11-19-14; 8:45 am]

BILLING CODE 6355-01-P

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## DEPARTMENT OF COMMERCE

### International Trade Administration

#### 19 CFR Part 351

[Docket No.: 141104924-4924-01]

RIN 0625-AB01

#### Enforcement and Compliance; Change of Electronic Filing System Name

**AGENCY:** International Trade Administration, Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** The International Trade Administration's Enforcement and Compliance Unit publishes this rule to announce a change in the name of Enforcement and Compliance's electronic filing system from "IA ACCESS" to "ACCESS." Consistent with this action, this rule makes appropriate conforming changes in part 351 of title 19 of the Code of Federal Regulations. This action is being taken to ensure that the regulations reflect the change in nomenclature from Import Administration to Enforcement and Compliance.

**DATES:** This rule is effective November 24, 2014.

**FOR FURTHER INFORMATION CONTACT:** Laura Merchant, IT Manager, Enforcement and Compliance, Telephone (202) 482-0367; Shana Hofstetter, Attorney, Office of Chief Counsel for Trade Enforcement and Compliance, Telephone: (202) 482-3414.

**SUPPLEMENTARY INFORMATION:** On October 1, 2013, as part of an internal consolidation within the International Trade Administration, the name of the Import Administration was changed to Enforcement and Compliance to reflect the unit's new operational mandate.<sup>1</sup> This rule updates the regulations to reflect the new name of Enforcement and Compliance's electronic filing system from "IA ACCESS" to "ACCESS". This rule changes all

<sup>1</sup> See *Import Administration; Change of Agency Name*, 78 FR 62417 (Oct. 22, 2013).