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(3) The loss of important bodily functions or debilitating internal disorder. These terms include:

(i) Permanent injury to a vital organ, in any degree;

(ii) The total loss or loss of use of any internal organ,

(iii) Injury, temporary or permanent, to more than one internal organ;

(iv) Permanent brain injury to any degree or with any residual disorder (e.g. epilepsy), and brain or brain stem injury including coma and spinal cord injuries;

(v) Paraplegia, quadriplegia, or permanent paralysis or paresis, to any degree;

(vi) Blindness or permanent loss, to any degree, of vision, hearing, or sense of smell, touch, or taste;

(vii) Any back or neck injury requiring surgery, or any injury requiring joint replacement or any form of prosthesis, or;

(viii) Compound fracture of any long bone, or multiple fractures that result in permanent or significant temporary loss of the function of an important part of the body;

(4) Injuries likely to require extended hospitalization, including any injury requiring 30 or more consecutive days of in-patient care in an acute care facility, or 60 or more consecutive days of in-patient care in a rehabilitation facility;

(5) Severe burns, including any third degree burn over ten percent of the body or more, or any second degree burn over thirty percent of the body or more;

(6) Severe electric shock, including ventricular fibrillation, neurological damage, or thermal damage to internal tissue caused by electric shock.

(7) Other grievous injuries, including any allegation of traumatically induced disease.

Manufacturers may wish to consult with the Commission staff to determine whether injuries not included in the examples above are regarded as grievous bodily injury.

(c) A *particular model* of a consumer product is one that is distinctive in functional design, construction, warnings or instructions related to safety, function, user population, or other characteristics which could affect the

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product's safety related performance. (15 U.S.C. 2084(e)(2))

(1) The *functional design* of a product refers to those design features that directly affect the ability of the product to perform its intended use or purpose.

(2) The *construction* of a product refers to its finished assembly or fabrication, its materials, and its components.

(3) *Warnings or instructions related to safety* include statements of the principal hazards associated with a product, and statements of precautionary or affirmative measures to take during the use, handling, or storage of a product, to the extent that a reasonable person would understand such statements to be related to the safety of the product. Warnings or instructions may be written or graphically depicted and may be attached to the product or appear on the product itself, in operating manuals, or in other literature that accompanies or describes the product.

(4) The *function* of a product refers to its intended use or purpose.

(5) *User population* refers to the group or class of people by whom a product is principally used. While the manufacturer's stated intent may be relevant to an inquiry concerning the nature of the user population, the method of distribution, the availability of the product to the public and to specific groups, and the identity of purchasers or users of the product should be considered.

(6) *Other characteristics which could affect a product's safety related performance* include safety features incorporated into the product to protect against foreseeable risks that might arise during the use, handling, or storage of a product.

(d) The term *manufacturer* means any person who manufactures or imports a consumer product. (15 U.S.C. 2052(a)(4)).

[57 FR 34239, Aug. 4, 1992, as amended at 58 FR 16121, Mar. 25, 1993]

§ 1116.3 Persons who must report under section 37.

A manufacturer of a consumer product must report if:

(a) A particular model of the product is the subject of at least 3 civil actions filed in Federal or State Court;

(b) Each suit alleges the involvement of that particular model in death or grievous bodily injury;

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(c) The manufacturer is—

(1) A party to, or

(2) Is involved in the defense of or has notice of each action prior to entry of a final order, and is involved in the discharge of any obligation owed to plaintiff under the settlement of or in satisfaction of the judgment after adjudication in each of the suits; and

(d) During one of the 24-month periods defined in §1116.2(a), each of the three actions results in either a final settlement involving the manufacturer or in a court judgment in favor of the plaintiff.

For reporting purposes, a multiple plaintiff suit for death or grievous bodily injury is reportable if the suit involves three or more separate incidents of injury. The reporting obligation arises when at least three plaintiffs have settled their claims or when a combination of settled claims and adjudications favorable to plaintiffs reaches three. Multiple lawsuits arising from one incident involving the same product only count as one lawsuit for the purposes of section 37.

§ 1116.4 Where to report.

Reports must be sent in writing to the Commission's Office of Compliance and Enforcement, Division of Corrective Actions, Washington, DC 20207, telephone (301) 504-0608).

§ 1116.5 When must a report be made.

(a) A manufacturer must report to the Commission within 30 days after the final settlement or court judgment in the last of the three civil actions referenced in §1116.3.

(b) If a manufacturer has filed a section 37 report within one of the 24-month periods defined in §1116.2(a), the manufacturer must also report the information required by section 37(c)(1) for any subsequent settlement or judgment in a civil action that alleges that the same particular model of the product was involved in death or grievous bodily injury and that takes place during the same 24-month period. Each such supplemental report must be filed within 30 days of the settlement or final judgment in the reportable civil action.

§ 1116.6 Contents of section 37 reports.

(a) *Required information.* With respect to each of the civil actions that is the subject of a report under section 37, the report must contain the following information:

(1) The name and address of the manufacturer of the product that was the subject of each civil action;

(2) The model and model number or designation of the consumer product subject to each action;

(3) A statement as to whether the civil action alleged death or grievous bodily injury, and, in the case of an allegation of grievous bodily injury, a statement of the category of such injury;

(4) A statement as to whether the civil action resulted in a final settlement or a judgment in favor of the plaintiff; and

(5) In the case of a judgment in favor of the plaintiff, the name of the civil action, the number assigned to the civil action, and the court in which the civil action was filed.

(b) *Optional information.* A manufacturer furnishing a report may include:

(1) A statement as to whether any judgment in favor of the plaintiff is under appeal or is expected to be appealed (section 15 U.S.C. 2084(c)(2)(A));

(2) Any other information that the manufacturer chooses to provide (15 U.S.C. 2084(c)(2)(B)), including the dates on which final orders were entered in the reported lawsuits, and, where appropriate, an explanation why the manufacturer has not previously filed a report under section 15(b) of the CPSA covering the same particular product model that is the subject of the section 37 report; and

(3) A specific denial that the information it submits reasonably supports the conclusion that its consumer product caused a death or grievous bodily injury.

(c) *Statement of amount not required.* A manufacturer submitting a section 37 report is not required by section 37 or any other provision of the Consumer Product Safety Act to provide a statement of any amount paid in final settlement of any civil action that is the subject of the report.