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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

Portable Generators; Advance Notice of Proposed Rulemaking; Request for Comments and Information

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice of proposed rulemaking (“ANPR”) initiates a rulemaking proceeding that could result in mandatory performance standards for portable generators. The notice discusses a broad range of regulatory approaches that could be used to reduce portable generator-related deaths and injuries, particularly those related to carbon monoxide poisoning.¹ The Commission invites public comment on these alternatives and any other approaches that could reduce portable generator-related deaths and injuries due to carbon monoxide poisoning, as well as shock/electrocution, fire, and burns. The Commission also invites interested persons to submit an existing standard, or a statement of intent to modify or develop a voluntary standard, to address the risk of injury described in this ANPR. The Commission issued a separate notice of proposed rulemaking (NPR) at 71 FR 50003 on August 24, 2006, relating specifically to enhancing the effectiveness of warning labels for portable generators, and invited public comment on its proposal.

DATES: Written comments and submissions in response to this ANPR must be received by the Office of the Secretary not later than February 12, 2007.

¹ Acting Chairman Nancy A. Nord and Commissioner Thomas H. Moore each filed a statement. The statements are available from the Office of the Secretary or on the Commission’s Web site at <http://www.cpsc.gov>.

ADDRESSES: Comments may be filed by e-mail to cpssc-os@cpssc.gov. Comments may also be filed by facsimile to (301) 504–0127 or by mail or delivery, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland. Comments should be captioned “Portable Generator ANPR.”

FOR FURTHER INFORMATION CONTACT: Janet L. Buyer, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504–7542; e-mail: jbuyer@cpssc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

One of CPSC’s strategic goals is to reduce the number of non-fire carbon monoxide (CO) poisoning deaths associated with consumer products by 20% from the average of the years 1999 and 2000 by the year 2013. The total yearly estimated non-fire related CO deaths for each of the years 1999 through 2002 are 109, 138, 130 and 188, respectively. Since 1999, the percentage of estimated CO poisoning deaths specifically associated with generators has been increasing annually. In 1999, generators were associated with 7 (6%) of the total yearly estimated CO poisoning deaths for that year. In 2000, 2001 and 2002, they were associated with 19 (14%), 22 (17%) and 46 (24%) deaths out of the total estimates for each of those years.

Staff began working on ways to reduce CO emissions from engine-powered equipment, including portable generators, in 2002. This work included testing portable generators, analyzing the CO hazard related to generators, investigating the feasibility of a gas-sensing interlock mechanism and making recommendations to the voluntary standards organization, Underwriters Laboratories, on ways to reduce CO emissions and other hazards associated with portable generators. Staff then sought guidance from the Commission on how to proceed. On October 12, 2005, Commission Chairman Hal Stratton sent a memorandum to the Executive Director directing the staff to undertake a thorough review of the status of portable generator safety in light of CO deaths and injuries attributable to consumer

use of portable generators. The staff was directed to address, at a minimum, the following issues: (1) Feasibility of safety cut-offs that would shut down a generator before CO reaches unsafe levels; (2) sufficiency of warning labels to address the danger of CO poisoning associated with portable generators used within or near residences; (3) development of portable generator performance requirements that would substantially reduce CO emissions; (4) feasibility of weatherization of portable generators (including ground fault circuit interrupter (GFCI) protection) for use in wet and/or cold outdoor environments; (5) creation of an information and education campaign; and (6) potential benefits of the creation of a private sector consortium made up of generator manufacturers that would cooperatively develop a technical solution that adequately addresses the current CO poisoning hazard.

B. The Product

Portable generators offer a means of providing electrical power to a location that either temporarily lacks it or is not provided with electrical service at all. A portable generator has an internal combustion engine to produce rotational energy, which is used to generate electricity. The engine may be fueled by gasoline, diesel, natural gas, or liquid propane. Most importantly, it is the engine that produces carbon monoxide as a product of combustion.

The estimated number of portable generators owned by households ranged from about 9.2 million units in 2002 to 10.6 million units in 2005. Over 1 million units are estimated to have been purchased by consumers in each of the years 2003–2005. Approximately 40% of portable units purchased by consumers in these 3 years were in the 5.0 kilowatt (kW) to less than 6.5 kW power output range.

C. Risks Posed by Portable Generators

Generators pose four main hazards: CO poisoning, shock/electrocution, fire, and thermal contact burns. For the 16 year period 1990 through 2005, there have been at least 351 CO poisoning fatalities associated with generators reported to CPSC. For the same 16-year period, there have been at least 10 electrocution deaths and 8 fire-related deaths associated with generators reported to CPSC. Since some deaths are reported to CPSC months or years after

an incident occurred, counts for recent years may not be as complete as counts for earlier years.

Because the majority of deaths reported to CPSC involving portable generators are associated with the CO poisoning hazard, the staff's review of the voluntary standards and proposed alternatives has focused primarily on the CO hazard.

D. Voluntary Standards

Staff reviewed existing voluntary standards to determine the extent to which they may address CO poisoning hazards associated with generators. There is currently no U.S. voluntary safety standard specifically applicable to portable generators.²

1. UL 2201 "Portable Engine-Generator Assemblies," Proposed First Edition

Underwriters Laboratories (UL) is currently developing the first edition of UL 2201 "Portable Engine-Generator Assemblies," through an ANSI-accredited committee process using a Standards Technical Panel (STP). There have been four draft versions of the proposed UL 2201 standard since February 2003. CPSC staff has submitted comments and recommended the following for inclusion in the proposed standard: (1) Performance requirements to address consumer exposure to unsafe CO emissions; (2) performance requirements that would permit safe outdoor use of generators in rain and other poor weather conditions; (3) improvements to labeling, markings and instructions for portable generators to adequately warn consumers of the CO hazard and inform them of appropriate safety measures; and (4) requirements for tests to verify safe generator operability when used in cold, damp weather, which may cause icing of the air intake tract of the generator engine, thereby degrading its ability to operate outdoors. In December 2004, the UL STP decided that the draft proposed standard would move forward without performance requirements to address CO emissions and weatherization or testing requirements for cold weather operation.

Because consensus had not yet been achieved on the draft UL standard, in April 2006, UL issued an Outline of Investigation for portable generators which serves as the requirements with

which a product must conform in order to be eligible to bear the UL mark. UL's Outline of Investigation includes requirements for cautionary markings and advisory information as well as features that will facilitate safe use in rain (rainproof enclosure, rain tight while-in-use receptacle covers, and ground fault circuit protection on all alternating current output circuits).

Although such Outlines of Investigation are not consensus standards, they represent UL's judgment, together with due consideration of public comments. UL states that it is their intention that the draft proposed standard when finalized be adopted as an American National Standard upon consensus within the Standards Technical Panel (STP) at a later date.

2. International Standard ISO 8528-8:1995(e)

International Standard ISO 8528-8:1995(e) Reciprocating internal combustion engine driven alternating current generating sets—Part 8: Requirements and tests for low-power generating sets is a standard applicable to portable generators sold overseas. Similar to the draft proposed UL 2201, its requirements regarding the CO poisoning hazard are limited to labels and markings. However, in contrast to the proposed UL 2201, it does have a requirement that the generator be able to start up and operate at ambient temperatures between -15 degrees C and 40 degrees C (5 degrees F and 104 degrees F). But this requirement does not specify the ambient relative humidity that is needed to simulate icing conditions that may degrade the engine's ability to run outdoors.

3. CSA C22.2 No. 100-04 Motors and Generators

Canadian Standards Association CSA C22.2 No. 100-04 Motors and Generators is a standard that includes requirements for portable and standby generators sold in Canada. This standard lacks any performance requirements that address the CO poisoning hazard. Also, it does not have any requirements to ensure engine operability in cold, damp conditions.

E. Regulatory Alternatives To Address the Risks of Injury

Following is a discussion of some possible regulatory options available to the Commission.

Under section 7 of the CPSA, the Commission has the authority to adopt a consumer product safety standard consisting of performance requirements for the product and/or requirements that

the product be marked with or accompanied by warnings or instructions when such requirements are reasonably necessary to prevent or reduce an unreasonable risk of injury and death associated with the product. Such a rule could also include a certification labeling requirement as authorized by section 14 of the CPSA.

Among performance requirements for portable generators the staff may consider are weatherization, reducing the allowable CO emission rates, and/or interlock devices. The Commission could also consider incorporating a warning label for portable generators into any standard issued under the authority of Section 7 of the CPSA.³ Under section 8 of the CPSA, the Commission has the authority to ban portable generators if it finds that no feasible consumer product safety rule would adequately protect the public from an unreasonable risk of injury associated with them.

F. Request for Information and Comments

This ANPR is the first step in developing regulatory actions that will reduce portable generator-related deaths and injuries. The proceeding could result in a mandatory rule for portable generators. All interested persons are invited to submit to the Commission their comments on any aspect of the alternatives discussed above or any other approaches.

In accordance with section 9(a) of the CPSA, the Commission solicits:

1. Written comments with respect to the risk of injury and death identified by the Commission.
2. Written comments regarding the regulatory alternatives being considered, their costs, and other possible alternatives for addressing the risk.
3. Any existing standard or portion of a standard which could be issued as a proposed regulation.
4. A statement of intention to modify or develop a voluntary standard to

³ Under section 27(e) of the CPSA, the Commission has the authority to issue a rule requiring a consumer product manufacturer to provide the Commission with performance and technical data related to performance and safety as may be required to carry out the purposes of the CPSA, and to give notification of such performance and technical data at the time of the original purchase to prospective purchasers and to the first purchaser of the product. On August 24, 2006, the Commission issued a separate notice of proposed rulemaking (NPR) at 71 FR 50003 relating specifically to enhancing the effectiveness of warning labels for portable generators under authority of section 27(e) of the CPSA and invited public comment on its proposal. Depending on the outcome of that proceeding, at some future time the result might be incorporated into any consumer product safety standard issued under the authority of section 7 of the CPSA.

² The Occupational Safety and Health Administration (OSHA) does have regulations pertaining to portable generators used in the workplace, but these regulations focus primarily on electrical hazards (see, e.g., 29 CFR 1910.303(b)(1)(i); 29 CFR 1910.304(f)(7); 29 CFR 1910.305(a)(2); 29 CFR 1910.269(i)(3); 29 CFR 1926.403(a); 29 CFR 1926.404(b)(1)(ii); and 16 CFR 1926.404(f)(3)).

address the risk of injury discussed in this notice, along with a description of a plan (including a schedule) to do so.

In addition, the Commission is interested in receiving the following information:

1. Any information related to reducing the CO emission rate of engines used on portable generators, weatherization of portable generators, or interlocking device concepts.

2. Information concerning consumer use of generators, specifically, how long they own them, how frequently they use them and for what duration, and product life (in years).

3. Information on portable generator-related shock and electrocutions that have occurred due to use in wet conditions and what conditions are believed to constitute "wet conditions"?

4. Information or data on the primary reasons consumers purchase and/or use generators and for which appliances, tools, and products they use the generator to supply power.

5. Any technical data on engine performance while operating in temperatures below 40 degrees Fahrenheit combined with high humidity (conditions that induce icing).

6. Any information or technical data to support minimum clearance requirements for placement of an operating generator to address each of the following: Cooling air flow, combustion air flow, avoidance of exhaust impingement on combustible surfaces, and avoidance of CO accumulation in nearby structures.

7. Data on any shelter concepts for generators regarding CO level buildup in and dissipation from the immediate area around the shelter.

8. Any information on the application of an electrical isolation monitor on a generator system to actively measure the insulation resistance between circuit conductors and ground.

9. Any information on death and injury incidents involving CO, electrocution, and thermal hazards (fire and contact burns, etc.) including details of incident scenarios and nature and severity of injuries.

10. Any other relevant information and suggestions about ways in which the safety of consumer use of portable generators might be improved.

Dated: December 6, 2006.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E6-21131 Filed 12-11-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 1998N-0337C]

RIN 0910-AD47

Over-the-Counter Human Drugs; Labeling Requirements; Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its final rule that established standardized format and content requirements for the labeling of over-the-counter (OTC) drug products (Drug Facts Rule, codified at 21 CFR 201.66). This amendment proposes a definition and the option of alternative labeling requirements for "convenience-size" OTC drug packages.

DATES: Submit written comments by April 11, 2007; written comments on FDA's economic impact determination by April 11, 2007. See section X of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. 1998N-0337C and/RIN number 0910-AD47, by any of the following methods:
Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the Electronic Submissions portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Gerald M. Rachanow or Cazemiro R. Martin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5426, Silver Spring, MD 20993-0002, 301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized format and standardized content requirements for the labeling of OTC drug products (Drug Facts Rule). Those requirements are codified in 21 CFR 201.66.

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of all OTC drug products. This includes products marketed under a final OTC drug monograph, products marketed under an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), and products for which there is no final OTC drug monograph or approved NDA/ANDA.

In the Drug Facts Rule and in subsequent notices, FDA provided dates by which OTC drug products had to be in compliance with the new labeling requirements. FDA provided a chart in the Drug Facts Rule (64 FR 13254 at 13274) that summarized the time periods within which the various categories of marketed OTC drug products were required to comply with the final rule. Unless otherwise stated,