CONSUMER PRODUCT SAFETY COMMISSION

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

AGENCY: Consumer Product Safety Commission.

ACTION: Stay of enforcement.

SUMMARY: This notice announces the Commission's decision to stay enforcement of special packaging requirements for the orphan drug, Lidoderm®. The Commission will stay enforcement under the conditions stated at the end of this notice.

DATES: The stay will be effective on August 30, 2001.

FOR FURTHER INFORMATION CONTACT: Geri Smith, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0608, extension 1160.

SUPPLEMENTARY INFORMATION:

A. Background

Under the Poison Prevention Packaging Act (''PPPA''), the Commission has the authority to require special packaging for drugs (as well as certain other household products) if it finds that child resistant (''CR'') packaging is necessary to protect children from serious personal injury or illness from handling using or ingesting the drug and that CR packaging is technically feasible, practicable and appropriate. 15 U.S.C. 1472(a). In 1995, the Commission issued a rule requiring 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 dermal patch that contains lidocaine. Each Lidoderm® patch contains 700 mg lidocaine. Lidoderm® is marketed in the form of five patches inside a non-CR resealable foil envelope to maintain the integrity of the product. One non-CR carton of Lidoderm® contains six envelopes (each envelope contains five patches) for a total of 30 patches per carton.

In May 1999, Commission staff discovered that Lidoderm® was being packaged in non-CR packaging and notified the distributor, Endo Pharmaceuticals Inc. (''Endo'') of the special packaging requirement for lidocaine products. To comply with the PPPA, the immediate container for a product that requires special packaging must be CR. Thus, for Lidoderm® patches, each patch must be packaged in an individual CR pouch or a single resealable CR pouch must contain all of the patches (i.e., no carton and no foil envelope, only a resealable CR pouch). At Endo's request, the Commission granted Endo a temporary stay of enforcement on May 15, 2000, on the condition that Endo provide pharmacists with an outer CR package to dispense the product while it was developing a plan and timeline to package each patch in a CR pouch.

On August 14, 2000, 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.'' The petitioner argues that to do so is cost prohibitive and would force it to discontinue production of Lidoderm®. Endo asks for an exemption so that it may replace the non-CR carton with the CR pouch so that the six envelopes (5 patches per envelope) are marketed in the CR pouch, not in the non-CR carton.

B. The Product

Lidoderm® is a lidocaine-containing dermal patch available only by prescription. It is manufactured by Teikoku Seiyaku, Co., Ltd., a Japanese company, and the only manufacturer the Food and Drug Administration (''FDA'') has approved to manufacture Lidoderm®. Endo is the only distributor the FDA has approved for Lidoderm®. The FDA designated Lidoderm® as an orphan drug on October 24, 1995 and approved it for marketing on March 19, 1999. Endo started marketing Lidoderm® on September 15, 1999. Orphan drugs are intended for rare diseases affecting less than 200,000 people or affecting more than 200,000, but for which there is no expectation that the costs of drug development will be recovered from sales. The Orphan Drug Act encourages the development of orphan drugs, through economic incentives such as tax credits for clinical research and seven years of marketing exclusivity.

Lidoderm® is prescribed to treat post-herpetic neuralgia (''PHN''), a rare, chronic condition that results from nerve injury caused by shingles. Shingles occurs following reactivation of the herpes zoster virus (the same virus responsible for chickenpox) and is characterized by painful fluid-filled skin blisters. PHN is more common in the elderly. Approximately 10% of all patients with shingles develop PHN. Endo estimates that about 200,000 Americans have PHN. There is no cure for PHN, and treatment is aimed at controlling the pain by various methods including drug therapy (e.g., analgesics, antidepressants, topical anesthetics, and anticonvulsants), acupuncture, and nerve block.

Each carton of Lidoderm® contains 30 patches packaged in six resealable foil envelopes with five patches per envelope. Neither the carton nor the individual envelopes are CR. Currently, Endo is including a CR reclosable pouch large enough for the six envelopes in each carton. Each Lidoderm® patch is 22 square inches (10 cm x 14 cm) and contains 700 mg of lidocaine. The amount of lidocaine systemically absorbed from Lidoderm® depends on both the duration of exposure and the surface area of skin covered. The recommended dose is up to three patches at one time only once for up to 12 hours in a 24-hour period. Patches may be cut into smaller sizes prior to removal of the release liner. The petitioner did not provide data related to the stability of the lidocaine in a cut or used patch, but instructions on the product envelope advise that the patch adhesive contains water and will dry out if the package is left open.

According to the petition, Lidoderm® is unlike other patch systems in that the lidocaine in Lidoderm® is not contained in a reservoir, but is embedded in the patch adhesive. Therefore, the patch releases a low level of lidocaine into the skin over a long time period ensuring that it produces analgesia (pain reduction) rather than anesthesia (numbness). Since only a small percentage (3% ± 2%) of lidocaine is absorbed dermally from the Lidoderm® patch when used therapeutically, about 95% of the lidocaine will remain in a used patch. Endo states that the lidocaine is less accessible from this patch system than from other formulations (such as, creams and liquids) and that a child would need to chew or suck on the patch for some time before any lidocaine would be absorbed through the mouth or swallowed. However, there are no oral absorption data indicating the extent of oral exposure necessary for a child to absorb a toxic dose. Endo provides a warning with the product to store and dispose of Lidoderm® out of the reach of children and pets.

C. Endo's Request

In its petition, Endo asks essentially that the temporary stay of enforcement granted by the Commission on May 15, 2000, be made a permanent exemption from special packaging requirements. Endo argues that full compliance with the PPPA, which requires that the immediate container of a lidocaine-containing drug be CR, would be cost-prohibitive. Endo maintains that the costs of new equipment, plant re-engineering, and testing for FDA approval are prohibitive and would

force them to discontinue marketing Lidoderm®. Teikoku estimates a large total cost for the changes required to place each patch in a CR pouch. This includes the cost of: (1) New envelope processing machines; (2) producing three FDA submission batches; (3) extended specification compliance testing on all three batches; (4) accelerated stability testing; and (5) real-time stability testing. The petitioner maintains that ''manufacturing and packaging one patch per envelope would result in a significant increase in the cost of manufacturing Lidoderm® because there would be significant increases in the amount of labor and materials.''

Endo also argues that it would take much longer than the current packaging method to produce an equivalent amount of Lidoderm® in individual CR pouches. Endo states that this change in the production schedule for Lidoderm® is an ''undue burden'' for Teikoku because it would affect Teikoku's production of other products. Teikoku is unwilling to allow another manufacturer to take over production because the manufacturing process for Lidoderm® is proprietary. CPSC has not been able to verify the accuracy of Endo's cost estimates. However, Endo maintains that it will discontinue production of Lidoderm® if forced to place each patch in CR packaging. If that were to happen, Lidoderm® would no longer be a therapeutic option for PHN patients.

D. PPPA Requirements for an Exemption

The Commission's regulations provide for a company or other interested persons to submit a petition requesting an exemption from PPPA requirements. 16 CFR part 1702. Those rules require a petitioner to provide a justification for the exemption based on one or more of the following grounds: (1) Special packaging is not necessary to protect children from serious injury or illness from the substance; (2) special packaging is not technologically feasible, practicable, or appropriate for the substance; and/or (3) special packaging is incompatible with the substance. 16 CFR 1702.7. Similarly, the Commission's rules provide that if the Commission finds that a petitioner has presented ''reasonable grounds'' for an exemption, it shall publish a proposed amendment exempting that substance from special packaging requirements.

''Reasonable grounds'' are:

Information and data sufficient to support the conclusion that:

(a) The degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance, or

(b) Special packaging is not technically feasible, practicable, or appropriate for the substance, or

(c) Special packaging is incompatible with the particular substance.

16 CFR 1702.17.

In its petition, Endo states as its justification that ''it is not practicable to market each Lidoderm® patch in a child-resistant envelope.'' Endo argues that the high cost and practicable difficulties, discussed above, of packaging each individual Lidoderm® patch in a CR container justify an exemption.

Endo states that there have been no reports of adverse events or accidental exposures of Lidoderm® to children. Although Endo states that Lidoderm® does not present the same degree of poisoning risk to children as other lidocaine products, Endo does not argue and does not provide any data indicating that the lidocaine in Lidoderm® patches is not toxic to children. Thus, Endo does not seem to be relying on lack of toxicity to children as a justification for an exemption.

Legislative history of the PPPA indicates that the term ''practicability'' means that ''special packaging meeting the standard would be susceptible to modern mass-production and assembly-line techniques.'' S. Rep. 845 91st Cong., 2d Sess 10 (1970). Endo does not argue that Lidoderm® cannot be produced with CR packaging that complies with the PPPA. Rather, Endo asserts that such packaging would be so costly that it could not continue to market Lidoderm®. Thus, the Commission cannot make the requisite finding that CR packaging would not be practicable for Lidoderm® that would justify an exemption under the Commission's regulations.

E. Stay of Enforcement

Endo has, however, presented information indicating the need for the orphan drug Lidoderm®, the prohibitive cost involved in CR packaging for each Lidoderm® patch, the limited market for the product, and the protection for children that would be provided by packaging Lidoderm® patches in an outer CR package. The Commission finds that these circumstances justify the stay of enforcement. The stay will be issued with the following conditions:

1. Endo Pharmaceuticals must, as stated in section IV of the petition, ''replace the outer carton for Lidoderm® with a CR reclosable pouch containing six resealable foil envelopes (5 patches per envelope)'' with instructions to pharmacists that they must dispense Lidoderm® envelopes in the outer pouch. Moreover, additional outer CR pouches must be provided to pharmacists upon request in order to accommodate prescriptions of less than a full package of 30 patches.

2. The outer CR package must bear a prominent and conspicuous label stating the following:

''**WARNING:**

New and used patches could harm small children if chewed or swallowed. Envelopes in this package are NOT child resistant. You MUST keep envelopes inside this child-resistant package with the zipper closed. Keep new and used patches out of the reach of children.''

3. The envelopes containing the five Lidoderm® patches (the immediate packaging) must continue to bear the warning label ''Package not child resistant. Keep used and unused patches out of the reach of children.''

4. Lidoderm® must remain designated by the FDA as an orphan drug indicated solely for the treatment of PHN. If Endo obtains orphan drug status for Lidoderm® for the treatment of any other condition, Endo shall direct to the Commission's Office of Compliance, a request for a determination of whether the terms of this stay shall apply to the product.

5. Lidoderm® must be manufactured only by Teikoku Seiyaku Co., Ltd, at its present location in Japan under the current material operating conditions and procedures described in Section V of the petition. Any questions related to changes in such operating conditions or procedures can be directed to the Commission's Office of Compliance.

6. Endo Pharmaceuticals must (1) notify the Commission's Directorate for Health Sciences within five business days of becoming aware of any poisonings or other exposures (i.e., physical contact) to the patches by children under 5 years old; and (2) purchase American Association of Poison Control Center data for Lidoderm® once a year and submit it to the Commission's Directorate for Health Sciences.

7. Endo must report annually to the Office of Compliance confirming that the conditions upon which the stay has been granted remain in effect. Additionally, Endo must notify the Office of Compliance 30 days in advance of any change that materially affects its compliance with any provision of the stay.

Dated: August 24, 2001.

Todd Stevenson,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 01–21880 Filed 8–29–01; 8:45 am]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Availability of Funds for Grants To Support the Martin Luther King, Jr. Service Day Initiative; Correction

AGENCY: Corporation for National and Community Service.

ACTION: Notice; correction.

SUMMARY: The Corporation for National and Community Service published a document in the **Federal Register** of August 7, 2001, concerning grants to support service opportunities in conjunction with the federal legal holiday honoring the birthday of Martin Luther King, Jr. on January 21, 2002. The document contained an incorrect telephone number.

FOR FURTHER INFORMATION CONTACT: For further information, contact Rhonda Taylor, (202) 606–5000, ext. 282. You may request this notice in an alternative format for the visually impaired by calling (202) 606–5000, ext. 262. The Corporation's T.D.D. number is (202) 565–2799 and is operational between the hours of 9 a.m. and 5 p.m. local time in Washington, DC.

Correction

In the **Federal Register** of August 7, 2001, in FR Doc. 01–19682, on page 41207, correct the telephone number for the Corporation's office in North Carolina to read ''(919) 856–4731''.

Dated: August 24, 2001.

Rhonda Taylor,

Associate Director, Office of Public Liaison, Coordinator of National Service Programs.

[FR Doc. 01–21903 Filed 8–29–01; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0024]

Federal Acquisition Regulation; Submission for OMB Review; Buy American Act—Balance of Payments Program Certificate

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance (9000–0024).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Buy American Certificate. A request for public comments was published at 66 FR 37215, July 17, 2001. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before October 1, 2001.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVP), 1800 F Street, NW., Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Cecelia Davis, Acquisition Policy Division, GSA (202) 219–0202.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Buy American Act requires that only domestic end products be acquired for public use unless specifically authorized by statute or regulation, provided that the cost of the domestic products is reasonable. The Balance of Payments Program, unless specifically exempted by statute or regulation, the Government gives preferences to the acquisition of domestic end products or services, provided that the cost of the domestic items is reasonable. The Balance of Payments Program differs from the Buy American Act in that it applies to acquisitions for use outside the United States.

The Buy American Act—Balance of Payments Program Certificate collects data for both the Buy American Act and Balance of Payments Program. At one time, there was a separate certificate to collect information on the Balance of Payments Program (9000–0023) and the Buy American Act (9000–0024). Since the last renewal, the two certificates have been combined to collect the data for both. Therefore, two separate information collections (9000–0023 and 9000–0024) are no longer needed. Information collection 9000–0023, expires on September 30, 2001, and will not be renewed. Information collection 9000–0024 collects data for both the Buy American Act and the Balance of Payments Program.

B. Annual Reporting Burden

Respondents: 3,906.
Responses Per Respondent: 15.
Total Responses: 58,590.
Hours Per Response: .167.
Total Burden Hours: 9,785.

Obtaining Copies of Proposals

Requester may obtain a copy of the proposal from the General Services Administration, FAR Secretariat (MVP), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0024, Buy American Act—Balance of Payments Program Certificate, in all correspondence.

Dated: August 24, 2001.

Gloria Sochon,

Acting Director, Acquisition Policy Division.

[FR Doc. 01–21913 Filed 8–29–01; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before October 1, 2001.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Crystal Thomas, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10202, New