

Issued in Renton, Washington, on June 14, 2005.

**Kevin M. Mullin,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1700

#### Poison Prevention Packaging; Notice of Lifting of Stay of Enforcement for Lidoderm® Patch

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Lifting Stay of Enforcement.

**SUMMARY:** This notice announces the Commission's decision to lift a stay enforcement of special packaging requirements for the drug Lidoderm®. The Commission issued the stay in August of 2001. The manufacturer of Lidoderm® is now using packaging that complies with special packaging requirements.

**DATES:** The action will be effective on June 27, 2005.

**FOR FURTHER INFORMATION CONTACT:** Geri Smith, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-7529.

**SUPPLEMENTARY INFORMATION:** In 1995, the Commission issued a regulation under the Poison Prevention Packaging Act ("PPPA") requiring child resistant ("CR") packaging for lidocaine products with more than 5 milligrams (mg) of lidocaine in a single package. 16 CFR 1700.14 (a)(23).

Lidoderm® is a single-use dermal patch that contains lidocaine. Lidoderm® is prescribed to treat post-herpetic neuralgia ("PHN"), a rare, chronic condition that results from nerve injury caused by shingles. Each Lidoderm® patch contains 700 mg lidocaine. Under the PPPA, if a product requires special packaging, the immediate container of the product must be CR. This means that for Lidoderm® to comply with the PPPA, each patch must be packaged in an individual CR pouch, or multiple patches that are not packaged in individual CR pouches must be packaged together in a single resealable CR pouch without envelopes.

On August 14, 2000, the manufacturer of Lidoderm®, Endo Pharmaceuticals Inc. ("Endo"), petitioned the Commission for a partial exemption for

Lidoderm® from special packaging requirements stating that "it is not practicable to market each Lidoderm® patch in a child-resistant envelope." At that time, Lidoderm® was marketed in the form of five patches inside a non-CR resealable envelope. One non-CR carton of Lidoderm® contained six envelopes (each envelope contained five patches) for a total of 30 patches per carton. Endo asserted that placing each patch in a CR envelope would be cost prohibitive and would force it to discontinue production of Lidoderm®.

The Commission declined to issue the exemption that Endo requested because, as explained in the August 30, 2001 stay notice, under the PPPA, the expense of special packaging cannot be the basis for an exemption. 66 FR 45842. However, the Commission did agree to stay enforcement of the special packaging requirements for Lidoderm® under certain conditions specified in the notice of the stay. Id.

Endo has informed the Commission that it is now packaging Lidoderm® patches in CR packaging in full compliance with the PPPA requirements (each single-use patch is packaged in an individual CR pouch). Because the stay of enforcement is no longer necessary, the Commission has decided to lift the stay. This means that Lidoderm®, like any other item requiring special packaging under the Commission's PPPA regulations, must comply with all PPPA special packaging requirements.

Dated: June 22, 2005.

**Todd Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 05-12673 Filed 6-24-05; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD13-05-022]

**RIN 1625-AA00**

#### Safety Zones: Fireworks Displays in the Captain of the Port Portland Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing safety zones on the waters of the Suislaw, Willamette, Columbia, Coos, and Chehalis Rivers, located in the Area of Responsibility of the Captain of the Port, Portland, Oregon, during fireworks displays. The Captain of the

Port, Portland, Oregon, is taking this action to safeguard watercraft and their occupants from safety hazards associated with these displays. Entry into these safety zones is prohibited unless authorized by the Captain of the Port.

**DATES:** This rule is effective from 9:30 p.m. on July 2, 2005 until 11 p.m. on July 23, 2005.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket (CGD13-05-022) and are available for inspection or copying at the U.S. Coast Guard MSO/Group Portland, 6767 N. Basin Ave, Portland, Oregon 97217 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Petty Officer Charity Keuter, c/o Captain of the Port, Portland 6767 N. Basin Avenue, Portland, Oregon 97217, (503) 240-2590.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. Publishing a NPRM would be contrary to public interest since immediate action is necessary to ensure the safety of vessels and spectators gathering in the vicinity of the various fireworks launching barges and displays. If normal notice and comment procedures were followed, this rule would not become effective until after the dates of the events. For this reason, publishing an NPRM and making this rule effective less than 30 days after publication in the **Federal Register** in this case would be impracticable and contrary to the public interest.

##### Background and Purpose

The Coast Guard is establishing temporary safety zones to allow for safe fireworks displays. All events occur within the Captain of the Port, Portland, OR, Area of Responsibility (AOR). These events may result in a number of vessels congregating near fireworks launching barges and sites. The safety zones are needed to protect watercraft and their occupants from safety hazards associated with fireworks displays. This safety zone will be enforced by representatives of the Captain of the Port, Portland, Oregon. The Captain of the Port may be assisted by other Federal and local agencies.

## Discussion of Rule

This rule, for safety concerns, will control vessels, personnel and individual movements in a regulated area surrounding the fireworks event indicated in section 2 of this Temporary Final Rule. Entry into these zones is prohibited unless authorized by the Captain of the Port, Portland or his designated representative. Captain of the Port, Portland, Oregon, will enforce these safety zones. The Captain of the Port may be assisted by other Federal and local agencies.

## Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed this rule under that Order. This rule is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures act of DHS is unnecessary. This expectation is based on the fact that the regulated areas established by the proposed regulation will encompass small portions of the Columbia, Willamette, Coos, Chehalis and Siuslaw Rivers in the Portland AOR on different dates, all in the evening when vessel traffic is low.

## Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit a portion of the Willamette, Columbia, Coos, Chehalis and Siuslaw Rivers during the times mentioned in section 2(a)(1–8) at the conclusion of this rule. These safety zones will not have significant

economic impact on a substantial number of small entities for the following reasons. This rule will be in effect for only sixty minutes during two evenings when vessel traffic is low. Traffic will be allowed to pass through the zone with the permission of the Captain of the Port or his designated representatives on scene, if safe to do so.

## Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

## Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

## Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

## Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by State, local, or tribal government, in the aggregate, or the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such

expenditure, we do discuss the effects of this rule elsewhere in this preamble.

## Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

## Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

## Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

## Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian tribal governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

## Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

## Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these

standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

## Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. This rule establishes safety zones which have a duration of no more than two hours each. Due to the temporary safety zones being less than one week in duration, an Environmental Checklist and Categorical Exclusion is not required.

## List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for Part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A temporary section 165.T13–006 is added to read as follows:

### § 165.T13–006 Safety Zones: Fireworks displays in the Captain of the Port Portland Zone.

(a) *Safety Zones.* The following areas are designated safety zones:

(1) Florence Chamber 4th of July Fireworks Display, Florence, OR:

(i) Location. All water of the Siuslaw River enclosed by the following points: 43°58'05" N, 124°05'54" W following the

shoreline to 43°58'20" N, 124°04'46" W then south to 43°58'07" N, 124°04'40" W following the shoreline to 43°57'48" N, 124°05'54" W then back to the point of origin.

(ii) This paragraph will be enforced from 9:30 p.m. to 11 p.m. on July 4, 2005.

(2) Oaks Park July 4th Celebration, Portland, OR

(i) Location. All water of the Willamette River enclosed by the following points: 45°28'26" N, 122°39'43" W following the shoreline to 45°28'10" N, 122°39'54" W then west to 45°28'41" N, 122°40'06" W following the shoreline to 45°28'31" N, 122°40'01" W then back to the point of origin.

(ii) This paragraph will be enforced from 9:15 p.m. to 10:30 p.m. on July 4, 2005.

(3) Rainier Days Fireworks Celebration, Rainier, OR

(i) Location. All water of the Columbia River enclosed by the following points: 46°06'04" N, 122°56'35" W following the shoreline to 46°05'53" N, 122°55'58" W then south to 46°05'24" N, 122°55'58" W following the shoreline to 46°05'38" N, 122°56'35" W then back to the point of origin.

(ii) This paragraph will be enforced from 9:30 p.m. to 11 p.m. on July 9, 2005.

(4) Ilwaco July 4th Committee Fireworks, Ilwaco, WA

(i) Location. All water of the Columbia River extending out to a 700' radius from the launch site at 46°18'17" N, 124°01'55" W.

(ii) This paragraph will be enforced from 9:30 p.m. to 11 p.m. on July 2, 2005.

(5) Milwaukie Centennial Fireworks Display, Milwaukie, OR:

(i) Location. All water of the Willamette River enclosed by the following points: 45°26'41" N, 122°38'46" W following the shoreline to 45°26'17" N, 122°38'36" W then west to 45°26'17" N, 122°38'55" W following the shoreline to 45°26'36" N, 122°38'50" W then back to the point of origin.

(ii) This paragraph will be enforced from 9:30 p.m. to 11 p.m. on July 23, 2005.

(6) Splash Aberdeen Waterfront Festival, Aberdeen, WA:

(i) Location. All water of the Chehalis River extending out to 500 feet of the following points: 46°58'40" N, 123°47'45" W.

(ii) This paragraph will be enforced from 9:30 p.m. to 11 p.m. on July 4, 2005.

(7) City of Coos Bay July 4th Celebration, Coos Bay, OR:

(i) Location. All water of the Coos River extending out to 1200 feet of the

following points: 43°22'12" N, 124°12'39" W.

(ii) This paragraph will be enforced from 9:30 p.m. to 11 p.m. on July 4, 2005.

(8) Booming Over the Bay Annual Fireworks, Westport, WA:

(i) Location. All water of the Chehalis River extending out to 500 feet of the following points: 46°54'18" N, 124°06'07" W.

(ii) This paragraph will be enforced from 9 p.m. to 11 p.m. on July 4, 2005.

(b) *Regulations.* In accordance with the general regulations in Section 165.23 of this part, no person or vessel may enter or remain in this zone unless authorized by the Captain of the Port or his designated representatives.

Dated: June 17, 2005.

**Paul D. Jewell,**

*Captain, U.S. Coast Guard, Captain of the Port, Portland, OR.*

[FR Doc. 05–12649 Filed 6–24–05; 8:45 am]

**BILLING CODE 4910–15–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

[COTP Jacksonville 05–051]

RIN 1625–AA00

### Safety Zone; St. Johns River, Jacksonville, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone around a fireworks barge as it launches fireworks. The rule prohibits entry into the security zone without the permission of the Captain of the Port Jacksonville or his designated representative. The rule is needed to protect participants, vendors, and spectators from the hazards associated with the launching of fireworks.

**DATES:** This rule is effective from 9:15 p.m. on July 4, 2005, until 10:15 p.m. on July 4, 2005.

**ADDRESSES:** Documents mentioned in this preamble as being available in the docket are part of docket [COTP Jacksonville 05–051] and are available for inspection and copying at Coast Guard Marine Safety Office Jacksonville, 7820 Arlington Expressway, Suite 400, Jacksonville, Florida 32211, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Jamie Bigbie at Coast Guard