other than skin tissue is being considered. A substance could also be labeled corrosive based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: Existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(4) The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in 1500.41; and/or a substance that can be considered a primary irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data. *Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or means a substance for which a positive test is obtained when tested by the method described in 1500.42; and/or means a substance that can be considered an eye irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

* * * * *

■ 3. Amend § 1500.40 by revising the introductory text to read as follows:

§ 1500.40 Method of testing toxic substances.

Guidelines for testing the toxicity of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis, including any of the following: existing human and animal data, structure activity relationships, physicochemical properties; and chemical reactivity, or validated *in vitro* or *in silico* testing are recommended to evaluate existing information before *in vivo* tests are considered. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing the toxic substances referred to in § 1500.3(c)(1)(ii)(C) and (c)(2)(iii) is as follows:

* * * * *

■ 4. In § 1500.41, add five sentences at the start of the introductory text to read as follows:

§ 1500.41 Method of testing primary irritant substances.

Guidelines for testing the dermal irritation and corrosivity properties of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis or a validated *in vitro* test method is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include all of the following that are available: human and animal data, structure activity relationships, physicochemical properties, and dermal toxicity. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing the dermal corrosivity and primary irritation of substances referred to in § 1500.3(c)(3) and (4), respectively, is a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. * * *

* * * * *

■ 5. Amend § 1500.42 by adding introductory text, revising the first sentence of paragraph (a)(1), and revising paragraph (c) to read as follows:

§ 1500.42 Test for eye irritants.

Guidelines for *in vivo* and *in vitro* testing of ocular irritation of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis or a validated *in vitro* test method is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include any of the following: Existing human and animal data on ocular or dermal irritation, structure activity relationships, physicochemical properties, and chemical reactivity. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. Additionally, the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid or minimize pain and distress in ocular safety testing is recommended.

(a)(1) In the method of testing the ocular irritation of a substance referred to in § 1500.3(c)(4), six albino rabbits are used for each test substance * * *

* * * * *

(c) To assist testing laboratories and others interested in interpreting ocular irritation test results, the CPSC animal testing policy Web page at *http://www.cpsc.gov/library/animaltesting.html* will contain the scoring system defined in the U.S. EPA's Test Guideline, OPPTS 870.2400: Acute Eye Irritation [1] or the OECD Test Guideline 405: Acute Eye Irritation/Corrosion.[2]

Dated: November 29, 2012.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2012–29258 Filed 12–7–12; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

[CPSC Docket No. CPSC–2012–0005]

Requirements for Child-Resistant Packaging: Products Containing Imidazolines Equivalent to 0.08 Milligrams or More

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (CPSC, Commission, or we) is issuing a rule to require child-resistant (CR) packaging for any over-the-counter or prescription product containing the equivalent of 0.08 milligrams or more of an imidazoline, a class of drugs that includes tetrahydrozoline, naphazoline, oxymetazoline, and xylometazoline, in a

[1] EPA. 1998. Health Effects Test Guidelines, OPPTS 870.2400 Acute Eye Irritation. EPA 712–C–98–195. Washington, DC: U.S. Environmental Protection Agency. (Available: *http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/EPA/EPA_870_2400.pdf*)

[2] OECD. 2002. OECD Guideline for the Testing of Chemicals 405: Acute Eye Irritation/Corrosion. Paris: Organisation for Economic Co-operation and Development. (Available: *http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg405.pdf*)

single package. Imidazolines are a family of drugs that are vasoconstrictors indicated for nasal congestion and/or ophthalmic irritation. Products containing imidazolines can cause serious adverse reactions, such as central nervous system (CNS) depression, decreased heart rate, and depressed ventilation in children who accidentally ingest them. Based on the scientific data, the Commission has determined that availability of 0.08 milligrams or more of an imidazoline in a single package, by reason of its packaging, is such that special packaging is required to protect children under 5 years old from serious personal injury or illness due to handling or ingesting such a substance. The Commission takes this action under the Poison Prevention Packaging Act of 1970 (PPPA) and voted to publish this notice in the **Federal Register**.

DATES: *Effective date:* This rule is effective December 10, 2013.

Applicability: This rule applies to products packaged on or after that date.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. Relevant Statutory and Regulatory Provisions

The Poison Prevention Packaging Act of 1970 (PPPA), 15 U.S.C. 1471–1476, authorizes the Commission to establish standards for the ''special packaging'' of any household substance if: (1) The degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance, and (2) the special packaging is technically feasible, practicable, and appropriate for such substance.

Special packaging, also referred to as ''child-resistant (CR) packaging,'' is: (1) Designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and (2) not difficult for ''normal adults'' to use properly. 15 U.S.C. 1471(4). Household substances for which the Commission may require CR packaging include (among other categories) foods, drugs, or cosmetics, as these terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). 15 U.S.C. 1471(2)(B). The Commission has issued performance requirements for special packaging. 16 CFR 1700.15, 1700.20.

Section 4(a) of the PPPA, 15 U.S.C. 1473(a), allows the manufacturer or packer to package a nonprescription product subject to special packaging standards in one size of non-CR packaging, only if the manufacturer (or packer) also supplies the substance in CR packages of a popular size, and the non-CR packages bear conspicuous labeling stating: ''This package for households without young children.'' 15 U.S.C. 1473(a), 16 CFR 1700.5.

To protect children younger than 5 years old from serious personal injury following ingestion, the rule requires CR packaging for any over-the-counter (OTC) or prescription product containing the equivalent of 0.08 milligrams or more of an imidazoline (including tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline) in a single package.

B. Imidazolines

Imidazolines are a family of drugs that are used as decongestants in eye drops and nasal products. Imidazolines are used as topical decongestants because they produce vasoconstriction when administered to the eye or nasal mucosa. In the eye, the imidazolines relieve redness due to minor eye irritations by causing vasoconstriction of the blood vessels on the surface of the eye and eyelid (Facts and Comparisons, Ophthalmic Decongestants, Pharmacology, 2011). The onset of vasoconstriction after topical application is within minutes. As nasal decongestants, imidazolines temporarily relieve nasal congestion or stuffy nose due to the common cold, hay fever, or other upper respiratory allergies (Facts and Comparisons, Nasal Decongestants, Pharmacology 2011). The imidazolines cause vasoconstriction in mucous membranes, which decreases blood flow and leads to shrinking of swollen nasal mucosa and increased drainage of the sinuses.

Topical and nasal administration of imidazolines results in little absorption into the general circulation. Orally ingested imidazolines, however, are absorbed into the general circulation leading to systemic effects. Even though death from ingesting imidazolines is rare, ingestion can result in severe life-threatening consequences, such as central nervous system (CNS) depression and cardiovascular effects. Specific symptoms of CNS depression upon ingestion of imidazolines range from drowsiness to coma, with a concurrent depression of the respiratory system. Other reported CNS side effects include: Headache, lightheadedness, dizziness, tremor, insomnia, nervousness, restlessness, giddiness, psychological disturbances, prolonged psychosis, and weakness. Imidazolines have led to CNS depression and insomnia in different children. Prominent cardiovascular effects in response to overdose include low blood pressure and slowed heart rate. The medical literature and evidence from collected samples demonstrate that despite the danger of ingesting imidazolines, imidazoline-containing products are not manufactured in CR packaging.

Eye drops containing imidazolines are widely available at drug, grocery, and mass market retailers. Imidazoline eye drops generally come in small squeeze bottles. The most common size is the 1/2-ounce (15 milliliters) bottle, and the second most common size appears to be a 1-ounce bottle (30 milliliters). One-quarter ounce (8 milliliters) bottles are also available.

Nasal sprays containing imidazolines are widely available at drug, grocery, and mass market retailers. Some packages are used by rapidly squeezing the bottle to spray the product into a nostril. Other packages have a pump mechanism that activates the spray. As with eye drops, 1/2-ounce containers are the most common container size, and 1-ounce bottles are the second most common size.

We are aware of approximately 45 manufacturers who sell topical decongestant products under about 64 different labels. Because some manufacturers produce both nasal and ophthalmic products, the number of manufacturers within the market for topical decongestants is not the sum of the manufacturers of ophthalmic products, plus the manufacturers of nasal products.

We estimate that approximately 45 million units of ophthalmic decongestants containing imidazolines are sold annually, with estimated annual sales receipts of approximately $180 million. We estimate that approximately 39 million units of nasal products containing imidazolines are sold annually, generating annual sales receipts of approximately $233 million.

Commission staff examined 12 packages—10 eye drops, 1 nasal spray, and 1 nasal drops—of over-the-counter products that contain imidazolines. The 10 eye drop samples were packaged in squeeze-to-dispense plastic dropper bottles. The nasal spray was packaged in a plastic bottle with an attached metered

pump sprayer, and the nasal drop was packaged in a squeeze-to-dispense plastic dropper bottle. All of the eye drop product bottles were finished with continuous threads, and the bottle openings were fitted with plastic dropper plugs. The nasal spray bottle was finished with continuous threads onto which a metered pump dispenser was attached. The pump mechanism was not child resistant. The nasal drops were packaged in a squeeze-dropper bottle, finished with continuous threads, and the bottle opening was fitted with a dropper plug. None of the samples of eye drops, nasal spray, or nasal drops was packaged using special packaging.

C. The Proposed Rule

On January 25, 2012, the Commission issued a notice of proposed rulemaking (NPR) that proposed requiring CR packaging for imidazoline preparations containing 0.08 milligrams or more of imidazolines in a single package. 77 FR 3646.

The Commission received five comments in response to the proposed rule. Two comments address the amount of time necessary to develop, test, and produce CR packaging for imidazolines, and they request additional time beyond the 1-year effective date proposed in the NPR. Two comments pertain to imidazoline nasal and ophthalmic packaging, and one comment concerns the derivation of the proposed regulation level of 0.08 milligrams or more of imidazolines in a single package. We respond to each of these comments below.

Effective Date

Comment: Two commenters indicate that the proposed effective date of 1 year is too short. One commenter concludes: ''it is not feasible for manufacturers to comply with the proposed one (1) year effective date'' and opines that 2 years would be required at a minimum. Regarding nasal products, the commenter contends that this amount of time is required because it will probably be necessary to replace the commonly used single-piece cap with two-component CR protection caps. The commenter also notes that most ophthalmic finishes [1] are 13mm–15mm; that there are no CR closures available smaller than 18mm; and therefore, new CR packages will also be required for ophthalmic products. The commenter provides a timeline identifying the various steps of the CR packaging development, testing, and approval process, and the time range for the expected completion of each stage. The commenter requests that the Commission consider a 1-year stay of enforcement in addition to the 1-year effective date recommended in the NPR to allow manufacturers 2 years after publication of the rule to comply. This commenter also states that additional time beyond the one year effective date and one year stay of enforcement may be required by some manufacturers, especially if the products in question are subject to U.S. Food and Drug Administration (FDA) requirements for new drug applications (NDAs) or abbreviated new drug applications (ANDAs). This additional approval process, the commenter reports, could require an additional 6 to 12 months. This commenter also requests that manufacturers be granted extended stays of enforcement on a case-by-case basis, if required.

A second commenter states that it manufactures sterile eye drops that require ''specialized aseptic processing,'' notes that the process for developing CR packages suitable for sterile ophthalmic products is complex and ''based upon historical experience with the regulated design and qualification activities required for aseptically filled sterile products,'' and requests that the effective date of the rule be extended to 24 months.

Response: We agree with the first commenter's analysis of the steps necessary to comply with a CR packaging requirement and the time frames associated with each step. We also agree with the second commenter's statement that producing sterile products will take 24 months, such that a conditional 12-month stay of enforcement is warranted. We address our assessment of the anticipated duration of each step in the process of developing, testing, and producing CR packaging, and we highlight each step identified in the commenter's submission. The first commenter states that design development will take 2 to 4 months, and we believe that this range is typical for modern computer-assisted design processes. We note that there are several nonpatented designs, and one patented design for CR packaging for imidazoline products that, if purchased or licensed by a manufacturer, could reduce the duration of the design development stage to 1 month or less. The commenter states that prototype tooling will take from 4 to 6 months, and we have been advised by independent sources that mold tool production typically takes 4 to 5 months, with an additional month for production testing to ensure that the mold tool can be used at the intended production rate. The commenter estimates that CR protocol testing will take approximately 3 months, and we have been advised by CR protocol test providers that such testing for child-resistant and senior-friendly packaging typically takes 2 to 4 months, depending on the complexity of the CR system. The commenter states that industrial scale-up for packaging and validation will take from 7 to 11 months because of the possibility that existing filling and capping equipment will need to be replaced, or at least significantly modified, depending on the design of the CR closure. Independent sources have advised us that this work should take less than 6 months if a similar sterile process is already in place and between 6 and 12 months if new equipment must be installed. According to the commenter, adoption and validation of the new filling line will take between 3 and 6 months, which is the time range provided by manufacturers of similar products in connection with previous regulatory activity. The commenter states that stability testing will take between 3 and 12 months, a timeframe that is consistent with FDA Stability Test Guidelines of 1 year for regular stability testing and 6 months for accelerated stability testing, which is intended to increase the rate at which the degradation reactions take place. The commenter states that the FDA review process for an NDA or an ANDA can take from 6 months to a year. The FDA advises that 10 months is the median review time for NDAs, while the ANDA review process typically does not take as long; however, permission must be obtained before filing an ANDA, which can take up to 6 months alone.

Based on the foregoing review and analysis of the steps necessary to develop, test, and produce CR packaging for products that contain imidazolines, as well as the time frames for each of those steps, the Commission agrees that more than 1 year may well be necessary. Thus, the Commission will grant a conditional 1-year stay of enforcement to provide additional time to produce CR packaging for these products. This issue is discussed further in Section VI of the preamble.

Packaging Issues

Comment—One commenter notes that the NPR failed to consider one type of nasal spray package. The package in question ''is a glass bottle which houses the imidazoline drug product, with a crimped seal holding the pump in place and with [a] detachable nozzle.'' The

[1] The word ''finish,'' in this sense, refers to the protruding threads on the bottle's opening, which hold the cap or closure. A container and its corresponding closure must have matching finishes.

metered pump is housed in a metal case, the rim of which is crimped to the glass bottle. A plastic nozzle is placed over the pump, and the overcap is attached to the nozzle. Consumers access the product by squeezing the package between the thumb and first two fingers, causing an aerosolized form of the product to be released from the nozzle's tip.

The commenter believes that this package is inherently child resistant because it is a unit-dose package. The commenter requests that CPSC staff provide clarification ''as to what could constitute a pass or failure of such a package.''

Response: We disagree with the commenter's fundamental premise that unit-dose packages are inherently child resistant. In fact, we believe that unit-dose packages are not inherently CR. It is likely that a child can easily access the contents because neither the pumping action, nor the overcap or nozzle attachments are CR, and it is reasonably foreseeable that a child could access more than the regulated quantity of the contents. Either the pump action or the overcap must be child resistant.

Comment—One commenter asks: ''for nasal sprays that contain Imidazoline equivalent to 0.08 milligrams or more, is Child-Resistant packaging required for crimp-on pumps?'' The commenter acknowledges that continuous thread (CT) closures and squeezable packages permit a child to have access to the entire contents, but states that metered-dose pumps crimped onto a rigid bottle would permit a child access to ''only one dose at a time.'' In addition, the commenter states: ''it is not likely to be ingested due to its aerosol form.''

Response—As stated in the response to the previous comment, unit-dose packaging is not inherently CR. Child-resistant packaging is required for the pump action and/or the overcap. We also disagree that an aerosolized form of the product would not be ingested by a child.

Regulated Level of Imidazoline

Comment— One commenter asks whether the lowest observed adverse effect level (LOAEL) (*i.e.,* 0.75 mg) should first be normalized to mg/kg and then extrapolated to a 25-pound child before applying a tenfold safety factor, resulting in a no observable adverse effect level (NOAEL) of 0.18 mg.

Response—The proposed regulated level (0.08 mg imidazoline) was based upon an actual imidazoline case with a safety factor applied to the dose ingested. Notably, ingestions expressed as normalized doses show that adverse effects occurred at levels within about the same range of imidazoline (0.1–0.3 mg/kg). Moreover, another case in the medical literature documents an adolescent who developed persistent cardiovascular and neurological effects after ingestion of approximately 0.07 to 0.1 mg/kg of tetrahydrozoline, which is also consistent with the proposed imidazoline level *e.g.,* 0.07 mg/kg (lower end of range) × 11.4 kg child = ~ 0.8 mg ÷ 10 fold-safety factor = 0.08 mg.

II. Toxicity of Imidazolines

The Commission's Directorate for Health Sciences reviewed the toxicity of imidazolines. Imidazolines are used as topical decongestants because they produce vasoconstriction when administered to the eye or nasal mucosa. In the eye, the imidazolines relieve redness due to minor eye irritations by causing vasoconstriction of the blood vessels on the surface of the eye and eyelid (Facts and Comparisons, Ophthalmic Decongestants, Pharmacology, 2011). The onset of vasoconstriction after topical application is within minutes. As nasal decongestants, imidazolines temporarily relieve nasal congestion or stuffy nose due to the common cold, hay fever, or other upper respiratory allergies (Facts and Comparisons, Nasal Decongestants, Pharmacology 2011). The imidazolines cause vasoconstriction in mucous membranes, which decreases blood flow and leads to shrinking of swollen nasal mucosa and increased drainage of the sinuses.

The therapeutically effective dose of imidazolines occurs within a narrow dose range, with toxic effects occurring at doses close to, or at, therapeutic levels. CNS depression (ranging from drowsiness to deep sedation) may occur after recommended doses in infants. Overdoses (doses not specified) of these medications have caused initial spikes of high blood pressure, leading to slowed heart rate, drowsiness, and rebound low blood pressure in adults. A shock-like syndrome with abnormally low blood pressure and slowed heart rate may also occur. Warnings on tetrahydrozoline- and naphazoline-containing OTC drugs state that their use may cause CNS depression, leading to coma in pediatric patients. Xylometazoline and oxymetazoline symptoms of overdose include: extreme tiredness, sweating, dizziness, a slowed heartbeat, and coma.

When the drug is absorbed, it can act systemically within the body. Topical administration of imidazolines to the eye produces local effects to the blood vessels of the eye, but little is absorbed into the general circulation. (For purposes of this document, we interpret ''absorption'' as the passage of a drug from its site of administration into the blood plasma.)

Nasal administration of imidazolines causes an intense degree of vasoconstriction, and therefore, negligible absorption of the drug into the general circulation (POISINDEX,® 2011). However, with oral ingestion, imidazolines are absorbed into the general circulation, leading to systemic effects. These drugs are absorbed quickly, and symptoms can occur in as little as 1 hour, peaking at 8 hours, and resolving after 12–36 hours. Even though the symptoms resolve in a relatively short amount of time, ingestion of imidazolines can result in severe life-threatening consequences, including decreased breathing, decreased heart rate, and loss of consciousness, which require hospitalization to ensure recovery.

FDA regulations pertaining to ''Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use,'' at 21 CFR 341.80(c)(2)(iv), require the product label for products containing naphazoline hydrochloride at a concentration of 0.05 percent to state: ''Do not use this product in children under 12 years of age because it may cause sedation if swallowed.'' Specific symptoms of CNS depression upon ingestion of imidazolines range from drowsiness to coma, with a concurrent depression of the respiratory system. Other observed CNS side effects include: Headache, lightheadedness, dizziness, tremor, insomnia, nervousness, restlessness, giddiness, psychological disturbances, prolonged psychosis, and weakness. Imidazolines have led to CNS depression and insomnia in different individuals. The insomnia, seen in a few cases, may be an unpredictable, idiosyncratic reaction (*i.e.,* a drug effect that occurs in a small number of people due to age, genetics, or disease state). Prominent cardiovascular effects in response to overdose include rebound low blood pressure and slowed heart rate.

No specific treatment for imidazoline overexposure exists. Naloxone (an opioid blocker) has been used without consistent success. Gastric lavage is not recommended more than 1 hour after ingestion because the imidazolines are absorbed quickly after ingestion, leading to CNS depression and a greater risk of aspiration into the lungs. Activated charcoal may be used up to 1 hour after ingestion; but again, due to the CNS depression, there is a greater risk of aspiration into the lungs. Therefore, treatment of the clinical effects from

imidazolines is supportive, based on symptoms. For example, mechanical respiration would be administered to those with severe respiratory depression.

III. Ingestion and Injury Data

As discussed more extensively in the NPR, staff reviewed several sources for information on adverse health effects from ingestion of imidazolines. These sources are the National Electronic Injury Surveillance System (NEISS), and the FDA's Adverse Event Reporting System (AERS).

The CPSC's Directorate for Health Sciences maintains the Children and Poisoning (CAP) system, a subset of NEISS records containing additional information obtained through NEISS involving children under 5 years old. 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 approximately 100 hospitals selected as a probability sample of all 5,000+ U.S. hospitals with emergency departments. The system's foundation rests on emergency department surveillance data, but the system also has the flexibility to gather additional data at either the surveillance or the investigation level. Surveillance data enable the Commission to make timely national estimates of the number of injuries associated with (but not necessarily caused by) specific consumer products. This data also provides evidence of the need for further study of particular products. Subsequent follow-back studies yield important clues to the cause and likely prevention of injuries and deaths. For additional information on NEISS, see the CPSC's Web site at: *http://www.cpsc.gov/cpscpub/pubs/3002.html.*

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. We searched the CAP database for incidents between January 1997 and December 2011, involving household products that typically contain imidazolines. During that time, there were an estimated 6,650 emergency room-treated injuries associated with household products containing imidazolines involving children under 5 years old. Table 1 below shows the injury estimates for each of the product groups involved in these incidents. Four-fifths of the estimated injuries (82 percent) involved eye drops.

TABLE 1—ESTIMATED IMIDAZOLINE PRODUCT-RELATED INJURIES TO CHILDREN UNDER 5 YEARS OLD, 1997–2011, BY PRODUCT GROUP

Product	Estimated injuries	Coefficient of variation	Sample size	95% Confidence interval
Eye drops	5,437	0.18	161	3,564 – 7,309
Nose Sprays [2]	1,213	0.29	37	534 – 1891
Total	6,650	0.16	198	4,550 – 8,749

Source: U.S. Consumer Product Safety Commission National Electronic Injury Surveillance System and Children and Poisoning System, 2011.

As set forth in tabular form in the NPR, In-Depth Investigations (IDIs) were assigned in connection with certain NEISS-reported imidazoline ingestion incidents. A selection of these IDIs reveals various scenarios in which children between the ages of 13 months and 4 years gained access to imidazoline products including young children who removed caps from eye drop bottles left within their reach; obtained an eye drop bottle from an older sibling; used a chair to access an eye drop bottle in a medicine cabinet; and took a bottle of eye drops out of his mother's purse. *See* NPR, Table 2, section III.A (77 FR 3649), for a summary of IDIs of selected incidents.

The AERS is a database of voluntary reports from health care professionals and consumers, along with mandatory reports from manufacturers. AERS is maintained by the FDA and contains reports of adverse events and medication errors for all FDA-approved drugs and therapeutic biologic products. We asked the FDA for all AERS reports mentioning the imidazolines tetrahydrozoline, oxymetazoline, xylometazoline, or naphazoline. FDA provided 1,041 reports for 772 distinct cases for us to review involving both children and adults occurring between October 1968 and August 2010. We checked for cases related to imidazolines, excluded the cases with concomitant drugs, and determined that 67 cases (with 115 total reports) were in scope for consideration in this rulemaking.

Reports through the AERS system show a wide variety of adverse events associated with the use of imidazolines across all ages. The top three system/organ classes with reported adverse events were psychiatric disorders (52 reports); nervous system disorders (47 reports); and respiratory, thoracic, and mediastinal disorders (38 reports). Sixty-two out of 67 in-scope cases (93 percent) reported an adverse event in one of the top three system/organ classes. (Reports can include more than one adverse event, so individual reports may be recorded in more than one system/organ class.) Our review of these cases is contained in the January 11, 2012, Staff Briefing Package: *http://www.cpsc.gov/LIBRARY/FOIA/FOIA12/brief/imidazolines.pdf.*

The volumes of imidazoline ingestions in children (under the age of 5) that were reported from two sources, the FDA's AERS database (MedWatch reports) and the medical literature, ranged from several drops to a high of 30 mL (2 tablespoons). The volume ingested was unknown in several imidazoline cases. As set forth in Table 3 in the NPR, very serious adverse effects occurred in response to small oral doses of imidazolines. For example, a 2-year-old child who ingested between 1 and 1.5 mg of tetrahydrozoline, experienced decreased blood pressure and respiration, and he was placed on mechanical respiration in the pediatric intensive care unit for 18 hours. Also, a 16-month-old child who ingested between 1.25 and 2.5 mg of tetrahydrozoline experienced decreased heart rate, depressed respiration, and was admitted to the hospital overnight.

In MedWatch reports of adverse events occurring in response to ingestion of imidazolines, 43 cases occurred in children under 5 years old.

[2] The estimate for this category is highly variable due to small sample size and high coefficient of variation. These numbers should be interpreted with caution.

Tetrahydrozoline ingestions constituted the majority of the cases (88 percent). There were no reported deaths related to imidazoline ingestion. *See: http://www.cpsc.gov/LIBRARY/FOIA/FOIA12/brief/imidazolines.pdf:* January 11, 2012, Staff Briefing Package, for a complete list of cases.

The most recent imidazoline ingestion case cites the lowest dose of ingestion of which we are aware that caused severe adverse symptoms in a child. The case involved a 25-day-old infant who suffered apnea after being treated with tetrahydrozoline nasal drops (0.05 percent). The mother inadvertently administered the nasal drops by the oral route three times per day with 0.5 ml/day (0.25 mg). The immature kidney and liver function of the newborn caused the drugs to clear the newborn's system more slowly than in an adult. CPSC staff reviewing this case report considered the three doses of nasal drops to be additive and calculated the total dose for this case to be 0.75 mg. After the second dose, the child was not feeding well and had low muscle tone. Two hours after the second dose, he developed apnea. After the third dose was administered, the child was brought to the hospital and admitted with a respiratory rate of four breaths per minute and a slowed heart rate. The infant was treated with naloxone, resolving the apnea and bradycardia. After 2 days, the child was in good condition and was discharged. After follow-up 10 days later, the child was in normal condition (Katar et al. 2010).

Our review of the ingestion data is contained in: *http://www.cpsc.gov/LIBRARY/FOIA/FOIA12/brief/imidazolines.pdf:* January 11, 2012, Staff Briefing Package.

IV. Level for Regulation

The Commission is issuing a rule requiring special packaging for any over-the-counter or prescription product containing the equivalent of 0.08 milligrams or more of an imidazoline in a single package. The absorption of imidazolines after oral ingestion can lead to unpredictable and profound CNS depression, including depressed respiration and cardiovascular events. Data indicate that children under 5 years old are accidentally ingesting imidazoline-containing products. Even though death from imidazoline exposure is rare, many of these events result in serious life-threatening consequences requiring hospitalization and intensive care monitoring for recovery. *See* NPR, Section Table 3, section III.C (77 FR 3650), for a summary of relevant cases of imidazoline ingestion.

Mindlin (1966) reported a case in which a 1-year-old girl ingested ½ to 1 teaspoon (2.5–5 mL) of tetrahydrozoline eye drops and suffered CNS depression with slowed respiration and decreased heart rate. Based on this ingestion, recent publications define 2.5 mL tetrahydrozoline (0.05 percent, 1.25 mg) as the dose at which serious toxicity from imidazoline exposure can occur after ingestion (Holmes and Berman, 1999; Eddy and Howell 2000). The preamble to the proposed FDA rule for OTC nasal decongestants reported that the minimum oral dose of oxymetazoline in an adult causing measurable cardiovascular effects (on blood pressure and heart rate) was 1.8 mg of oxymetazoline (41 FR 38312, 38398 (September 9, 1976)). This minimum dose may be lower for children because they appear to be more sensitive to imidazoline effects than adults (Brainerd and Olmstead, 1956). Cases indicate that ingestion of as little as 0.75 mg of imidazolines can result in serious illness in children, requiring supportive therapy (Katar et al., 2010; Summary see Table 3). The most recent case of imidazoline ingestion is reviewed in section III of this preamble. It involved a 25-day-old infant who suffered apnea after being treated with tetrahydrozoline nasal drops (0.05 percent). CPSC staff reviewing this case report calculated the total dose for this case to be 0.75 mg, which is the lowest dose the ingestion of which we are aware, caused severe adverse symptoms in a child.

Because serious effects on the heart and breathing rates occur with the ingestion of as little as 0.75 mg of tetrahydrozoline, we consider this the lowest observed adverse effect level (LOAEL). All of the imidazolines cause potent central and peripheral sympathetic effects, but tetrahydrozoline has the highest potency for CNS sedative/depressive effects and the lowest potency for cardiac effects. Oxymetazoline and naphazoline are the most potent imidazolines for peripheral cardiac effects and have an 8–10 times lower maximum daily dose than tetrahydrozoline (0.4 mg, 0.3 mg and 3.2 mg, respectively). Xylometazoline and oxymetazoline have a longer duration of action than tetrahydrozoline (12 hrs., 10 hrs., and 4–6 hrs., respectively).

Applying a safety factor of 10 to the LOAEL to derive a recommended regulated level of 0.08 mg for all imidazolines is appropriate in order to protect children from serious health effects following ingestion of this family of drugs. The level of 0.08 mg would require all known imidazolines currently on the market to be placed in CR packaging. The assumptions underlying the use of safety factors are that by using these factors, both the public health and sensitive populations are protected. Further assumptions hold that humans are somewhere between 10 and 1,000 times more sensitive to some toxic agents than animals, and adults are less sensitive than children. Hence, a safety assessment can be conducted using the proper toxicological evaluation with different populations to establish the NOAEL (no observable adverse effect level) or its equivalent. We used a tenfold safety factor to divide the LOAEL to reach a NOAEL level.

The regulated dose level is expected reasonably to protect children under 5 years of age from serious personal injury or illness. The Commission proposed this level and received one comment on it, which we addressed in Section I of the preamble.

V. Statutory Considerations

A. Hazard to Children

As noted above, the toxicity data concerning children's oral ingestion of imidazolines demonstrate that they can cause serious illness and injury to children. Moreover, imidazolines are available to children in common household products, such as eye drops and nasal sprays. Products containing imidazolines currently do not use CR packaging. The Commission concludes that a regulation is needed to ensure that products subject to the regulation will be placed in CR packaging by any current, as well as new manufacturers.

Pursuant to Section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission finds that the degree and nature of the hazard to children from handling, using, or ingesting imidazolines is such that special packaging is required to protect children from serious illness. The Commission bases this finding on the toxic nature of imidazolines and the accessibility of products containing imidazolines in the home.

B. Technically Feasibility, Practicability, and Appropriateness

In issuing a standard for special packaging under the PPPA, the Commission also is required to find the special packaging is ''technically feasible, practicable and appropriate.'' 15 U.S.C. 1472 (a)(2). For special packaging to be technically feasible, the technology must be available, or can be readily developed and implemented to produce packaging that conforms to established standards. A package is practicable if the special packaging is adaptable to modern mass production

and assembly line techniques. Finally, packaging is appropriate if the packaging will adequately protect the integrity of the substance and will not interfere with its intended storage or use. All three of these conditions must be met before we can require special packaging for a product.

The definition of ''packaging'' is ''the immediate package or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household.'' The PPPA defines ''special packaging'' as packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of substance within a reasonable time and not difficult for normal adults to use properly. 15 U.S.C. 1471(4). The child-resistance and adult-use-effectiveness of special packaging are measured by performance, testing packaging with children and senior adults, respectively.

We evaluated packaging representative of OTC products that contain imidazolines. The specimens represent products from all four imidazoline families: naphazoline hydrochloride (HCL), oxymetazoline HCL, tetrahydrozoline HCL, xylometazoline, and a naphazoline HCL combination product. None of the samples used special packaging. The eye drops were packaged in squeeze-to-dispense plastic dropper bottles. The nasal spray was packaged in a plastic bottle with an attached metered-pump sprayer, and the nasal drops were packaged in a squeeze-to-dispense plastic dropper bottle. *See* January 11, 2012, Staff Briefing Package, for a more detailed discussion of the products: *http://www.cpsc.gov/library/foia/foia12/brief/imidazolines.pdf.*

With changes to package size and/or type, certain types of packaging, such as ASTM Type IA, ASTM Type ID, and a CR metered-pump sprayer design, are available to the market to replace the non-CR continuously threaded (NCRCT) and the non-CR (NCR) metered-spray pump packages. Product packaging assembly line techniques used for the NCR packages can be adapted for some of the CR packages already in the marketplace. Other product manufacturers may use packages that could require changes in assembly- and filling-line techniques. New package sizes also may need to be designed. These new packages would require new tools to be produced. It could take up to 2 years from initiating tool design to final production of a new package, depending upon the complexity of the package. The Commission did not receive any comments asserting that CR packaging for products containing imidazolines was not technically feasible, practicable, or appropriate; although two comments addressed the amount of time required to develop, test, and produce CR packaging for products containing imidazolines. As will be discussed in further detail in Section VI, we have determined that a 12-month effective date, with an additional 12-month conditional stay of enforcement will provide sufficient time for manufacturers to produce CR packaging in compliance with this rule.

Based on the foregoing, the Commission concludes that available data support the findings that CR packaging for household products containing imidazolines is technically feasible, practicable, and appropriate.

C. Other Considerations

In establishing a special packaging standard under the PPPA, the Commission must consider the following:

1. Reasonableness of the standard;
2. Available scientific, medical, and engineering data concerning special packaging and childhood accidental ingestions, illness, and injury caused by household substances;
3. Manufacturing practices of industries affected by the PPPA; and
4. Nature and use of the household substance.

15 U.S.C. 1472(b). The Commission has considered these factors with respect to the various determinations made in this notice, and finds that the rule is reasonable and otherwise appropriate.

VI. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than 1 year from the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n.

The Commission stated in the preamble to the NPR that because it could take up to 1 year to produce a new package for some companies, any final rule would become effective 1 year after publication of the final rule in the **Federal Register**.

As discussed in section I.C. of this preamble, the Commission received comments indicating that more than 12 months would be necessary to design, develop, test, and manufacture CR packaging for many of the products containing imidazolines currently on the market. Two commenters indicated that a design could be modified, tested, and in commercial use in approximately 24 months. The Commission agrees that this time seems reasonable because companies will need to develop custom packaging, and the FDA must approve the packaging for acceptable sterilization and stability qualities.

Because there are more than 60 products manufactured by approximately 45 companies that will be affected by this rule, and because the vast majority of these companies will likely require more than 1 year to comply with this rule, the Commission has determined to grant a 12-month conditional stay of enforcement of the rule for products containing the equivalent of 0.08 milligrams of imidazolines in one package, rather than require each manufacturer to request a stay of enforcement for each affected product. The Commission believes that it is important to establish accountability in meeting the CR requirements for products containing imidazolines within 24 months of the publication of this rule.

Therefore, the Commission sets the following conditions for the 1-year stay of enforcement. First, the manufacturer of an imidazoline product containing the equivalent of 0.08 milligrams of imidazolines or more must notify the Commission prior to the effective date of the final rule of its intent to avail itself of the stay, which notice shall include a detailed time line setting forth the steps necessary to produce CR packaging for its product(s) and the range of time anticipated for completion of each step. Manufacturers should be aware that submitting the required notice on or near the effective date of the rule may not allow Commission staff sufficient time to review their notice for completeness prior to the effective date of the rule. Second, each manufacturer providing notice of its intent to avail itself of the stay must submit quarterly reports to the Commission for each affected product, beginning on the effective date of the rule, and on or before the first day of each subsequent quarter during the one year stay period. The quarterly report must provide 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 that are subject to the rule. If a manufacturer fails to provide the above-referenced notice in a timely fashion or timely submit any quarterly report, its imidazoline-containing products will be subject to enforcement of the CR packaging

requirement set forth in this rule as of the effective date of the rule.

The rule would add a new paragraph 33 to 16 CFR 1700.14(a), which contains a list of substances requiring special packaging. Pursuant to § 1700.14(a), all substances listed in § 1700.14 must meet the requirements for special packaging contained in § 1700.20(a) (on testing procedures for special packaging). Section 1700.14(a)(33) provides that any over-the-counter or prescription product containing the equivalent of 0.08 milligrams or more of an imidazoline (tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline) in a single package, must be packaged in accordance with the provisions of § 1700.15(a), (b), and (c). Section 1700.15(a) contains general requirements for special packaging, such as the special packaging must continue to function with the effectiveness specifications set forth in § 1700.15(b). Section 1700.15(b), pertaining to effectiveness specifications, provides criteria that special packaging tested pursuant to § 1700.20 must meet. Finally, § 1700.15(c) provides that special packaging subject to this paragraph (c) may not be reused.

VII. Environmental Impact

Generally, our regulations are considered to have little or no potential for affecting the human environment, and environmental assessments and impact statements are not usually required. *See* 16 CFR 1021.5(a). More specifically, requiring CR packaging for certain imidazoline-containing products is not expected to have an adverse impact on the environment. Accordingly, the rule falls within the categorical exclusion in 16 CFR 1021.5(b)(2) for product certification rules and an environmental assessment or environmental impact statement is not required.

VIII. Executive Order 12988 (Preemption)

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. Section 7 of the PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, ''no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard.'' 15 U.S.C. 1476(a). A state or local standard may be excepted from this preemptive effect if: (1) The state or local standard provides a higher degree of protection from the risk of injury or illness than the PPPA standard; and (2) the state or political subdivision applies to the Commission for an exemption from the PPPA's preemption clause and the Commission grants the exemption through a process specified at 16 CFR part 1061. 15 U.S.C. 1476(c)(1). In addition, the federal government, or a state or local government, may establish and continue in effect a nonidentical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the federal, state, or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the rule regarding CR packaging for household products containing an imidazoline above the regulated level would preempt nonidentical state or local special packaging standards for such imidazoline-containing products.

IX. Regulatory Flexibility Act (Economic Analysis)

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act (RFA) generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. Section 603 of the RFA calls for agencies to prepare, and make available for public comment, an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. 5 U.S.C. 603. Section 605(b) of the RFA, however, states that this requirement does not apply if the head of the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities and the agency provides an explanation for that conclusion.

Nasal and ophthalmic products are classified within the NAICS 325412 *Pharmaceutical Preparation Manufacturing* industry. According to the U.S. Small Business Administration's Office of Advocacy, a firm classified within NAICS 325412 is considered a small business if the firm has fewer than 750 employees. Based on such classification, out of the approximately 45 firms that manufacture imidazoline-based eye drops and nasal sprays, approximately 20 firms are defined as ''small businesses.'' There may be more manufacturers, in particular, firms that manufacture under generic labels, which were not identified but that may be small businesses.

As noted in the NPR, the Commission's Directorate of Economic Analysis prepared a preliminary assessment of the impact of a rule to require special packaging for products containing imidazolines equivalent to 0.08 milligrams or more in a single package. Based on this assessment, the Commission concluded that the proposed requirement for products containing imidazolines, if finalized, would not have a significant impact on a substantial number of small businesses. The Commission requested additional information on the possible impact on small businesses, but we received no such comments. Moreover, the preliminary analysis demonstrated that the incremental costs of CR packaging for manufacturers are low, estimated at no more than a few cents per unit for imidazoline products, some of which costs manufacturers are likely to be able to pass on to consumers. The Commission concludes that the rule regarding CR packaging for certain imidazoline products would not have a significant economic impact on a substantial number of small entities.

X. References

Please see all citing references in staff's briefing package for the proposed rule, available at: *http://www.cpsc.gov/library/foia/foia12/brief/imidazolines.pdf* and for the final rule, available at *http://www.cpsc.gov/LIBRARY/FOIA/FOIA13/brief/imidazfinal.pdf.*

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission amends 16 CFR part 1700 to read as follows:

PART 1700—[AMENDED]

■ 1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91–601, secs. 1–9, 84 Stat. 1670–74, 15 U.S.C. 1471–76. Secs 1700.1 and 1700.14 also issued under Pub. L. 92–573, sec. 30(a), 88 Stat. 1231. 15 U.S.C. 2079(a).

■ 2. Section 1700.14 is amended by adding paragraph (a)(33) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) * * *

(33) *Imidazolines.* Any over-the-counter or prescription product containing the equivalent of 0.08

milligrams or more of an imidazoline (tetrahydrozoline, naphazoline, oxymetazoline, or xylometazoline) in a single package, must be packaged in accordance with the provisions of § 1700.15(a), (b), and (c).

* * * * *

Dated: November 29, 2012.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2012–29203 Filed 12–7–12; 8:45 am]

BILLING CODE 6355–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–68357; File No. S7–44–10]

RIN 3235–AK87

Extension of Dates for Certain Requirements and Amendment of Form 19b–4

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; extension of dates for certain requirements.

SUMMARY: The Commission is amending its regulations under the Securities Exchange Act of 1934 (''Exchange Act'') to extend the dates for certain requirements therein and amending the General Instructions to Form 19b-4 to clarify the process for submitting advance notices and security-based swap submissions to the Commission. The Commission is extending the dates with respect to the requirements that designated clearing agencies for which the Commission is the supervisory agency file advance notices and clearing agencies file security-based swap submissions with the Commission in an electronic format to dedicated email addresses to December 10, 2013 in order to prevent the scenario that such filings are required to be filed with the Commission through a system that is not yet technologically able to accept them.

DATES: The effective date for this release is December 10, 2012.

FOR FURTHER INFORMATION CONTACT: Kenneth Riitho, Special Counsel, at 551–5592; and Wyatt A. Robinson, Attorney-Adviser, at 551–5649, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–7010.

SUPPLEMENTARY INFORMATION:

I. Introduction

On June 28, 2012, the Commission adopted amendments to Rule 19b–4 and Form 19b–4 to define and describe when notices of proposed changes to rules, procedures, or operations are required to be filed by designated financial market utilities in accordance with Section 806(e) of Title VIII of the Dodd-Frank Act [1] (''Advance Notices''), to set forth the process for filing such Advance Notices with the Commission, and to specify the process for a clearing agency's submission for review of any security-based swap, or any group, category, type, or class of security-based swaps that the clearing agency plans to accept for clearing (''Security-Based Swap Submissions'').[2] The effective date for the amendments to Rule 19b–4 was August 13, 2012. The effective date for all amendments to Form 19b–4 and 17 CFR 249.819 is December 10, 2012.

Rule 19b–4(n)(1)(i) requires a DCA [3] for which the Commission is the supervisory agency to provide an Advance Notice to the Commission of any proposed change to its rules, procedures, or operations that could materially affect the nature or level of risks presented by such DCA.[4] Except as provided in Rule 19b–4(n)(1)(ii), a DCA for which the Commission is the supervisory agency is required to submit such Advance Notice to the Commission electronically on Form 19b–4. Rule 19b–4(n)(1)(ii) requires a DCA that files an Advance Notice with the Commission prior to December 10, 2012 to file such Advance Notice in an electronic format to a dedicated email address established by the Commission.[5]

Rule 19b–4(o)(2)(i) requires that except as provided in Rule 19b–4(o)(2)(ii), a clearing agency shall submit each Security-Based Swap Submission to the Commission electronically on Form 19b–4.[6] Rule 19b–4(o)(2)(ii) requires a clearing agency that files a Security-Based Swap Submission with the Commission prior to December 10, 2012 to file such Security-Based Swap Submission in electronic format to a dedicated email address established by the Commission.[7]

The amendments to Form 19b–4 contained in the Adopting Release provide that, among other things, after December 10, 2012, Advance Notices and Security-Based Swap Submissions, and amendments, extensions, and withdrawals thereto, shall be filed in an electronic format through the Electronic Form 19b-4 Filing System (''EFFS'').[8]

II. Discussion

A. Rules 19b–4(n)(1)(ii) and 19b–4(o)(2)(ii)

The Commission stated in the Adopting Release that it was in the process of designing and implementing EFFS system upgrades that are necessary for Advance Notices and Security-Based Swap Submissions to be filed through EFFS.[9] The Commission anticipated in the Adopting Release that the EFFS system upgrades would be completed no later than December 10, 2012.[10] Prior to December 10, 2012, DCAs for which the Commission is the supervisory agency are required to file Advance Notices and clearing agencies are required to file Security-Based Swap Submissions through dedicated email addresses established by the Commission.[11]

Though the Commission has made progress on designing and implementing the EFFS system upgrades since the date of the Adopting Release, the Commission has determined that additional time is required to design, test, and implement the EFFS system upgrades. Therefore, the Commission is amending Rule 19b–

[1] Section 806(e) of Title VIII of the Dodd-Frank Act requires any financial market utility designated by the Financial Stability Oversight Council (''Council'') as systemically important to file with its supervisory agency 60 days advance notice of changes to its rules, procedures, or operations that could materially affect the nature or level of risk presented by the financial market utility. 12 U.S.C. 5465(e)(1)(A).

[2] *See* Securities Exchange Act Release No. 67286 (June 28, 2012), 77 FR 41602 (July 13, 2012) (''Adopting Release'').

[3] Six clearing agencies registered with the Commission are DCAs: Chicago Mercantile Exchange Inc. (''CME''), The Depository Trust Company (''DTC''), Fixed Income Clearing Corporation (''FICC''), ICE Clear Credit (''ICC''), National Securities Clearing Corporation (''NSCC''), and The Options Clearing Corporation (''OCC''). However, the Commission is the supervisory agency for only DTC, FICC, NSCC, and OCC.

[4] *See* 17 CFR 240.19b–4(n)(1)(i).

[5] *See* 17 CFR 240.19b–4(n)(1)(ii). Currently, DCAs file Advance Notices with the Commission via the dedicated email address *AdvanceNoticeFilings@sec.gov.*

[6] *See* 17 CFR 240.19b–4(o)(2)(i).

[7] *See* 17 CFR 240.19b–4(o)(2)(ii). The Commission has established the dedicated email address *SBSwapsSubmissions@sec.gov* for Security-Based Swap Submissions.

[8] Adopting Release at 41653, 41654. Currently, EFFS is used by self-regulatory organizations (''SRO''), which include registered clearing agencies, to file proposed rule changes electronically with the Commission pursuant to Exchange Act Section 19(b) and Rule 19b–4.

[9] *See* Adopting Release at 41606, 41620.

[10] *See id.*

[11] *See id.* The Commission has maintained a dedicated email address to receive Advance Notices and a dedicated email address to receive Security-Based Swap Submissions since July 19, 2012. The Commission has received five Advance Notices and zero Security-Based Swap Submissions through November 28, 2012.