under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2002–22–06 Honeywell International, Inc., (formerly AlliedSignal, Inc. and Textron Lycoming): Amendment 39–12931. Docket No. 2002–NE–21–AD.

Applicability: This airworthiness directive (AD) is applicable to Honeywell International, Inc., (formerly AlliedSignal, Inc. and Textron Lycoming) LF507 and ALF502R series turbofan engines with combustion chamber liner assembly part number (P/N) 2–131–520–03 installed. These engines are installed on, but not limited to, BAE Systems Avro 146 and BAE 146 series aircraft.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Compliance with this AD is required as indicated, unless already done.

To prevent separation of the combustor dome baffle from the combustion chamber liner assembly and the flow of hot combustor gases on oil and fuel lines which could result in an engine fire, an in-flight shutdown, and damage to the airplane, do the following:

Removal Requirements

(a) Within 250 cycles-in-service (CIS) after the effective date of this AD, remove from service engines that have combustion chamber liner assemblies, P/N 2–131–520–03, listed by serial number (SN) in Table 1 of this AD. Replace that SN combustion chamber liner assembly with a serviceable part. Table 1 follows:

TABLE 1.—AFFECTED COMBUSTION CHAMBER LINER ASSEMBLIES

Serial Nos. to be removed from service
990992700016.
990992700018 thru 990992700028.
990992700077 thru 990992700078.
990992700081.
990992700083.
990992700085 thru 990992700090.

Initial and Repetitive Inspections

(b) On engines that have combustion chamber liner assemblies with more than 2,000 CIS on the effective date of this AD, perform an initial borescope inspection of combustion chamber liner assembly P/N 2–131–520–03 within 500 CIS after the effective date of this AD in accordance with paragraphs 2(A)(1) through 2(A)(8) of the Accomplishment Instructions of Honeywell alert service bulletin (ASB) ALF/LF A72–1076, Revision 1, dated August 30, 2002.

(c) Thereafter, at each successive 500 CIS, perform a borescope inspection of combustion chamber liner assembly P/N 2–131–520–03 in accordance with paragraphs 2(A)(1) through 2(A)(8) of the Accomplishment Instructions of Honeywell ASB ALF/LF A72–1076, Revision 1, dated August 30, 2002.

Optional Terminating Action

(d) Replacement of combustion chamber liner assembly, P/N 2–131–520–03, with the new improved durability combustion chamber liner assembly, P/N 2–131–520–04, constitutes terminating action to the borescope inspection requirements of paragraph (c) of this AD. Information regarding the replacement of combustion chamber liner assembly P/N 2–131–520–03 with P/N 2–131–520–04 can be found in Honeywell service bulletin ALF/LF 72–1078, dated June 28, 2002.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (LAACO). Operators must submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, LAACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the LAACO.

Special Flight Permits

(f) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done.

Documents That Have Been Incorporated by Reference

(g) The initial and repetitive borescope inspections of combustion chamber liner assembly, PN 2–131–520–03, must be done in accordance with the Honeywell International, Inc. ASB ALF/LF A72–1076, Revision 1, dated August 30, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Honeywell International, Inc. (formerly AlliedSignal, Inc. and Textron Lycoming), *Attn:* Data Distribution, M/S 64–3/2101–201, P.O. Box 29003, Phoenix, AZ 85038–9003, telephone: (602) 365–2493; fax: (602) 365–5577. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

Effective Date

(h) This amendment becomes effective on November 18, 2002.

Issued in Burlington, Massachusetts, on October 22, 2002.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 02–27433 Filed 10–31–02; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging Requirements; Exemption of Hormone Replacement Therapy Products

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its child-resistant packaging requirements to exempt hormone replacement therapy (''HRT'') products containing one or more progestogen or estrogen substances. Current exemptions cover some HRT products, but not others. This rule would uniformly exempt from child resistant packaging requirements all HRT products that rely solely on the activity of one or more progestogen or estrogen substances.

DATES: The rule is effective November 1, 2002, and applies to products packaged on or after that date.

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

SUPPLEMENTARY INFORMATION:

A. Background

The Poison Prevention Packaging Act of 1970 (''PPPA''), 15 U.S.C. 1471–1476, authorizes the Commission to issue standards for the special packaging of household substances, such as drugs, when (1) Child resistant packaging is necessary to protect children from serious personal injury or illness due to the substance and (2) the special packaging is technically feasible, practicable, and appropriate for the substance. Accordingly, a Commission rule requires that oral prescription drugs be in child resistant (''CR'') packaging. 16 CFR 1700.14(a)(10).

The Commission's regulations allow exemptions from this requirement for substances that have low acute toxicity. 16 CFR 1702.1(b) and 1702.7. Current regulations provide four PPPA exemptions for sex hormones: (1) Oral contraceptives in mnemonic packages containing one or more progestogen or estrogen substances; (2) conjugated estrogen tablets in mnemonic packages; (3) norethindrone acetate tablets in mnemonic packaging; and (4) medroxyprogesterone acetate tablets. 16 CFR 1700.14(a)(10)(iv), (xvii), (xviii) and (xix). Some HRT products fall within these exemptions, but because of the way these exemptions are written, other HRT products currently require CR packaging.

On February 19, 2002, the Commission published a notice of proposed rulemaking (''NPR'') proposing to exempt from the special packaging requirements HRT products containing one or more progestogen or estrogen substances. 67 FR 7319. This rule will make the exemption of HRT products more uniform by exempting all HRT products that rely solely on the activity of one or more progestogen or estrogen substances.[1]

B. HRT Products

HRT is used to replace the estrogen and progesterone that normally decline following menopause (the cessation of menstruation). Women may experience a range of menopausal symptoms. Additionally, menopause accelerates bone depletion that commonly occurs with aging, leading to osteoporosis.

HRT has been used to relieve a number of menopausal symptoms and help to prevent osteoporosis. HRT consists of using estrogen alone or various combinations of estrogens and progestins, similar to oral contraceptives. Some are natural hormones (*e.g.*, estradiol) and others are semi-synthetic or synthetic (*e.g.*, norgestimate). Since available HRT products contain estrogen/progestin combinations similar to oral contraceptives, it is reasonable and consistent to exempt them similarly.

Recently, studies have raised questions about the health effects of HRT. A Women's Health Initiative study indicated that women treated for about 5 years with a combination of estrogen and progestin had an increased risk of breast cancer, heart disease, stroke and blood clots compared to placebo. While this study suggests that HRT may not be indicated for long term use, it did not examine different doses, different estrogen or progestins or alternative formulations. It is likely that physicians may consider prescribing short term hormone therapy for menopausal symptoms after evaluating the risks and benefits for individual patients. Because the acute toxicity of HRT is low and its use is likely to continue even with the questions raised about its long term use, the Commission believes that a rule uniformly exempting HRT products from CR packaging requirements is appropriate.

C. Toxicity Data

Human toxic doses for estrogens or progestins have not been defined. Exposure summaries in the Poisindex® for estrogens, progestins, and oral contraceptives state that acute toxicity is unlikely following overdosage. Gastrointestinal effects (*e.g.*, nausea, vomiting, abdominal cramps) may occur after an acute overdose, but typically no treatment is necessary.

The medical literature provides little information concerning acute overdosage of progestins or estrogens. One case mentioned in the NPR showed that a single dose of 160 mg estradiol valerate (80 tablets/2 mg each), ingested by a 19-year-old woman in a suicide attempt, produced little toxicity. The woman slept easily during the night of the ingestion and the next evening presented in the emergency clinic in generally good condition with nausea and a headache.

For the NPR, the staff reviewed poisoning data from the American Association of Poison Control Centers (''AAPCC'') Toxic Exposure Surveillance System (''TESS'') showing acute exposures in children less than five years old to estrogens, progestins, and oral contraceptives from 1993 to 1998. There were no deaths and most of the exposures were non-toxic.

For this final rule, the staff reviewed available AAPCC data since the NPR was published, and found no major outcomes or deaths in any of the hormone categories in 1999 and 2000 (the most recent data available).

D. Public Comment on the NPR

The Commission received one comment in response to the NPR. It came from Berlex Laboratories, which wrote that it currently markets estrogen replacement therapy, long-acting contraception, and oral contraception products and plans to market an oral HRT product in the near future. Berlex states that the proposed exemption is ''beneficial in terms of cost and efficiency'' and provides ''drug producers greater flexibility in meeting the needs of the HRT patient population.''

E. Effective Date

With this rule, the Commission issues an exemption from the child-resistant packaging requirements generally applicable to oral prescription drugs. Thus, the rule imposes no new requirements, but lifts requirements currently in existence for some HRT products (some HRT products are already exempt from CR packaging requirements). Under these circumstances the Commission believes it is appropriate for the rule to become effective on the date it is published in the **Federal Register**.

F. Impact on Small Business

As discussed in the NPR, the Commission preliminarily concluded that the proposed amendment exempting HRT products from special packaging requirements would not have a significant impact on a substantial number of small businesses or other small entities. This conclusion was based on the fact that the exemption would actually increase the packaging options for manufacturers because it would allow them to package the affected HRT products in non-CR packages. Thus, the exemption is not likely to have a significant impact on a substantial number of companies, regardless of size.

G. Environmental Considerations

In the NPR, the Commission also discussed possible impact on the environment as required by the National

[1] Commissioner Thomas H. Moore issued a statement, which is on file in the Commission's Office of the Secretary, Room 501, 4330 East-West Highway, Bethesda, Maryland 20814.

Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review. The Commission found that, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

H. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations.

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 non-identical 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).

Accordingly, with the exceptions noted above, the rule exempting HRT products from special packaging requirements would preempt non-identical state or local special packaging standards for those products.

The Commission has also evaluated the rule in light of the principles stated in Executive Order 13132 concerning federalism, even though that Order does not apply to independent regulatory agencies such as CPSC. The Commission does not expect that the rule will have any substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among various levels of government.

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 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. The introductory text of paragraphs (a) and (a)(10) is republished. Section 1700.14 is amended by adding new paragraph (a)(10)(xxi) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(10) *Prescription Drugs.* Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with the provisions of § 1700.15(a),(b), and (c), except for the following:

* * * * *

(xxi) Hormone Replacement Therapy Products that rely solely upon the activity of one or more progestogen or estrogen substances.

* * * * *

Dated: October 28, 2002.

Todd Stevenson,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Jacqueline Ferrante, Ph.D., Directorate for Health Sciences, to the Commission, ''Final Rule to Exempt Hormone Replacement Therapy Products from the Special Packaging Requirements of the Poison Prevention Packaging Act,'' October 9, 2002.

2. Memorandum from Robert Franklin, Directorate for Economic Analysis, to Jacqueline Ferrante, Ph.D., Project Manager, ''Small Business and Environmental Considerations Related to Exempting HRT Products from PPPA Requirements,'' September 9, 2002.

[FR Doc. 02–27745 Filed 10–31–02; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–02–118]

Drawbridge Operation Regulations: Danvers River, MA

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Kernwood Bridge, mile 1.0, across the Danvers River in Massachusetts. This temporary deviation will allow the bridge to remain in the closed position from 7 a.m. on November 12, 2002 through 8 p.m. on November 14, 2002. This temporary deviation is necessary to facilitate structural repairs at the bridge.

DATES: This deviation is effective from November 12, 2002 through November 14, 2002.

FOR FURTHER INFORMATION CONTACT: John McDonald, Project Officer, First Coast Guard District, at (617) 223–8364.

SUPPLEMENTARY INFORMATION: The Kernwood Bridge has a vertical clearance in the closed position of 8 feet at mean high water and 17 feet at mean low water. The existing regulations are listed at 33 CFR 117.595.

The bridge owner, Massachusetts Highway Department, requested a temporary deviation from the drawbridge operating regulations to facilitate structural maintenance, replacement of the pinion bearing and support frame, at the bridge. The bridge must remain closed during these repairs. The bridge opening records indicate this bridge has received few requests to open during the requested closure time during past years.

This deviation from the drawbridge operation regulations will allow the bridge to remain in the closed position from 7 a.m. on November 12, 2002 through 8 p.m. on November 14, 2002.

This deviation from the drawbridge operation regulations is authorized