DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0487]

21 CFR Parts 880 and 890

Medical Devices; Protective Restraints; Revocation of Exemptions From the 510(k) Premarket Notification Procedures and Current Good Manufacturing Practice Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the classification regulations for protective restraints and wheelchair accessories intended for use as restraints, by revoking the existing exemptions for these devices from premarket notification and current good manufacturing practices (CGMP) regulations. FDA is also modifying the classification regulations for protective restraints and for wheelchair accessories to clarify the definitions of these devices. FDA is taking these actions in response to a number of recent reports of deaths and serious injuries that may have been associated with improper supervision of restrained patients or improper application of protective restraints. FDA believes that these actions will have minimal economic effect and will not disrupt the supply of these devices. In a notice published elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance document for the preparation of premarket notification (510(k)) submissions for protective restraints.

DATES: Effective September 3, 1996.

FOR FURTHER INFORMATION CONTACT: Viola S. Hibbard, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the Federal Register of October 21, 1980 (45 FR 69678 at 69729), FDA published a final rule, in accordance with the procedures contained in section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), classifying as a device a protective restraint, usually a wristlet, anklet, or other type of strap, that is intended for medical purposes and that limits a patient's movement to the extent necessary for treatment, examination, or protection of the patient. In that regulation, FDA exempted manufacturers of protective restraints, which are class I devices, from the premarket notification procedures in part 807 (21 CFR part 807), and the CGMP regulations in part 820 (21 CFR part 820), with the exception of §§ 820.180 and 820.198, relating to general requirements concerning records and complaint files, respectively. FDA granted these exemptions because, at that time, FDA did not have information that caused serious concerns about safety problems related to the use of protective restraint devices.

Since the October 1980 publication of these classifications that exempted protective restraints from premarket notification and CGMP requirements, FDA has become aware of numerous reports of serious injuries and deaths that have been attributed to incorrect supervision, handling, or application of protective restraints. In the Federal Register of June 19, 1992 (57 FR 27397), FDA, in response to these adverse event reports, published a proposed rule to revoke the exemptions from premarket notification procedures and CGMP regulations for protective restraints and wheelchair accessories intended for use as protective restraints. FDA's proposed revocations complement the Health Care Financing Administration (HCFA) regulations (42 CFR part 483) and HCFA's February 5, 1992 (57 FR 4516), proposed rulemaking that address clinical indications for use of restraints that protect individuals from inappropriate use of restraints for discipline or convenience. The revocation of the exemption from the premarket notification procedures will permit the agency to monitor the marketing of these devices, and review and identify unclear labeling that may result in incorrect application of the devices. The revocation of the exemption from CGMP requirements will help ensure that restraints are safe by conforming to appropriate specifications for design, materials, performance, and labeling. A 60-day comment period, ending on August 18, 1992, was provided to allow interested persons an opportunity to submit comments on the proposed changes.

In addition to this rule, FDA has taken other steps to ensure that protective restraints are used safely. On July 15, 1992, FDA issued a Safety Alert on potential hazards with restraint devices (Ref. 1) to hospital administrators, directors of nursing, directors of emergency room services, and long-term care facilities. FDA also issued a letter to manufacturers in February 1992 stating that FDA considered restraints to be prescription devices which must bear a prescription legend as prescribed in § 801.109 (21 CFR 801.109) to help ensure appropriate medical intervention in the application and use of restraints (Ref. 2).

FDA received 24 comments in response to the proposal of June 19, 1992, from individuals, manufacturers, professional societies, and consumer and health associations. The comments were primarily supportive of FDA's proposed actions. Several comments, however, stated that FDA should consider additional regulation of protective restraints. These comments are discussed below.

II. Summary and Analysis of Comments and FDA's Response

A. General Comments

1. One comment stated that it would be helpful for FDA to recommend that facilities use one standard brand of each type of restraint (e.g., vest) to provide consistency and increase the likelihood that the restraint would be applied correctly. Another comment suggested restraints be uniformly designed so the front and back are easily identifiable.

Although standardization of brands in a facility may increase the likelihood that restraints will be applied correctly, it is critical that the correct type and size restraint be applied to maximize the safety of these devices. Accordingly, FDA encourages standardization as long as it can be achieved without compromising the use of the appropriate restraint type and size. Ultimately, however, this decision must be made by each facility. FDA cannot endorse one uniform design. Restraints used under different circumstances must necessarily incorporate different designs.

2. Several comments indicated support for a prescription requirement by licensed health care practitioners, specifying the appropriate restraint type, duration of application, and circumstances for use. One comment stated that FDA has avoided the issue of whether anyone other than a licensed health care worker should be permitted to apply restraints. Another comment stated that FDA did not address the issue of appropriate frequency of monitoring.

The determination of appropriate individuals to apply restraints or appropriate frequency of monitoring is beyond the scope of this regulation. However, FDA believes the use of restraints should be limited to those circumstances when they are clearly clinically indicated, and that they

should be used only for a strictly defined period of time and only under the supervision of a licensed health care provider. For these reasons, FDA informed protective restraint manufacturers in February 1992 that it considered these devices to be prescription devices that may only be used under the direction of a licensed health care practitioner. In addition, FDA strongly encourages that after restraints are prescribed by a licensed health care practitioner, they be applied only by adequately trained personnel, in accordance with State licensure and Federal certification requirements for facilities.

3. While several comments were supportive of FDA's proposal to revoke 510(k) and CGMP exemptions, three comments opposed the revocation of the exemptions. One comment suggested withdrawing the proposed regulations until more complete information is available. Another comment stated that the revocations are unjustified based on the relatively small number of associated deaths and injuries compared to the large annual usage of restraints. Another comment by a manufacturer stated that the revocations were unwarranted because it was unaware of any deaths or serious injuries associated with its restraint products.

FDA disagrees that it needs to have more complete information before it revokes premarket notification and CGMP requirements. Although complete information concerning the problems associated with restraints is not available, FDA does have sufficient information about these problems to warrant revocation of the exemptions from premarket notification and CGMP requirements. As explained in the preamble to the proposed rule, the revocation of these exemptions will allow FDA to gather more information to help ensure the safety of these devices.

FDA believes that the exemption revocations are justified based on the numbers of reports of deaths and injuries associated with protective restraint use. FDA notes that since publication of the proposed rule of June 19, 1992, the total numbers of deaths and serious injuries reported under the Device Experience Network (DEN), which includes the mandatory Medical Device Reporting Program and the MedWatch Reporting Program, have increased from 41 deaths and 16 serious injuries to 130 deaths and 48 injuries. In addition, several comments support FDA's belief that injuries and deaths associated with protective restraints are seriously underreported.

FDA does not agree with the comment from one manufacturer that revocations of the exemptions were not warranted for its restraints because the manufacturer was not aware of any deaths or serious injuries associated with its products. Reports of these problems encompass many different restraint types, regardless of manufacturer or design; various types of patient populations, regardless of clinical indications for the use of the restraint; and various types of health care facilities, including hospitals, home use situations, and nursing homes. The fact that problems have been reported from a wide spectrum of protective restraint types and situations indicates that the problems associated with protective restraints are not specific to one particular type of restraint. Moreover, given the probability of underreporting of protective restraint-associated deaths and injuries, the absence of complaints for one particular manufacturer does not indicate that that manufacturer's devices are free of the problems associated with other restraints.

4. One comment from a restraint manufacturer disagreed with the economic impact analysis of the proposed rule and stated that revocations of the exemptions would result in substantial economic costs. To avoid incurring the costs associated with compliance with the regulation, the manufacturer stated that their company may disavow the ''medical device'' classification of their product line and continue to sell their restraint devices to interested members of the health care industry.

FDA advises that protective restraints, within the meaning of section 201(h) of the act (21 U.S.C. 321(h)), are medical devices because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Therefore, on or after the effective date of this final rule, any manufacturer distributing a restraint device not meeting the provisions of this final rule would violate the act by distributing devices that are: (1) Misbranded, in that no premarket notification submission has been filed pursuant to section 510(k) of the act (21 U.S.C. 360(k)); and (2) adulterated, if CGMP requirements are not met under section 520(f) of the act (21 U.S.C. 360j(f)). FDA strongly discourages any noncompliance with this regulation and is prepared to take enforcement actions against persons who violate this regulation. Such actions may include seizure, injunction, civil penalties, and criminal prosecution.

Furthermore, FDA disagrees that a substantial economic impact would result from these regulations. The comment estimated that the company would incur costs of $200,000 for 100 510(k) applications and as much as $500,000 to attain compliance with CGMP's, which could force the company out of business. The comment did not present any data to support claims of substantially higher costs for complying with CGMP's.

FDA has reconsidered its economic analysis and believes that the costs of premarket notification submissions and compliance with CGMP's are considerably lower than suggested in this comment. Also, FDA expects to allow some grouping by product category in a 510(k) submission as discussed in comment 10 of this document, which should limit the number of 510(k)'s that have to be submitted by any particular manufacturer.

5. One comment questioned the benefit of simply revoking the exemptions, but believed that the revocations were necessary as an interim measure while reclassification of the devices to a more stringent regulatory category is considered. Three comments believed the proposed revocations to be a totally inadequate response to problems with restraints and inconsistent with requirements issued by HCFA. These comments stated that FDA should convene a device classification panel to determine whether restraint devices should be reclassified to class II or III.

FDA is continuing to evaluate the need for reclassification of these devices. However, FDA believes that revocation of the premarket notification exemption will facilitate more immediate improvements in the labeling of restraint devices that quickly will provide increased safety and effectiveness in the use of restraints, and that revocation of CGMP exemptions will facilitate improvements in the manufacture of restraint devices. FDA believes that these measures will greatly reduce the risk associated with use of protective restraints. FDA retains the option to reclassify the devices at a later time, if such additional action is believed necessary to protect the public health.

FDA disagrees that its actions are inconsistent with those of HCFA. As stated in the preamble to FDA's June 19, 1992, proposed rule, the intent of HCFA's requirements on use of restraints in nursing homes is to protect nursing home residents from use of restraints for purposes of convenience or discipline. FDA's actions complement these requirements by ensuring that for those instances where

restraints are clinically indicated, the labeling and instructions for use of the restraints will facilitate correct application by health care providers.

6. One comment requested immediate recall action on restraints that have a higher association with death and serious injury than others. The comment believed that criss-crossed vests were the most dangerous, although the comment acknowledged that the higher number of death reports associated with vest restraints may be due to more frequent use of those devices.

FDA does not believe that the criteria for requiring the recall of any particular protective restraint have been met. Under section 518(e) of the act (21 U.S.C. 360h(e)), FDA may order a recall of a device only after finding that the device would cause serious adverse health consequences or death. FDA does not have information that any type of restraint, including criss-crossed vests *if used properly*, would cause serious adverse health consequences or death. Furthermore, restraints can provide benefits that outweigh the risks for some patients, for example, by preventing patients with medically related cognitive deficits from involuntarily discontinuing life-support or other needed medical interventions, by temporarily reducing the mobility of agitated patients who may otherwise hurt themselves or others, or by helping patients feel safer in a bed or wheelchair. FDA does not believe that recalling these restraints where the benefits outweigh the risks would be in the best interest of the public health. Furthermore, FDA believes that the risks associated with restraints will be further reduced by the measures taken in this regulation. FDA, however, will certainly initiate 518(e) recall action in the future if the agency determines that individual circumstances warrant such action.

7. Four comments requested that FDA resume plans to conduct clinical and human factors engineering tests on restraining devices to assess their safety and effectiveness. Several comments stated that FDA should gather and study information from other sources besides DEN, including the Consumer Product Safety Commission, HCFA, State and local agencies that regulate nursing homes, the courts, review of patient records, review of the literature, and consultation with experts in the field.

FDA notes that in developing its course of action regarding protective restraints, the agency gathered considerable information from many other sources besides DEN, including literature reviews, interviews with health care professionals and professional organizations, visits to user facilities, and discussions with manufacturers of restraints. It is the manufacturers' responsibility to conduct testing to assess safety and effectiveness. FDA, however, would welcome any additional research information regarding restraint use from health and consumer groups and encourages research by such groups that would promote safer use of restraints. By revoking the premarket notification and CGMP exemptions, FDA will gain further information that will enable the agency to ensure safe use of these devices. FDA will continue to evaluate information received from other available sources.

8. One comment stated that FDA has ''exhibited confusion'' about the appropriate circumstances for use of restraints. The comment noted that the proposed rule states that restraints may be needed to keep agitated patients from hurting themselves, but an FDA Medical Alert warned that restraints may only add to this agitation and confusion and therefore may place the patient in jeopardy.

Whether restraints should be used may vary depending on the circumstances presented by the individual patient. While FDA realizes that restraints can adversely affect a patient by increasing agitation, they may sometimes be necessary under certain circumstances to restrain agitated patients from harming themselves. The determination of whether restraint use is appropriate should be made by clinicians for each patient individually, after assessing the risks and benefits of restraint use.

9. Several comments that supported the revocations suggested that manufacturers who fail to submit a 510(k) or fail to adhere to CGMP's should not only be prohibited from future sales of restraints, but should be compelled to remove from use (at the manufacturers' expense) all previously sold restraint products.

FDA disagrees that recalling devices is necessarily an appropriate remedy for failure to comply with CGMP or premarket notification requirements. As explained in comment 6 of this document, FDA will initiate recalls only if the statutory criteria under section 518(e) of the act are met, and will decide whether those criteria are met on a case-by-case basis. As stated in FDA's response to comment 4 of this document, manufacturers who fail to comply with CGMP and premarket notification requirements are subject to various enforcement actions by FDA.

10. Five comments requested that manufacturers be allowed to submit 510(k)'s by product category (e.g., vests, limb holders etc.), rather than for each individual product, because some products differ only in minor design aspects, while their function, application, and use is identical.

FDA agrees that grouping of similar devices in a 510(k) submission would be acceptable to a limited extent. For example, vests of similar design but composed of different fabrics might be grouped into one 510(k). However, submissions for devices differing substantially in design (and therefore risk) should not be grouped in a single 510(k). FDA will review this issue on a case-by-case basis.

11. One comment expressed concern regarding what criteria FDA is using to determine safety and effectiveness, and whether manufacturers could be assured that 510(k)'s will not be delayed on the basis of individual reviewers' perceptions of what constitutes safe and effective.

FDA advises that there will be uniformity in the criteria that reviewers consider to determine the safety and effectiveness of these devices. Section 513(i) of the act (21 U.S.C. 360c(i)) and its implementing regulations in part 807 (21 CFR part 807) describe the criteria used by FDA to determine substantial equivalence. FDA provided guidance that described labeling for restraints at an October 1991 meeting with a medical device trade organization. This guidance has been incorporated into a draft 510(k) submission guidance that will be used by FDA reviewers to assist in evaluating 510(k) submissions. Additional general labeling guidance is available in the Human Health Services (HHS) publication ''Labeling: Regulatory Requirements for Medical Devices'' (Ref. 3), the Office of Device Evaluation's labeling guidance document (Ref. 4), and the publication ''Write It Right,'' a guidance on labeling for home use products (Ref. 5). The draft 510(k) submission guidance recommends that manufacturers' 510(k) submissions for restraints address the following: (1) Specific intended use of the device; (2) ease of release of the device in the event of emergencies; (3) tear strength of the materials; (4) potential for injury (e.g., whether there are abrasive materials, such as metal fasteners, that would come in contact with the patient's skin, and similar considerations); (5) ease of identification of size; (6) completeness, conspicuousness, and simplicity of directions and labeling; (7) care/cleaning instructions; (8) whether the material is biocompatible; and (9) any safety testing data available for the device, including an analysis of bench simulation testing data; and for certain circumstances, (10) patient testing data.

Manufacturers may contact the reviewing division to discuss the appropriate content of their submissions on a case-by-case basis. FDA, elsewhere in this issue of the Federal Register, is publishing a notice of availability of this draft guidance and requesting comments on it.

12. Five comments stated that to ensure that protective restraints continue to be available for medical use, manufacturers need to be able to continue to market their products during the interim period between the effective date of the final rule revoking the 510(k) exemptions and the date that products are cleared by FDA. The comments also stated that manufacturers need to be given a reasonable amount of time (at least 6 months) after their final labeling is approved to exhaust the remaining existing supplies of their products and phase in products with the new labeling. Additionally, three comments stated that manufacturers need to be given a reasonable amount of time (for example, 2 years) to attain compliance with CGMP's.

FDA realizes that there will be a time period between the filing of a 510(k) submission required by this regulation, and FDA's determination, based on that submission, of whether the device has marketing clearance. During the time period between the filing of a 510(k) and the FDA's substantial equivalence decision, FDA, in exercising its enforcement discretion, does not intend to initiate enforcement action relating to the distribution of protective restraint devices that are adulterated under 21 U.S.C. 351(f)(1)(B) because they fail to have FDA marketing clearance if: (1) The devices were initially introduced into interstate commerce prior to September 3, 1996; and (2) the sponsor has filed a 510(k) submission as of September 3, 1996.

FDA, however, intends to exercise its enforcement discretion to initiate regulatory action against protective restraint devices that have not received marketing clearance after June 4, 1997 if FDA has been unable to reach a decision determining substantial equivalence because the 510(k) submission fails to contain sufficient information. FDA will notify the sponsor if such additional information is necessary.

FDA has extended the effective date of the final rule requiring submission of 510(k)s and compliance with CGMP's from 90 days to 180 days. FDA believes this time period is appropriate.

FDA first informed restraint manufacturers about FDA's planned actions regarding 510(k) and CGMP requirements at a meeting with a medical device trade organization in October 1991. FDA again notified manufacturers in FDA's June 19, 1992, proposed rule, that the agency intended to revoke these exemptions. Given the fact that industry has been on notice since 1991 of FDA's plans to revoke these exemptions, FDA does not believe manufacturers need an additional 2 years to comply with CGMP's or 6 months after their labeling is approved to exhaust supplies of labeling.

B. Restraint Identification

13. Two comments agreed with FDA's identification of a protective restraint as it was published in the proposed rule. Several comments stated that the identification of restraint used in the proposed rule is too narrow, leaving major gaps in the coverage of a growing list of potentially dangerous devices that are routinely used to restrain patients or residents and that are ''falsely marketed'' as alternatives to restraints. To alleviate these concerns, several comments suggested using the broader definition of restraint proposed by HCFA in order to include the concept of a method of restriction of movement.

FDA disagrees that the identification of protective restraints is too narrow and leaves major gaps that do not cover devices that are ''falsely marketed'' as alternatives to restraints. Although the identification gives examples of protective restraints, such as wristlets, vests, and straps, the identification of protective restraints is not limited to those examples. The identification is based on the product's intended use. Under § 801.4, evidence of a device's intended use is not limited to labeling claims or to verbal representations. It may be shown by the circumstances that the device is offered and used for a purpose for which it is neither labeled nor advertised. FDA considers any actions that otherwise represent a device's intended use, as well as labeling, to determine a device's intended use. Therefore, even devices that are ''falsely marketed'' as alternatives to restraints will fall under the identification of protective restraint if their intended use is to function as a protective restraint. If a manufacturer intends a device to be used as a restraint or is aware that the device is used as a restraint, that manufacturer must comply with requirements for protective restraints. FDA encourages consumers or health care workers to report instances where manufacturers of such products are not complying with the requirements for protective restraints.

Other comments suggested that the identification should state that a restraint is any device which a resident cannot remove easily and which restricts freedom of movement or easy access to their body. FDA does not agree that the protective restraint identification should be this broad. FDA may only regulate as devices products that fall within the definition under section 201(h) of the act. Many products that restrict freedom of movement or easy access to the body do not fall under FDA's jurisdiction (e.g., safety belts, car seats). Also, even if products that restrict freedom or access are medical devices (e.g., geriatric chairs), FDA believes it is inappropriate to identify all such devices as protective restraints where that is not the intended use of such devices.

14. One comment objected to the use of ''or others'' after ''protection of the patient'' at the end of § 880.6760 (21 CFR 880.6760) because it is an established rule that restraints may only be used to ''ensure the physical safety of the resident *or other residents*'' (Social Security Act, section 1919 (42 U.S.C. 1396q)). The comment also objected to the use of the term ''patients'' in the restraint identification, because it is not appropriate in many non-hospital settings. The term ''patients or other residents'' was suggested as a substitute.

FDA disagrees with the comments. Restraints are sometimes used in situations to protect individuals other than the person in restraints. For example, hospitals may use restraints in emergency rooms to protect staff, or other patients/residents from harm (e.g., due to patient drug abuse or comparable circumstances). With regard to the objection to the term ''patients'' in the context of non-hospital settings, FDA believes that since restraints are medical devices, any resident who is restrained constitutes a patient within the broad meaning of the term in this section while wearing the restraint. Therefore, FDA rejects these comments.

15. One comment stated that FDA should define bedrails and geriatric chairs as restraints.

FDA notes that bedrails and geriatric chairs are currently classified under §§ 880.5100, 880.5110, 880.5120, and 880.5140 (bedrails); and §§ 890.3100 and 890.3110 (21 CFR 890.3100 and 890.3110) (geriatric chairs). For the reasons stated in response to comment 13 of this document, FDA believes that the current definition of restraints is appropriate.

16. One comment requested that FDA modify the restraint identification to exclude from the regulation those restraints that are used with radiotherapy linear accelerators and simulators, because of the controlled

conditions under which such restraints are used and the benefit they provide. The comment requested that the identification of a restraint be modified as follows:

A protective restraint is a device * * * that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others, excluding restraints which are used for a short duration under the continual supervision of qualified personnel.

FDA does not believe that it would be appropriate to modify the restraint identification to exclude restraints which are used for a short duration under continual supervision from 510(k) and CGMP requirements. These requirements are necessary for restraints that are intended to be used for short periods of time under supervision because such restraints may pose risks to patients if they are not used in the manner the manufacturer intended. FDA advises that ''restraints'' for use with radiation therapy systems are included under the classification regulations for radiation therapy systems in §§ 892.5050 and 892.5300 (21 CFR 892.5050 and 892.5300). Under those classification regulations, such restraints are already subject to 510(k) and CGMP requirements. Manufacturers of restraints that are accessories to other devices should submit their 510(k) submissions to the appropriate reviewing division for the primary device.

C. Wheelchair Accessories

17. Two comments supported the proposal to revise the classification regulation for wheelchair accessories labeled or otherwise represented as restraints. One comment, however, stated that restraints should not be classified as wheelchair accessories because this minimizes the importance of decisions regarding whether a restraint should be used at all and the selection of the appropriate type of restraint.

FDA disagrees that the chosen classification of wheelchair accessories intended for use as restraints diminishes the importance of decisions regarding use of those devices. FDA specifically emphasized in the proposed rule and in the July 1992 FDA Safety Alert that the same safety considerations, including proper selection and labeling, are equally important for wheelchair accessories that are used as protective restraints.

18. Two comments recommended that FDA adopt an identification of wheelchair accessories intended for use as restraints that includes all accessories and all wheelchair components that are manufactured and marketed with the intent of restricting the patients' movement, regardless of whether the devices are labeled or represented as restraints.

FDA agrees with these comments. As discussed in paragraph 13 of this document, the definition of protective restraint includes any device that ''is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.'' In stating in FDA's June 19, 1992, proposed regulation that FDA was exempting wheelchair accessories from CGMP and premarket notification requirements that were not ''labeled or otherwise represented'' as a protective restraint, FDA did not mean to imply that it was exempting those wheelchair accessories that are not labeled or represented as restraints if they are intended for use as restraints. To clarify that all wheelchair accessories which are intended to be used as protective restraints must comply with premarket notification and CGMP requirements, FDA is replacing the words ''labeled or otherwise represented'' with ''intended for use'' in the final regulation.

D. Labeling/Human Factors

19. Six comments requested that the agency consider the wide variety of protective restraints available and evaluate each device according to its intended use/size/design, without imposing a ''blanket'' labeling requirement for all restraints. For example, devices such as vests should be labeled to clearly distinguish the front and back of the restraint, whereas other restraints which have no front and back should not be required to have such labeling.

FDA agrees that a ''blanket'' labeling requirement in this sense should not be imposed and that the risks and benefits of each restraint device should be reviewed individually in determining appropriate specific labeling for restraint devices. FDA believes, however, that similar protective restraints should have similar labeling. FDA also believes that protective restraints should include step-by-step instructions on how to apply the device and where to secure the ties, have securely attached warning labels that clearly identify the front and back of the restraints, and warn users of the dangers of reversal, preferably using pictorials. Additional labeling instructions are listed in the draft guidance document discussed in comment 12 of this document.

20. Several comments expressed concern that the FDA regulation implies that the only danger of restraints is in their potential misapplication and that they are safe when used in accordance with the manufacturer's instructions, and that HCFA's regulations will be undermined.

FDA disagrees with these comments. FDA's regulation does not imply that it alone will ensure safe and effective use of restraints. As explained more fully in both the preamble to FDA's June 1992 proposed rule and comment 5 of this final rule, FDA's regulations and HCFA's regulations complement each other, they do not undermine each other. HCFA laws and regulations ensure that restraints are only used on persons who need restraints, and FDA's regulations will help ensure that if clinically appropriate, such restraints will be applied safely.

21. Several comments requested that FDA require that restraint labeling contain specific information including information about all potentially harmful effects from the use of restraints, including hazards, side effects, warnings/precautions, and contraindications for their use. The comments also requested requiring clear delineation in the device labeling as follows: (1) The front and back of the restraint; (2) top and bottom of the restraint; (3) length of time the restraint can be applied safely; (4) frequency with which the restraint should be released; (5) frequency with which the patient should be monitored; and (6) minimum standards or qualifications of personnel to administer restraints. Several comments stated that labeling should be required to be on the inside or underside of the device in as discrete a manner as possible to convey necessary information and/or instructions to users, in order to preserve the dignity and self-esteem of the individual being restrained.

FDA advises that this regulation will allow FDA to review the labeling for protective restraints, and that all labeling must provide material information related to its safe use in accordance with section 502(a) of the act (21 U.S.C. 352(a)). In the preamble to the proposed rule, FDA stated certain labeling practices that FDA believes are necessary to help ensure the safe use of devices. Also, specific suggested labeling is stated in the draft guidance document discussed in comment 11 of this document. After receipt of individual premarket notifications, FDA will review the labeling on a case-by-case basis.

With regard to placement of labeling, FDA encourages placement of labeling in a manner that respects the patient's dignity, as long as the placement does

not compromise the visibility of the labeling to the person applying the restraint.

22. Several comments noted support for the utilization in all product labeling of pictorials, languages other than English, and textual information written for low language comprehension levels, in sufficiently large type to clearly express the message. Several comments suggested that the use of languages other than English is not feasible and that the manufacturer's obligation should be limited to adequate step-by-step instructions in English, with translations made available by individual employers.

FDA agrees that pictorials and text materials written for low language comprehension levels are important for effective conveyance of application and hazard information. FDA also encourages manufacturers that distribute devices for use by populations who do not use English as a first language to provide instructions in foreign languages to the extent possible and in accordance with the foreign language requirements of § 801.15(c). FDA has discussed human factors considerations related to labeling with manufacturers, including the selection of legible font types and sizes. Under 21 U.S.C. 352(c) labeling statements required by or under the authority of the act must be placed with conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. See 21 CFR 801.15.

23. Several comments suggested that in addition to improved labeling, posters should be made available for use and kept in accessible view, such as in the restrained patient's room, nurses stations, and physical therapy facilities.

FDA agrees that posters could be very helpful in promoting proper use of restraints and has encouraged manufacturers to develop such posters. Several manufacturers have already implemented instructions on posters. Placement of such posters should be done in such a way that they will be readily accessible to personnel but still comply with nursing facility requirements for a homelike environment, in accordance with provisions of 42 CFR 483.15(h)(1).

24. One comment noted that warnings and instructions for restraints should be conveyed in a form suitable for home use as well as institutional use.

FDA agrees with the comment and encourages use of FDA's guidance on developing user instruction manuals for medical devices used in home health care (Ref. 5). The document, entitled ''Write It Right,'' has been distributed to all domestic and foreign medical device manufacturers. Copies may be obtained from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, 800–638–2041.

25. One comment stated that experience demonstrates that product labels and directions cannot in and of themselves protect patients from injury or death. The comment stated that while the labeling guidelines proposed by FDA represent a positive step in recognizing the potential dangers of inappropriately applied or inappropriately supervised use of restraints, such guidelines may do more to help shield manufacturers involved in product liability suits than to protect patients from avoidable accidents.

FDA agrees that product labeling alone cannot protect patients from injury or death. However, well-presented labeling that is written in a salient, informative, and concise manner can motivate the user to read instructions, which can reinforce demonstration instruction and prevent misuse of devices. Studies, as early as 1960, illustrate that behavior can be affected by warnings and safety posters in the workplace (Ref. 6). More recent studies demonstrate that user behavior is clearly influenced by the presence and location of warnings and adequate instructions for use (Ref. 7).

FDA agrees that clearer labeling may in some instances help shield manufacturers from product liability. However, regardless of any effect on product liability, improved labeling, which may help reduce the incidence of injury and death is important. To supplement the beneficial effects of improved labeling, FDA advises that adequate training and education of health care providers is necessary for safe and effective use of restraints.

26. One comment stated that knots tied in some restraints are often difficult to untie in the event of an emergency, and if it were at all possible, restraints that tie should be replaced by those that release with a clasp of some kind.

FDA supports the development of safe innovations that would improve the ease of use of restraint devices.

E. Sizing/Color Coding

27. Several comments stated that a universal color coded sizing system should be adopted throughout the industry to help facilitate selection of the appropriate restraint size and reduce incidences of misapplication of an incorrect size that could lead to deaths or injuries.

FDA agrees with the comments. FDA also notes the availability of a voluntary new sizing standard for women over the age of 55, which might be of use in designing restraints for geriatric patients, who typically have upper torso dimensions that are substantially different from younger patients. The standard, entitled ''The Development of Body Measurement Tables for Women 55 and Older and the Relationship to Ready to Wear Garment Sizes,'' is available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

28. One comment from a manufacturer noted that for 54 years their company has manufactured restraints in accordance with a particular color code for size, and that this color code has become the most commonly used and understood color code by users of restraints. The comment stated that if FDA decides to adopt a different color standard than what the comment perceives as the ''prevailing standard,'' it will create serious confusion among users because of the extensive user familiarity with that color coding standard. Another comment stated that color coding sizes for restraints would have a substantial financial impact on industry.

This regulation is not requiring the adoption of a color-coded sizing standard. However, FDA encourages manufacturers to develop an industry-wide voluntary standard.

29. Two comments noted that manufacturers produce a selection of sizes of certain types of restraints (e.g., vests), but that this does not ensure that facilities have purchased adequate sizes or the entire line of vest restraints for utilization in their facility.

FDA advises that selection of the appropriate size and type of restraint is critical for safe and effective use of the device and that clinicians and purchasing agents should consult medical practice guidelines and instructions for use in determining the appropriate size.

F. Flame Retardancy

30. FDA explicitly solicited comments regarding whether some or all restraints should be made of flame resistant materials. Several comments supported a universal requirement for flame resistant restraints, citing the following reasons:

(1) There have been reports to FDA of at least six patients dying or being injured as a result of deliberately or accidentally igniting their restraints;

(2) Clinicians report having seen many restraints with ash and cigarette burns in them, further indicating a

safety problem with respect to flammable materials;

(3) Many of the persons who are restrained may retain their right to smoke in designated areas. These patients may have poor posture control or hand dexterity, or may be confused, increasing the chances of an accident. Also, visitors and other residents unaware of a potential fire hazard may give smoking materials to the resident without staff knowledge;

(4) Many nursing home residents may use oxygen, or be in close proximity to other residents who use oxygen, increasing the danger of fire.

Alternatively, multiple comments opposed requiring all protective restraints to be constructed of flame resistant material, citing the following reasons:

(1) Adequate and appropriate supervision is the best means of prevention of burn and smoke inhalation injuries to individuals who are being restrained;

(2) Many other items found on or near the bed are not flame resistant, such as bed linens, pajamas, clothing, and even the patient's hair, so having restraints made of flame resistant materials would not serve a useful purpose. Residents might be better served through establishment of a smoke-free environment;

(3) Labeling of restraints as flame resistant might actually encourage smoking in bed by providing a false sense of security to both residents and health care providers, who might relax smoking policies;

(4) The availability and effectiveness of flame resistant restraints is limited by current technology. Some device components are not readily available in flame resistant material, so requiring restraints with this property might be prohibitively expensive. Also, textile materials treated with flame resisting chemicals will burn if a source of ignition is present, and the flame retardancy of some devices is destroyed after the first laundering of the device. Warnings against the exposure of protective restraints to ignition sources should adequately address concerns related to burn injuries;

(5) Flame resistant vests are now marketed with very little success due to the higher price (approximately 30 percent). This cost outweighs the negligible benefit that might be derived with a universal requirement for flame resistant restraints.

Several comments also stated that FDA should study the actual contribution to patient safety that would be afforded by flame resistant restraints versus the economic impact of replacing devices currently in use. One comment suggested that the comfort and care of the patient should be the primary concern and that secondary issues should include whether fire resistant materials make the restraint less flexible or more likely to cause rubbing or irritation; the effect on safety features of the device; and the extent of protection flame resistant materials would actually offer in the event of fire.

FDA has carefully considered the comments submitted and concluded that although there are potential fire hazard concerns for some patients, adequate and appropriate supervision is the most effective and useful means of preventing fire-related injuries associated with restrained patients. Some additional benefit, however, may occur by using flame-resistant restraint material on patients who smoke. Although FDA does not believe it is appropriate to require the use of flame-resistant materials for all restraints, FDA recommends that health care institutions develop and implement policies for the use of flame-resistant restraints for patients who smoke while in restraints.

G. Training, Education, and Guidelines for Use

31. Several comments advocated increased training, education, and FDA development of guidelines for restraint use to promote the safe application of restraint devices. Several comments suggested that FDA should publish a consumer (family) guide or brochure on the appropriate use of restraints, the risks and benefits of restraint prescription and application, and the potential side effects and hazards of restraint use.

FDA agrees that adequate training and education for users of restraints in all care scenarios is critical to the safe and effective use of restraints and FDA strongly encouraged increased education about restraint use in its July 1992 Safety Alert issued to health care professionals. FDA has actively participated with health care associations in the development of guidelines for use of medical devices in the past and is willing to participate in such efforts for protective restraints. FDA advises that in using restraints, institutions are required to meet all State and local laws and HCFA requirements, and are encouraged to meet guidelines developed by professional health care organizations. With regard to publication of a consumer guide, the FDA 1992 Safety Alert on restraints contains information about restraint use specifically directed towards patients and family members. Copies of FDA's Safety Alert are available upon request from the Office of Surveillance and Biometrics (HFZ–500), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857.

32. One comment stated that because the liability burden for patient morbidity and mortality caused by restraints is increasingly shifted to nursing home staff, FDA should consider requiring manufacturers to offer training and accessible advice to nursing homes with device questions or problems, as a component of the new premarket notification and CGMP rules.

Such requirements are beyond the scope of this rulemaking. However, FDA encourages health care facilities to request training when purchasing restraints and if such training is not made available, to reconsider their purchasing policies. Manufacturers have already been strongly urged by FDA to develop training videos and other materials to assist health care facilities in training their staff in the proper application and use of their products.

H. Chemical Restraints

33. Two comments noted that they do not support the use of pharmaceutical options as chemical restraints in substitute for physical restraints and stated that FDA is well positioned to address the issue of the misuse of chemical restraints. The comments recommended that FDA consider labeling recommendations for manufacturers of drug products frequently used for chemical restraint.

FDA is advised that guidelines for the use of chemical restraints in nursing homes are being finalized by HCFA, but such controls are beyond the scope of this medical device rule. If the comments wish to express concerns regarding labeling of specific drug products believed to be misused as chemical restraints, those comments should be referred to FDA's Center For Drug Evaluation and Research, Division of Neuropharmacological Drug Products (HFD–120), 5600 Fishers Lane, Rockville, MD 20857.

III. The Final Rule

Persons required to file premarket notification submissions under section 510(k) of the act (21 U.S.C. 360(k)) and the procedures in subpart E of 21 CFR part 807 must file a premarket notification submission for any protective restraint device already marketed or intended to be introduced or delivered for introduction into interstate commerce for commercial distribution on or after September 3, 1996.

All protective restraints that are introduced or delivered for introduction into interstate commerce on or after September 3, 1996, are required to be manufactured in compliance with the CGMP regulations in 21 CFR part 820.

In a notice published elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance document for the preparation of a premarket notification (510(k)) submission.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule only removes an exemption and subjects manufacturers of patient restraints to the same requirements as manufacturers of other devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''FDA Safety Alert: Potential Hazards with Restraint Devices,'' Food and Drug Administration, Rockville, MD, July 15, 1992.

2. Johnson, R., FDA, letter to restraint manufacturers, February, 1992.

3. ''Labeling: Regulatory Requirements for Medical Devices,'' HHS Publication No. FDA 89–4203, Food and Drug Administration, Rockville, MD, August, 1989.

4. Office of Device Evaluation, ''Device Labeling Guidance,'' No. G91–1, Food and Drug Administration, Rockville, MD, March 8, 1991.

5. ''Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care,'' Food and Drug Administration, Rockville, MD, August, 1993.

6. Laner, S., and R. G. Sell, ''An Experiment on the Effect of Specially Designed Safety Posters,'' *Occupational Psychology*, 34:153–169, 1960.

7. Wolgalter, M. S. et al., ''Effectiveness of Warnings,'' *Human Factors*, 29(5):599–612, 1987.

List of Subjects

21 CFR Parts 880 and 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 880 and 890 are amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 880.6760 is revised to read as follows:

§ 880.6760 Protective restraint.

(a) *Identification*. A protective restraint is a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.

(b) *Classification*. Class I (general controls).

PART 890—PHYSICAL MEDICINE DEVICES

3. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 890.3910 is revised to read as follows:

§ 890.3910 Wheelchair accessory.

(a) *Identification*. A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.

(b) *Classification*. Class I (general controls). If the device is not intended for use as a protective restraint as defined in § 880.6760 of this chapter, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, and is also exempt from current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Dated: February 15, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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