PART 895—BANNED DEVICES

■ 6. The authority citation for part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 7. Add § 895.102 to read as follows:

§ 895.102 Powdered surgeon's glove.

(a) *Identification.* A powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

■ 8. Add § 895.103 to read as follows:

§ 895.103 Powdered patient examination glove.

(a) *Identification.* A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

■ 9. Add § 895.104 to read as follows:

§ 895.104 Absorbable powder for lubricating a surgeon's glove.

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

Dated: December 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30382 Filed 12–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2015–N–0701]

General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Crib; Classification of Medical Bassinet

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to rename pediatric hospital beds as pediatric medical cribs and establish special controls for these devices. FDA is also establishing a separate classification regulation for medical bassinets, previously under the pediatric hospital bed classification regulation, as a class II (special controls) device. In addition, this rule continues to allow both devices to be exempt from premarket notification and use of the device in traditional health care settings and permits prescription use of pediatric medical cribs and bassinets outside of traditional health care settings.

DATES: This order is effective on January 18, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Final Rule

Pediatric medical cribs that meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)) (referred to as pediatric medical cribs or cribs intended for medical purposes) (product code FMS) are regulated by FDA and will have to comply with the special controls identified in this rule for pediatric medical cribs. Cribs that do not meet the device definition (referred to as cribs for non-medical purposes) must meet the Consumer Product Safety Commission's (CPSC's) regulations and guidelines.

In the **Federal Register** of December 28, 2010 (75 FR 81766), the CPSC issued a final rule prohibiting the use of the drop-side rail design for non-medical cribs in consumer households as of June 28, 2011. CPSC's rule established new standards for full-size and non-full-size cribs intended for non-medical purposes, which effectively prohibited the manufacture or sale of cribs intended for non-medical purposes with a drop-side rail design in households, child care facilities, family child care homes, and places of public accommodation. This rule did not affect pediatric medical cribs regulated by FDA, which typically contain a drop-side rail design that includes movable and latchable side and end rails. Although drop-side cribs intended for non-medical purposes are now prohibited, there is still a need for pediatric medical cribs with drop-side rails inside and outside of traditional health care settings. Pediatric medical cribs with drop-side rails are extremely helpful for patient care in hospital settings and even outside of traditional health care settings, such as day care centers caring for infants and children with disabilities, because they allow parents and care givers easy access to children to perform routine and emergency medical procedures, including, but not limited to, cardiopulmonary resuscitation (CPR), blood collection, intravenous (IV) insertion, respiratory care, and skin care. These drop-side rail cribs also make it easier for hospital staff to facilitate safe patient transport and reduce the chance of care giver injury.

Over the last 5 years, FDA has received over 500 adverse event reports, or Medical Device Reports (MDRs), associated with open pediatric medical cribs, through the Agency's Manufacturer and User Facility Device Experience (MAUDE) database. There were adverse event reports of serious injuries, including reports of entrapment, which were predominantly entrapments of extremities (legs or arms). The majority of MDRs for medical cribs were for malfunctions such as drop-side rails not latching or lowering, brakes not holding, wheels or casters breaking, and where applicable, scales not reading correct weights. As a result of the risks to health and need for continued use of pediatric medical cribs in traditional health care settings and non-traditional settings, FDA is revising the identification for § 880.5140 (21 CFR 880.5140) to include only pediatric

medical cribs, establishing special controls for these devices, and changing the name of the classification regulation.

In addition, FDA has received adverse event reports from hospitals regarding incidents of medical bassinet tipping and improper cleaning of the basket or bed component that caused cracks and crazing, which have resulted in patient injury. Historically, medical bassinets have been regulated as pediatric hospital beds (§ 880.5140, product code NZG). As a result, this rule creates a separate regulation for medical bassinets and establishes special controls for this device type to provide a reasonable assurance of safety and effectiveness.

B. Summary of the Major Provisions of the Final Rule

In this final rule, FDA is amending the classification ''pediatric hospital bed'' in § 880.5140 to change the name of the classification regulation from ''pediatric hospital bed'' to ''pediatric medical crib'' and imposing special controls for pediatric medical cribs to provide a reasonable assurance of safety and effectiveness for these devices. This rule also creates a separate regulation, under § 880.5145, for medical bassinets and imposes special controls for this device type to provide a reasonable assurance of safety and effectiveness. In addition, use of pediatric medical cribs and medical bassinets outside of traditional health care settings will be limited to prescription use in accordance with § 801.109 (21 CFR 801.109). The Agency believes that the applicable special controls established and imposed by this final rule, together with the general controls, will provide reasonable assurance of the safety and effectiveness of these devices. Also, once this rule is effective, the Agency will move the following medical devices listed under § 880.5140 to classification regulations of other class II devices with similar intended uses and premarket notification requirements: Pediatric cribs with integrated air mattresses; youth beds; pediatric stretchers; and crib enclosure beds as identified in section II.C of this final rule.

C. Legal Authority

Pediatric medical cribs and medical bassinets are medical devices under section 201(h) of the FD&C Act. For devices, FDA has the authority under section 513(a)(1)(B) of the FD&C Act (21 U.S.C. 360c(a)(1)(B)) to issue a regulation to establish special controls for class II devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. Under this authority, FDA is establishing special controls for the class II pediatric medical cribs and medical bassinets (§§ 880.5140 and 880.5145).

D. Costs and Benefits

This rule establishes special controls for medical bassinets and pediatric medical cribs, and permits use of these devices outside of traditional health care settings for prescription use only. This regulation will also change the name of the classification regulation for ''pediatric hospital beds'' to ''pediatric medical cribs'' and establish a separate classification regulation for medical bassinets as a class II device. The special control requirements set forth in this rule will clarify safety standards and minimize the risk of injury to pediatric patients, providing reasonable assurance of safety and effectiveness. The special control requirements that are definitely not currently practiced are the warning labeling requirements for both devices. The special controls will clarify for manufacturers the safety standards and help minimize the risk of injury to pediatric patients. The benefits of the new warning label are not readily quantifiable, but it is expected to reduce the risk of the bassinet from tipping or other user error and thus, reduce potential injury to pediatric patients. Additionally, the provision permitting prescription use of medical bassinets and pediatric medical cribs outside of traditional health care settings will benefit pediatric patients who require the specialized care provided by these devices. Costs estimated in this analysis include costs related to the new warning labeling requirements, the prescription use and performance testing for medical bassinets and pediatric medical cribs, as well as physical modification of pediatric cribs. The annual costs are $2,379,400, and include the costs of the warning labels and prescription provision. The cost of performance testing is $3,360 per unit and the cost of modifying a pediatric crib is $1,125 per unit.

II. Background

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act establishes three categories (classes) of devices, based on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Most generic types of devices that were on the market before May 28, 1976, the date of the 1976 amendments (generally referred to as preamendments devices), have been classified by FDA through the issuance of regulations in accordance with the procedures set forth in section 513(c) and (d) of the FD&C Act into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as post-amendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA initiates one of the following procedures: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act, to a predicate device that is already legally marketed. The Agency determines whether new devices are substantially equivalent to predicate devices through review of premarket notifications under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and its implementing regulations, codified in title 21 of the Code of Federal Regulations (21 CFR) part 807, subpart E, require persons who intend to market a new device that does not require a premarket approval application under section 515 of the FD&C Act (21 U.S.C. 360e) to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

Section 513(a)(1)(B) of the FD&C Act defines class II devices as those devices for which the general controls in section 513(a)(1)(A) by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the Agency deems necessary to provide such assurance (see also 21 CFR 860.3(c)(2)).

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. Devices under the pediatric hospital bed classification regulation, including pediatric cribs and medical bassinets, were made exempt from premarket notification, subject to certain limitations, in accordance with section 510(m) of the FD&C Act (63 FR 59222 at 59229, November 3, 1998).

A. Need for the Regulation/History of This Rulemaking

Pediatric medical cribs are medical devices intended for the treatment, cure, or mitigation of diseases or illnesses of pediatric patients. Prior to the issuance of this final rule, a pediatric hospital bed is was defined as ''a device intended for medical purposes that consists of a bed or crib designed for the use of a pediatric patient, with fixed end rails and movable and latchable side rails. The contour of the bed surface may be adjustable.'' FDA classified pediatric medical cribs in 1980 as pediatric hospital beds (§ 880.5140, product code FMS), class II devices (45 FR 69678 at 69695, October 21, 1980), and exempted them in 1998 from premarket notification (510(k)) under section 510(m) of the FD&C Act in the final rule (63 FR 59222 at 59229). Pediatric medical cribs with drop-side rails are extremely helpful for patient care in hospital settings and even outside of traditional health care settings, such as day care centers caring for infants and children with disabilities, because they allow parents and care givers easy access to children in order to perform routine and emergency medical procedures, including, but not limited to, CPR, blood collection, IV insertion, respiratory care, and skin care.

FDA published a proposed rule in the **Federal Register** of October 8, 2015 (80 FR 60809), proposing to (1) change the identification and name of § 880.5140, *Pediatric hospital bed* to *Pediatric medical crib,* and remove references to ''beds'' within the regulation, as appropriate, (2) establish special controls for pediatric medical cribs, (3) rearrange the devices within § 880.5140 so that it includes only pediatric medical cribs and move other devices that were within the prior hospital bed regulation to more appropriate classification regulations, and (4) create a separate regulation for medical bassinets with special controls. This rule finalizes those proposals.

Pediatric medical cribs that meet the definition of a device in section 201(h) of the FD&C Act are regulated by FDA. Cribs that do not meet the definition of device must meet the CPSC's regulations and guidelines. Because drop-side rail cribs for non-medical purposes and pediatric medical cribs are regulated by different agencies, CPSC consulted with FDA about the impact their final rule (75 FR 81766) could have on settings, such as nursery schools and day care centers, where pediatric medical cribs with drop-side rails are often used for pediatric patients after they have been discharged from a health care facility. In comparison to CPSC's experience with drop-side rail cribs for non-medical purposes, FDA received fewer and less severe adverse event reports for pediatric medical cribs with the drop-side design. In addition, FDA determined that there is a need for continued access to pediatric medical cribs with drop-side rails inside and outside of traditional health care settings because of the utility of the drop-side design (Ref. 1). Based on the consultation with CPSC, FDA determined that it should establish special controls to provide reasonable assurance of the safety and effectiveness of pediatric medical cribs and permit continued use of these devices outside of traditional health care settings.

This rule also creates a separate classification regulation for medical bassinets, § 880.5145. Historically, medical bassinets have also been regulated as pediatric hospital beds (§ 880.5140, product code NZG). A medical bassinet is a non-powered device that consists of two components: (1) A basket, the sleep or bed component, which is typically made of plastic and (2) a frame with wheels, which holds the basket or bed component (FDA refers to this component as a ''basket or bed component'' interchangeably in this rule). The basket or bed component is a box-like structure, generally made of a clear, high-impact resistant plastic material, with an open top and four walls to keep the infant in place. Medical bassinets are typically used in hospital settings for infants up to 5 months in age. The beneficial features of medical bassinets are portability, ease of cleaning, and, when it is made of a clear material, the ability to see the infant from all sides.

Based on the risks to health identified in FDA's proposed rule for pediatric medical cribs and bassinets, along with MDRs the Agency received from January 2005 to September 2015, FDA determined that general controls alone are insufficient to provide a reasonable assurance of safety and effectiveness for these devices for their intended use. Thus, with this rule, FDA is imposing special controls on these devices, which along with general controls, will provide reasonable assurance of safety and effectives of these devices and will permit their continued use in traditional health care settings. FDA will also permit the use of pediatric medical cribs with drop-side rail designs and bassinets outside of traditional health care settings through prescription use only. The special controls are designed to address the adverse event reports for pediatric medical cribs and bassinets. For pediatric medical cribs, there were adverse event reports of serious injuries including reports of entrapment, which were predominantly extremity entrapments of legs or arms. The majority of these reports were for malfunctions such as drop-side rails not latching or lowering, brakes not holding, wheels or casters breaking, and where applicable, scales not reading correct weights. For medical bassinets, hospitals have reported to FDA incidents of tipping and improper cleaning of the basket or bed component that caused cracks and crazing, which have resulted in patient injury.

B. Summary of Comments to the Proposed Rule

FDA requested comments on the proposed rule (80 FR 60809), and the comment period closed on December 7, 2015. The Agency received 11 comments on the proposed rule by the close of the comment period; some of the comments contained comments on more than one issue. We received comments from a cross-section of consumers, device manufacturers, and professional and trade associations. All of the comments supported the changes identified in the proposed rule in whole or in part; however, some comments suggested changes to the proposed special controls or requested clarification of matters discussed in the proposed rule. See section IV for the description of comments on the proposed rule and FDA's responses.

C. General Overview of Final Rule

FDA is amending the classification pediatric hospital bed in § 880.5140 to change the name of the classification regulation from ''pediatric hospital bed'' to ''pediatric medical crib'' and to establish special controls for pediatric medical cribs to provide a reasonable assurance of safety and effectiveness. This rule also creates a separate regulation, under § 880.5145, for

medical bassinets and establishes special controls for this device type to provide a reasonable assurance of safety and effectiveness. In addition, use of pediatric medical cribs and medical bassinets outside of traditional health care settings will be limited to prescription use in accordance with § 801.109. The Agency believes that the applicable special controls, together with the general controls, will provide reasonable assurance of the safety and effectiveness of these devices.

Devices that do not meet the final identification under § 880.5140 for ''pediatric medical crib'' will be administratively moved to more appropriate class II regulations for devices with more similar intended uses that are also class II, 510(k) exempt, and will not be located under the final pediatric medical crib classification regulation. Shortly after the effective date of this final rule, FDA will send manufacturers of the remaining pediatric hospital beds notices identifying the new classification regulation and product code under which the device will be classified. These devices include: Open pediatric medical cribs, medical bassinets, pediatric cribs with integrated air mattresses, youth beds, pediatric stretchers, and crib enclosure beds. A more complete list of the devices from§ 880.5140 and to where they are being moved is provided in table 1.

This action will not have any substantive effect on the current marketing status of the devices. However, manufacturers of these devices will need to refer to the new regulation classification and product code provided by the Agency in future interactions with FDA.

TABLE 1—MEDICAL DEVICES REMOVED FROM § 880.5140

New CFR regulation	Classification name	Device class
21 CFR 890.5170	Pediatric cribs with integrated air mattresses	II
21 CFR 880.5100 or 21 CFR 880.5120 (depending on whether they are powered).	Youth Beds	II
21 CFR 880.6910	Pediatric Stretchers	II
21 CFR 880.6760	Crib Enclosure Beds	II

III. Legal Authority

Pediatric medical cribs and medical bassinets are defined as medical devices under section 201(h) of the FD&C Act. For devices, FDA has the authority under section 513(a)(1)(B) of the FD&C Act to issue a regulation to establish special controls for class II devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. Under this authority, FDA is establishing special controls for the class II pediatric medical cribs and bassinets (§§ 880.5140 and 880.5145).

IV. Comments on the Proposed Rule and FDA's Responses

A. Introduction

In response to the proposed rule (80 FR 60809) to revise § 880.5140 to specify that it will only be for regulation of pediatric medical cribs, with proposed special controls and to create a separate regulation for medical bassinets, also with proposed special controls, FDA received 11 comments to Docket No. FDA–2015–N–0701. The comments and FDA's responses to the comments are summarized in this document. Certain comments are grouped together under a single number because the subject matter of the comments is similar. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

B. Specific Comments and FDA Response

(Comment 1) Multiple comments made recommendations that we revise the requirements for medical bassinet warning labels. One comment suggested that the warning label be affixed in a prominent location; another comment recommended that the warning label be required to be permanently affixed on all sides of the bassinet. One comment also recommended that the special control require 9 point font for visibility.

(Response 1) FDA believes that a warning label for medical bassinets should be readable, prominent, and in the same location on each device. While the proposed rule required the warning label to be placed on the bassinet cabinet, FDA has determined that some medical bassinets do not include a ''cabinet,'' but all of the devices do have a plastic basket or bed component. As a result, FDA has revised the special control requiring a warning label to specify that the label will need to be affixed to at least two sides of the plastic basket or bed component of the bassinet with the language in text of at least 9 millimeters in height.

(Comment 2) FDA received a comment requesting that FDA require warning labels for pediatric medical cribs.

(Response 2) Based on the adverse event reports received on pediatric medical cribs, FDA agrees that a warning label is warranted for pediatric medical cribs. These devices have a number of moving parts that can present a risk of head and limb entrapment, crushing, pinching, and lacerations to a pediatric patient. FDA has therefore revised the special controls for pediatric medical cribs to include a labeling requirement that mandates that a warning label be affixed to the medical crib that states that pediatric patients must be attended at all times whenever a movable side of the crib is in its lowest, or most open, position when accessing the child. This will serve as a mitigation for the risks of physical harm, such as falling out of the crib and possible pinching or lacerations to pediatric patients and help provide a reasonable assurance of safety and effectiveness of the device.

(Comment 3) Multiple comments requested clarification of the scope of the rule and the applicability of the special controls. One comment requested that the special controls identified in this rule apply to devices that have already been sold in interstate commerce.

(Response 3) After the effective date of this rule, manufacturers of pediatric medical cribs or medical bassinets, whether or not they have been legally marketed prior to January 18, 2017, must comply with the special controls identified in this rule to provide a reasonable assurance of safety and effectiveness of these devices. However, FDA does not intend to enforce the special controls for devices legally marketed prior to this date due to the logistical issues associated with requiring manufacturers to locate devices that have been sold.

(Comment 4) One comment suggested that we provide educational material for

users of prescription medical pediatric cribs in non-traditional health care settings that address use errors.

(Response 4) The FD&C Act and its implementing regulations require all devices to be accompanied by adequate instructions for use (see section 502(f) of the FD&C Act (21 U.S.C. 352(f)) and § 801.5). In addition, the special controls identified in this rule include a requirement for ''adequate instructions for users to care for, maintain, and clean the crib'' and for warning labels alerting users to risks associated with crib use. The Agency believes these requirements sufficiently address the commenter's concern regarding use error.

(Comment 5) One comment stated that this rule should not affect contractors or business owners who provide a unique service or product.

(Response 5) To the extent the unique product referred to in the comment is a pediatric medical crib or medical bassinet that meets the definition of a custom device in section 520(b) of the FD&C Act (21 U.S.C. 360j(b)), these devices are exempt from, among other things, premarket approval requirements and conformance to mandatory performance standards (sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e)). However, the definition of custom device is narrow and requires a fact specific analysis. FDA expects that few ''unique'' pediatric medical cribs or bassinets will qualify as custom devices. FDA notes that patient-specific or patient-matched devices—those that have ranges of different specifications on one general design—are not generally regarded as custom devices. Manufacturers should see FDA's ''Custom Device Exemption'' guidance document for more information (Ref. 2). It is important that this rule apply to all pediatric medical cribs and bassinets that do not meet the custom device exemption to provide the broadest protection to users.

(Comment 6) One comment requested that we expand the device identification for pediatric medical cribs to include specialty cribs that allow parents who are disabled to access their children.

(Response 6) This rule establishes an identification and special controls specific to pediatric medical cribs intended for medical purposes and use with a pediatric patient. FDA developed the special controls only after considering the manufacture, use, and risks to health specific to these cribs. The special controls were not developed with other cribs, such as the specialty cribs described in the comment, in mind. As a result, FDA disagrees with including specialty cribs used by disabled parents for access to their children under this regulation classification.

(Comment 7) One comment requested that FDA make the following changes to the proposed rule regarding pediatric medical crib dimensions: (1) Citing FDA's reference of ASTM F1169–13 (formerly the American Society for Testing and Materials), section 5.7.2.1, in relation to rail height requirement, the commenter stated that, ''Based on user need we believe that this reference should be removed to allow for full access to the patient without interference from the siderail [sic] in the lowest height position.'' The commenter stated that they believe dimensions should be determined through the design process and should balance risks and benefits. (2) The proposed rule suggested that ''no gap shall exist between the edge of the bottom rail and the top of the mattress surface,'' based on ASTM F1169–13. The commenter proposed instead that, based on International Electrotechnical Commission (IEC) 60601–2–52, a maximum gap of 2⅜ inches be allowed. The commenter stated that a requirement for ''no gap'' would be practically difficult to design. (3) The commenter also pointed out that the proposed requirement for the height of the side rail is inconsistent with the requirement provided by ASTM F1169–13, section 5.7.2.2, and recommended harmonization with ASTM F1169–13.

(Response 7) FDA agrees that clarification of dimensional requirements is needed for the special controls to mitigate entrapment, pinching, lacerations, and other risks associated with pediatric medical cribs. The Agency responds to the previous comments as follows: (1) Given the many potential differences in crib designs, including different mattress heights, a specific requirement for the height of a pediatric medical crib's side rail at the lowest position is unnecessary and may not mitigate the risk of falls as effectively in all designs. As a result, FDA has removed the specific height requirement when side rails are in their lowest position, but revised the height requirement when the rail is in the highest position (as described as follows in this response). Also, FDA has added a requirement for a warning label that states that pediatric patients should be attended to whenever a rail is in its lowest, or most open, position, regardless of design, to monitor and mitigate the risk of the patient falling out of the medical crib.

(2) FDA agrees that it may be difficult to design for ''no gap''; however, the Agency does not agree that 2⅜ inches is an appropriate maximum dimension, as this may leave room for entrapment or impingement. FDA has revised the special controls to eliminate the requirement for ''no gap,'' but is retaining the requirement that crib mattresses must fit tightly around all four sides of the crib, such that the occurrence of entrapment and impingement is prevented.

(3) FDA agrees that the proposed requirement height of 20 inches was incorrect because the measurement failed to include the CPSC standard as required in CPSC's guidance entitled ''Full-Size Baby Crib Business Guidance'' for a pediatric medical crib mattress that requires the height measurement for the mattress to be 6 inches thick (Ref. 3). As a result, FDA is revising the special control requirement to be consistent with that standard. The height of the rail and end panel as measured from the top of the rail or panel in its highest position to the top of the mattress support in its lowest position shall be at least 26 inches (66 centimeters). The mattress will also be required to not exceed 6 inches in thickness. This requirement is to ensure that high mattresses do not create a hazard by reducing the rail height.

(Comment 8) One comment opposed the proposed rule because it did not require any safety testing data be reviewed by FDA. According to the commenter, testing was especially important given the lack of scientific evidence that drop-side rail cribs provide important benefits in hospital settings.

(Response 8) Section 510(m)(2) of the FD&C Act permits FDA to exempt a class II device from the premarket notification requirements on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. Pediatric medical cribs have been exempt from premarket notification since 1998 and they have been essential to the provision of efficient medical care to pediatric patients since they entered the market. FDA reviewed the MedSun Survey (Ref. 1) and analyzed the MDRs submitted to the MAUDE database for medical cribs to identify the relevant risks to health associated with these devices (section IV of the proposed rule) and determined that, based on these risks, the number of MDRs received, and FDA's experience with these devices, there is sufficient information available to establish special controls that in combination with the general controls will provide a reasonable assurance of

safety and effectiveness by mitigating the risks to health associated with these devices (section VI of the proposed rule) without the need to reinstate the requirement for 510(k) review. The special controls require manufacturers to perform appropriate testing to demonstrate the mechanical and structural stability of their pediatric medical cribs, among other things. As a result, FDA does not agree that it needs to review the testing data through review of a manufacturer's premarket notification (510(k)) to provide reasonable assurance of the safety and effectiveness.

(Comment 9) One comment suggested that FDA make the effective date 120 days after the publication of this rule to allow manufacturers of devices legally on the market to have time to conduct gap analysis, plan for design changes, and comply with other special controls.

(Response 9) FDA does not intend to extend the effective date to 120 days for the established special controls in this rule for both pediatric medical cribs and bassinets because many of the special controls in this rule are consistent with current industry practice among many manufacturers of products currently on the market. As stated earlier, due to the CPSC rule prohibiting the use of cribs with a drop-side rail design for non-medical purposes, FDA believes it is necessary to allow consumers to use pediatric medical cribs and bassinets in non-traditional health care facilities as soon as possible if they are prescribed by a health care professional. As a result, FDA has decided to change the effective date from the proposed 60 days stated in the proposed rule to now being 30 days after its publication in the **Federal Register** as stated in this final rule to provide a reasonable assurance of safety and effectiveness of these devices.

Also, FDA is unaware of a possible shortage of devices entering the market due to manufacturers having to comply with the new special controls; however, FDA does not intend to enforce compliance with the special controls for manufacturers of new devices until they have been brought onto the market.

C. Clarifying Changes to the Rule

In addition to the revisions made to the special controls for pediatric medical cribs and bassinets based on the comments submitted for the proposed rule, FDA is making additional clarifying changes to the special controls. FDA has determined that CPSC's Standard for the Flammability of Mattresses and Mattress Pads (FF 4–72, Amended) and Standard for the Flammability (Open Flame) of Mattress Sets (16 CFR parts 1632 and 1633) are inapplicable to medical bassinets because the mattresses for medical bassinets do not meet the measurements required for CPSC's mattress flammability standards. FDA is therefore removing this special control.

In addition, FDA has revised the labeling special control for both medical cribs and medical bassinets to include adequate instructions for cleaning of the device. The labeling for adequate maintenance of a bassinet should include the use of proper cleaning materials to allow safe and continuous use of these devices for both pediatric patients and personnel in traditional health care settings.

FDA believes that the special controls, listed in the revised regulations § 880.5140 and new regulation § 880.5145, in combination with the general controls, will provide a reasonable assurance of safety and effectiveness for pediatric medical cribs and medical bassinets for their intended use.

V. Effective/Compliance Dates

This final rule will become effective 30 days after its publication in the **Federal Register**.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us 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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the expected costs associated with this rule are expected to be modest, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule establishes special controls for medical bassinets and pediatric medical cribs, and permits prescription use of these devices outside of traditional health care settings. This regulation will also change the name of the classification regulation for ''pediatric hospital beds'' to ''pediatric medical cribs'' and establish a separate classification regulation for medical bassinets as a class II device. The special control requirements set forth in this rule will clarify safety standards to help minimize the risk of injury to pediatric patients posed by these devices. Additionally, permitting use of pediatric medical cribs by prescription outside of traditional health care settings will benefit pediatric patients who require the specialized care provided by these devices. Costs estimated in this analysis include costs related to the new warning labeling requirements, the prescription and performance testing for medical bassinets and pediatric medical cribs, along with physical modification of pediatric medical crib design. The annual costs are $2,379,400, and include the costs of the warning labels and prescription provision. The cost of performance testing is $3,360 per unit and the cost of modifying a pediatric crib is $1,125 per unit.

The full discussion of economic impacts is available in Docket No. FDA–2015–N–0701 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 4).

VII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

VIII. Paperwork Reduction Act of 1995

The final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to

review by the Office of Management and Budget (OMB) and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding premarket notification submissions (part 807, subpart E), are approved under OMB control number 0910–0120. The collections of information regarding labeling (21 CFR part 801), including prescription device labeling and adequate directions for use, are approved under OMB control number 0910–0485. The collections of information regarding current good manufacturing practice quality systems (21 CFR part 820), including design controls (as referenced in §§ 880.5140(b)(1) and 880.5145(b)(1) and (3) of this document), are approved under OMB control number 0910–0073. The collections of information in 16 CFR parts 1632 and 1633, regarding mattress flammability, are approved under OMB control number 3041–0014.

In addition, FDA concludes that the warning labels for pediatric medical cribs and medical bassinets are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA. Rather, the labeling statements are ''public disclosure(s) of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that would have substantial direct effects 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 Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. MedSun Newsletter #66, ''Pediatric Hospital Cribs: MedSun Small Sample Survey Summary'' (November 2011), available at *http://www.fda.gov/downloads/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/Newsletters/UCM422131.pdf.*
2. FDA, ''Custom Device Exemption; Guidance for Industry and Food and Drug Administration Staff,'' (September 24, 2014), available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM415799.pdf.*
3. Consumer Product Safety Commission, ''Full-Size Baby Cribs Business Guidance,'' available at *http://www.cpsc.gov/en/Business—Manufacturing/Business-Education/Business-Guidance/Full-Size-Baby-Cribs/.*
4. Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Requirements for General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Crib; Classification of Medical Bassinet, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 880

Medical devices.

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

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Revise § 880.5140 to read as follows:

§ 880.5140 Pediatric medical crib.

(a) *Identification.* A pediatric medical crib is a prescription device intended for medical purposes for use with a pediatric patient that consists of an open crib, fixed end rails, movable and latchable side rail components, and possibly an accompanying mattress. The contour of the crib surface may be adjustable.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9. The special controls for this device are:

(1) Crib design and performance testing shall demonstrate the mechanical and structural stability of the crib under expected conditions of use, including the security of latches and other locking mechanisms when engaged;

(2) Materials used shall be appropriate for the conditions of use, allow for proper sanitation, and be free from surface defects that could result in injuries;

(3) The height of the rail and end panel as measured from the top of the rail or panel in its highest position to the top of the mattress support in its lowest position shall be at least 26 inches (66 centimeters). Any mattress used in this crib must not exceed a thickness of 6 inches;

(4) Hardware and fasteners shall be designed and constructed to eliminate mechanical hazards to the patient;

(5) The distance between components of the side rail (*i.e.,* slats, spindles, and corner posts) shall not be greater than 2⅜ inches (6 centimeters) apart at any point;

(6) The mattress must fit tightly around all four sides of the crib base, such that entrapment or impingement of occupant is prevented;

(7) The mattress for the crib shall meet the Consumer Product Safety Commission (CPSC) Standard for the flammability of mattresses and mattress pads (FF 4–72, amended) and Standard for the flammability (open flame) of mattress sets, 16 CFR parts 1632 and 1633, respectively; and

(8) Each device must have the following label(s) affixed:

(i) Adequate instructions for users to care for, maintain, and clean the crib; and

(ii) A warning label on at least two sides of the medical crib with the following language in text of at least 9 millimeters in height:

WARNING: Never leave a child unsupervised when the moveable side is open or not secured.

■ 3. Add § 880.5145 to subpart F to read as follows:

§ 880.5145 Medical bassinet.

(a) *Identification.* A medical bassinet is a prescription device that is a small bed intended for use with pediatric patients, generally from birth to approximately 5 months of age. It is intended for medical purposes for use in a nursery, labor and delivery unit, or patient room, but may also be used outside of traditional health care settings. A medical bassinet is a non-powered device that consists of two components: The plastic basket or bed component and a durable frame with wheels, which holds the basket or bed

component. The basket or bed component is a box-like structure, generally made of a clear, high impact-resistant plastic material, with an open top and four stationary walls to hold the pediatric patient. The frame can include drawers, shelving, or cabinetry that provides space to hold infant care items. The wheels or casters allow the bassinet to transport the infant throughout the care setting.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9. The special controls for this device are:

(1) The manufacturer must conduct performance testing to determine material compatibility with cleansing products labeled to clean the device. Testing must demonstrate that the cleaning instructions provided by the manufacturer do not cause crazing, cracking, or deterioration of the device;

(2) Manufacturers shall conduct performance testing to ensure the mechanical and structural stability of the bassinet under expected conditions of use, including transport of patients in the bassinet. Testing must demonstrate that failures such as wheel or caster breakage do not occur and that the device does not present a tipping hazard due to any mechanical failures under expected conditions of use; and

(3) Each device must have the following label(s) affixed:

(i) Adequate instructions for users to care for, maintain, and clean the bassinet; and

(ii) A warning label on at least two sides of the plastic basket or bed component with the following language in text of at least 9 millimeters in height:

WARNING: To avoid tipping hazards of this device, make sure that the basket or bed component sits firmly in the base and that all doors, drawers, and casters are secure.

Dated: December 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30193 Filed 12–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9805]

RIN 1545–BN18

Guidance Under Section 355(e) Regarding Predecessors, Successors, and Limitation on Gain Recognition; Guidance Under Section 355(f)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations that provide guidance regarding the distribution by a distributing corporation of stock or securities of a controlled corporation without the recognition of income, gain, or loss. The temporary regulations provide guidance in determining whether a corporation is a predecessor or successor of a distributing or controlled corporation for purposes of the exception under section 355(e) of the Internal Revenue Code (Code) to the nonrecognition treatment afforded qualifying distributions, and they provide certain limitations on the recognition of gain in certain cases involving a predecessor of a distributing corporation. The temporary regulations also provide rules regarding the extent to which section 355(f) of the Code causes a distributing corporation (and in certain cases its shareholders) to recognize income or gain on the distribution of stock or securities of a controlled corporation. These temporary regulations affect corporations that distribute the stock or securities of controlled corporations and the shareholders or security holders of those distributing corporations. The text of these temporary regulations also serves as the text of the proposed regulations in the related notice of proposed rulemaking (REG–140328–15) set forth in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective date:* These temporary regulations are effective on December 19, 2016.

Applicability date: For dates of applicability see § 1.355–8T(i) and (j).

FOR FURTHER INFORMATION CONTACT: Richard K. Passales, (202) 317–5024 or Marie C. Milnes-Vasquez, (202) 317–7700 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

1. Overview

On November 22, 2004, the Department of the Treasury (Treasury Department) and the IRS published in the **Federal Register** (69 FR 67873) a notice of proposed rulemaking (REG–145535–02) containing proposed regulations under section 355(e)(4)(D) of the Code (the proposed regulations). After considering the comments received on the proposed regulations and taking into account subsequently issued guidance as described in part 3. of this preamble, the Treasury Department and the IRS are issuing temporary regulations that adopt the proposed regulations with significant modifications based on the comments received on the proposed regulations. The temporary regulations also serve as the text of new proposed regulations in the related notice of proposed rulemaking (REG–140328–15) published in the Proposed Rules section in this issue of the **Federal Register**.

The temporary regulations amend 26 CFR part 1 under section 355 to provide necessary guidance under section 355(e)(4)(D) regarding the identity of predecessor and successor corporations of distributing and controlled corporations and to enable taxpayers to utilize the benefit of certain gain limitation rules. The temporary regulations also provide guidance regarding the extent to which section 355(f) precludes the application of section 355 to certain distributions and exchanges between members of an affiliated group. Finally, the regulations provide guidance regarding the application of section 336(e) to certain distributions of controlled stock to which section 355(e) applies.

A. Section 355 in General

Section 355(a) generally provides that if a distributing corporation (Distributing) distributes stock or securities of a controlled corporation (Controlled) to Distributing's shareholders or security holders and certain requirements are met, then no gain or loss is recognized by (and no amount is includible in the income of) Distributing's shareholders or security holders upon their receipt of the Controlled stock. Section 355(c) generally provides that Distributing does not recognize gain or loss on any distribution of qualified property to which section 355 (or so much of section 356 as relates to section 355) applies. Similar rules under section 361(c) apply in the case of a divisive reorganization under section