

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

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*Acting Manager, Transport Airplane
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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.

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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.