stator assembly's inner seal support to a serviceable configuration. This condition, if not corrected, could result in increased fatigue damage of the second stage turbine stator inner seal support, rotating knife seal, and the second and third stage turbine wheels which may result in an uncontained rotor failure and damage to the aircraft.

FAA's Determination of an Unsafe Condition and Proposed Actions

Since an unsafe condition has been identified that is likely to exist or develop on other Honeywell International Inc. TPE331 series turboprop and TSE331–3U turboshaft engines of the same type design, the proposed AD would require replacing the existing second stage turbine stator assemblies, P/N's 894528–1, –2, –3, –5, –6, –10, and –11, with serviceable assemblies.

Economic Effect

There are approximately 4,700 engines of the affected design in the worldwide fleet. The FAA estimates that 2,350 engines installed on aircraft of U.S. registry would be affected by this proposed AD, that it would take approximately 4.0 work hours per engine to do the proposed actions, and that the average labor rate is $60 per work hour. Required replacement parts would cost approximately $8,000 per engine. Based on these figures, the total cost of the proposed AD on U.S. operators is estimated to be $14,958,000.

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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:

Honeywell International Inc.: Docket No. 99–NE–53–AD.

Applicability: This airworthiness directive (AD) is applicable to Honeywell International Inc. (formerly AlliedSignal Inc., Garrett Engine Division, Garrett Turbine Engine Company, and AiResearch Manufacturing Company of Arizona) Model TPE331–1, –2, –2UA, –3U, –3UW, –5, –5A, –5AB, –5B, –6, and –6A series turboprop and TSE331–3U Model turboshaft engines with second stage turbine stator assemblies, part numbers (P/N's) 894528–1, –2, –3, –5, –6, –10, and –11. These engines are installed on, but not limited to Ayres S–2R series; Beech 18 and 45 series and model JRB–6, 3N, 3NM, 3TM, and B100 airplanes; Construcciones Aeronauticas, S.A. (CASA) C–212; De Havilland DH104 series 7AXC (Dove); Dornier 228 series; Fairchild SA226 series (Swearingen Merlin and Metro series); Grumman American G–164 series; Mitsubishi MU–2 and MU–2B series; Pilatus PC–6 series (Fairchild Porter and Peacemaker); Prop-Jets, Inc. Model 400; Rockwell Commander S2–R; Schweizer G–164 series; Shorts Brothers and Harland, Ltd. SC7 (Skyvan); and Twin Commander 680 and 690 series (Jetprop Commander) airplanes; and Sikorsky S–55 series (Helitec Corp. S55T) helicopters.

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 (c) 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 reduce fatigue damage of the second stage turbine stator inner seal support, rotating knife seal, and the second and third stage turbine wheels which may result in an uncontained rotor failure and damage to the aircraft, do the following:

(a) Replace second stage turbine stator assemblies, P/N's 894528–1, –2, –3, –5, –6, –10, and –11, with a new or reworked second stage turbine stator assembly at the next removal of the second stage turbine stator assembly from the engine or at the next turbine section inspection, but do not exceed 3,100 engine operating hours since last turbine section inspection. Information for replacing second stage turbine stator assemblies is available in Honeywell International Inc. Alert Service Bulletin (ASB) TPE331–A72–2082 dated May 16, 2001. Information for reworking second stage turbine stator assemblies is available in Honeywell International Inc. SB TPE331–72–2085RWK dated May 16, 2001.

(b) After the effective date of this AD, do not install any second stage turbine stator assemblyP/N's 894528–1, –2, –3, –5, –6, –10, and –11.

Alternative Methods of Compliance

(c) 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 request 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

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

Issued in Burlington, Massachusetts, on February 12, 2002.

Francis A. Favara,

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

[FR Doc. 02–3877 Filed 2–15–02; 8:45 am]

BILLING CODE 4910–13–U

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging Requirements; Proposed Exemption of Hormone Replacement Therapy Products

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing to amend 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 proposal would uniformly exempt all HRT products that rely solely on the activity of one or more progestogen or estrogen substances from child resistant packaging requirements.

DATES: Comments on the proposal should be submitted no later than May 6, 2002.

ADDRESSES: Comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814–4408, telephone (301) 504–0800. Comments may also be filed by telefacsimile to (301) 504–0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned ''Proposed HRT exemption.''

FOR FURTHER INFORMATION CONTACT: Jacqueline Ferrante, Ph.D., Division of Health Sciences, Directorate for Epidemiology and Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0477 ext. 1199.

SUPPLEMENTARY INFORMATION:

A. Background

The Poison Prevention Packaging Act of 1970 (''PPPA''), 15 U.S.C. 1471–1476, provides the Commission with authority to establish standards for the special packaging of household substances, such as drugs, when child resistant packaging is necessary to protect children from serious personal injury or illness due to the substance and the special packaging is technically feasible, practicable, and appropriate for such substance. Accordingly, the Commission 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 with low acute toxicity. Currently, there are 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. The proposed exemption would cover all HRT products that rely solely on the activity of one or more progestogen or estrogen substances.

B. HRT Products

HRT is used to replace the estrogen and progesterone that normally decline following menopause (the cessation of menstruation). Generally, women experience a range of symptoms with some reporting minimal discomfort, while others have more severe effects. Hot flashes are the most frequent symptom and often begin several years before other menopausal symptoms. Additionally, menopause accelerates bone depletion that commonly occurs with aging, leading to osteoporosis.

HRT relieves a number of menopausal symptoms (e.g., hot flashes and vaginitis) and helps to prevent osteoporosis. HRT consists of using estrogen alone or various combinations of estrogens and progestins. The latter regimen is similar to that for oral contraceptive products except the goal of therapy is to replace declining hormone levels rather than to prevent pregnancy.

Because the life expectancy of women in the United States is increasing, it is estimated that 40 million women will go through menopause in the next 20 years. Therefore, the pharmaceutical industry is developing new prescription products specifically designed and marketed for HRT post-menopausal women. Some of these products may not be covered under current PPPA regulations although their toxicity is as low as those products currently exempt.

Sex hormone products contain various estrogens and progestins. Some are natural hormones (e.g., estradiol) and others are semi-synthetic or synthetic (e.g., norgestimate). Synthetic hormones are usually developed to alter bioavailability (e.g., enhance oral absorption) or to reduce side effects. Since available HRT products contain similar estrogen/progestin combinations, it is reasonable and consistent to exempt them like oral contraceptives.

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.

There is little information in the medical literature concerning acute overdosage of progestins or estrogens. One case 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.

Poisoning data from the American Association of Poison Control Centers (''AAPCC'') Toxic Exposure Surveillance System (''TESS''), corroborate the lack of acute toxicity associated with sex hormones. The staff reviewed data 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. There was one major outcome out of 37,645 exposures to oral contraceptives, but no details are readily available relating to this case. It is possible that this oral contraceptive formulation contained iron or that the child was exposed to a second substance or product.

D. Impact on Small Business

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to exempt HRT products from special packaging requirements. The staff reports that it does not know the universe of companies that would be affected by the proposed exemption or how many companies would be small businesses. However, the exemption is not likely to have a significant impact on a substantial number of companies, regardless of size. 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. Although the cost to manufacturers of CR packaging is small—usually only a few cents per package—the exemption would allow manufacturers to use slightly cheaper packages and thus reduce the final cost of the HRT products.

Based on this assessment, the Commission preliminarily concludes 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.

E. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in

accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the proposed PPPA amendment.

The Commission's regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). Nothing in this proposed rule alters that expectation. (3) Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

F. 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).

Thus, with the exceptions noted above, the proposed 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 proposed 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 proposed 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 proposes to amend 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. Section 1700.14 is amended by adding new paragraph (a)(10)(xxi) to read as follows (although unchanged, the introductory texts of paragraph (a) and paragraph (10) are included below for context):

§ 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: February 12, 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, ''Proposed Rule to Exempt HRT Products from the Special Packaging Requirements of the PPPA,'' January 14, 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,'' December 20, 2001.

[FR Doc. 02–3999 Filed 2–15–02; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Los Angeles-Long Beach 02–003]

RIN 2115–AA97

Safety Zone; Long Beach, CA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone in the navigable waters of Long Beach, California for the National Water Ski Racing Association (NWSRA) Water Ski Race from 8 a.m. to 5 p.m. on March 23 and 24, 2002. This safety zone is necessary to provide for the safety of the crew and participants of the race and to protect the participating vessels. Persons and vessels are prohibited from entering into or transiting through this safety zone unless authorized by the Captain of the Port or his designated representative.

DATES: Comments and related material must reach the Coast Guard on or before March 6, 2002.

ADDRESSES: You may mail comments and related material to U.S. Coast Guard Marine Safety Office/Group Los Angeles-Long Beach, 1001 S. Seaside Avenue, Building 20, San Pedro, California, 90731. U.S. Coast Guard Marine Safety Office/Group Los Angeles-Long Beach maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for