

landing, considering all the FBW flight control system signal malfunctions that are not extremely improbable.

(3) The effect of spurious signals on the systems which are included in the control surface loop must not result in unacceptable transients or degradation of the airplane's performance. Specifically, signals that would cause a significant uncommanded motion of a control surface actuator must be readily detected and deactivated, or the surface motion must be arrested by other means in a satisfactory manner. Small amplitude residual system oscillations may be acceptable.

(b) It must be demonstrated that the output from the control surface closed loop system does not result in uncommanded, sustained oscillations of flight control surfaces. The effects of minor instabilities may be acceptable, provided that they are thoroughly investigated, documented, and understood.

Issued in Renton, Washington, on June 6, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Petition Requesting Amendment to Child-Resistance Testing Pass/Fail Criterion for Unit Dose Packaging (Petition No. PP 03-1)

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of petition.

SUMMARY: The current regulatory definition of a child-resistance test failure for unit dose, *i.e.*, non-reclosable packaging under the Poison Prevention Packaging Act (PPPA), is a child gaining access to the number of individual unit doses that constitute the amount that "may cause serious personal injury or serious illness" or more than eight individual unit doses, whichever is less. The Commission has received a petition (Petition No. PP 03-1) requesting that the Commission amend that requirement to eliminate the first criterion related to the toxicity of the substance to be packaged and define a unit dose packaging failure to be a child gaining access to more than eight individual unit doses. The Commission solicits written comments concerning the petition.

DATES: The Office of the Secretary must receive comments on the petition by August 15, 2003.

ADDRESSES: Comments on the petition, preferably in five copies, should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, telephone (301) 504-0800, or delivered to the Office of the Secretary, Room 501, 4330 East-West Highway, Bethesda, Maryland 20814. Comments may also be filed by facsimile to (301) 504-0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned "Petition PP 03-1, Petition for Amendment of the Child-Resistance Testing Requirements for Unit Dose Packaging." A copy of the petition is available for inspection at the Commission's Public Reading Room, Room 419, 4330 East-West Highway, Bethesda, Maryland. The petition is also available on the CPSC Web site at <http://www.cpsc.gov>.

FOR FURTHER INFORMATION CONTACT: Rockelle Hammond, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-6833; e-mail: rhammond@cpsc.gov.

SUPPLEMENTARY INFORMATION: By letter of March 17, 2003, and supplemental information provided by letter of May 5, 2003, the Healthcare Compliance Packaging Council (HCPC) requests a change to the Commission's regulatory requirements under the PPPA for testing the ability of unit dose child-resistant, *i.e.*, "special" packaging to resist attempts by children to open it. The HCPC request addresses the portion of the requirements defining a testing failure for unit dose packaging. Unit dose packaging is non-reclosable packaging typically including a limited number of tablets (usually one or two) per unit, *e.g.*, blister, strip or pouch packaging.

The HCPC members include companies involved in the manufacture of pharmaceutical-grade plastic films, aluminum, and paperboard used to produce unit dose blister and strip packaging, as well as manufacturers of machinery used to create unit dose formats. HCPC corporate members include firms that provide packaging services to the pharmaceutical manufacturers on a contract basis, as well as companies that purchase bulk quantities of drug products from pharmaceutical manufacturers and repackage those products into unit dose and other formats for use by hospitals, clinics, and other similar facilities.¹

¹March 17, 2003 HCPC letter at 3.

The child resistance testing requirements were promulgated under authority of the PPPA. The testing requirements are the mechanism for assessing the ability of a particular form of "special packaging" to resist attempts by children to gain access to its contents. The definition of a child-resistance test failure for unit dose packaging is a child gaining access to the number of individual unit doses that constitute the amount that may cause "serious personal injury or serious illness" or more than eight individual unit doses, whichever is less.²

The HCPC's specific request is as follows. "The definition of test failure for unit dose packaging should be an objective standard, *i.e.*, 'any child who opens or gains access to more than 8 individual units during the full 10 minutes of testing.'" The HCPC asserts that "unit dose packaging is inherently safer than cap-and-vial closures" and that "the current regulation creates a disincentive for pharmaceutical manufacturers and packagers to use safer unit dose packaging."³

The HCPC request has been docketed as petition number PP 03-1. The Commission is particularly interested in receiving comments on the petition from: (1) Consumers; (2) dispensing physicians; (3) poison control centers; (4) pharmaceutical manufacturers; (5) chain drug store, government, independent, and hospital pharmacies; and (6) drug repackagers, wholesalers and distributors.

Interested parties may obtain a copy of the petition by writing or calling the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0800. The petition is available on the CPSC World Wide Web site at <http://www.cpsc.gov>. A copy of the petition is also available for inspection from 8:30 a.m. to 5 p.m., Monday through Friday, in the Commission's Public Reading Room, Room 419, 4330 East-West Highway, Bethesda, Maryland.

Dated: June 10, 2003.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

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² 16 CFR 1700.20(a)(2)(ii).

³ March 17, 2003 HCPC letter at 3-5.