

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## 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:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to rename pediatric hospital beds as pediatric medical cribs and establish special controls for these devices. FDA is also proposing to establish a separate classification regulation for medical bassinets, previously under the pediatric hospital bed classification regulation, as a class II (special controls) device. The proposed regulation for both pediatric medical cribs and medical bassinets would also include the Consumer Product Safety Commission's (CPSC) mattress flammability standards for the mattresses intended for use with these devices. In addition, this proposed rule would require prescription use of pediatric medical cribs and bassinets.

**DATES:** Submit either electronic or written comments by December 7, 2015. See section VII of this document for the proposed effective date of a final rule based on this proposed rule.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2015-N-0701 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." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**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:

#### I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Device Amendments of 1990 (SMDA) (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the FDA Safety and Innovation Act (Pub. L. 112-

144), among other amendments, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) 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 classified automatically by statute (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), 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 report (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 were exempted 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).

## II. Regulatory History and Description of the Devices

FDA classified pediatric hospital beds (21 CFR 880.5140) as class II devices (45 FR 69678 at 69694, October 21, 1980), and later exempted them from premarket notification (510(k)), in a final rule published in the **Federal Register** of November 3, 1998 (63 FR 59222 at 59229). In § 880.5140, a pediatric hospital bed is 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.”

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 durable frame with wheels, which holds the basket or bed component (FDA refers to this component as a “basket or bed component” in this proposed 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 stationary walls to keep the baby in place. Medical bassinets are typically used in hospital settings for infants up to 5 months in age. Medical bassinets currently fall under the pediatric hospital bed classification regulation.

## III. Proposed Regulation

Pediatric medical cribs that meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)) are regulated by FDA (referred to as

pediatric medical cribs or cribs intended for medical purposes) (product code FMS) and, if this rule is finalized, will have to comply with the special controls identified in the final regulation for pediatric medical cribs. Cribs outside of the device definition (referred to as cribs for non-medical purposes) must meet the CPSC’s regulations and guidelines. A crib designed for the use of a pediatric patient may meet the medical device definition if it is intended for use in the cure, mitigation or treatment of disease (see section 201(h) of the FD&C Act).

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. Child care facilities, family child care homes, and places of public accommodation (e.g., hotels and motels) had to comply with the rule as of December 28, 2012. CPSC’s rule establishes new standards for full-size and non-full-size cribs used for non-medical purposes, which effectively prohibit the manufacture or sale of cribs 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 may contain a drop-side rail design that includes movable and latchable side and end rails.

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 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. CPSC, which regulates consumer products, including drop-side rail cribs not intended for medical purposes, received reports of deaths of children attributable to entrapment and/or strangulation caused by the malfunctioning of drop-side rail cribs.

Although drop-side cribs 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. CPSC and FDA have heard from medical device consumers and health care providers that 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, CPR, blood collection, 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 caregiver injury. Health care workers have stated that they need to have continued access to these medical cribs with drop-side rails (Ref. 1). Therefore, FDA is proposing to permit manufacturers to continue to manufacture and sell medical cribs with the drop-side rail design in traditional health care settings and to permit the use of pediatric medical cribs with drop-side rail designs outside of traditional health care settings through prescription use only (it is noted that State child care licensing agencies are generally responsible for overseeing day care providers while FDA is responsible for medical devices).

FDA is proposing to revise the identification in § 880.5140 to include only pediatric medical cribs, establish special controls for this device, and change the name of the classification regulation from “pediatric hospital bed” to “pediatric medical crib.” The Agency is taking these actions to clarify the devices that fall under this particular classification regulation and establish special controls the Agency believes are necessary for a reasonable assurance of safety and effectiveness. In addition, FDA is proposing that use of a pediatric medical crib be restricted to prescription use in accordance with 21 CFR 801.109. In order to use or administer use of pediatric medical cribs, authorization must be made by a practitioner licensed by law through a prescription for the device.

This rule also proposes to create a separate regulation for medical bassinets and establish special controls for this device type to provide a reasonable assurance of safety and effectiveness. In addition, FDA is proposing that use of medical bassinets be restricted to prescription use in accordance with 21 CFR 801.109. In order to use or administer use of medical bassinets, authorization must be made by a practitioner licensed by law through a prescription for the device. FDA proposes not to change the 510(k) exempt status of pediatric medical cribs and medical bassinets.

Devices currently under the pediatric hospital bed classification regulation include: Open pediatric medical cribs, medical bassinets, pediatric cribs with integrated air mattresses, youth beds, pediatric stretchers, crib enclosure beds, and cuddle-carrier infant beds. If this

proposed rule is finalized, devices that do not meet the definition of “pediatric medical crib” will be administratively moved to more appropriate class II regulations, and no longer be under the revised pediatric hospital bed classification regulation. At that time, FDA proposes to send manufacturers of the remaining pediatric hospital beds notices identifying the new classification regulation and product code under which the device will be classified.

If this proposed rule is finalized, FDA intends to move the following medical devices listed under § 880.5140 to devices with similar intended uses and class II regulations: Pediatric cribs with integrated air mattresses to 21 CFR 890.5170, “Powered flotation therapy bed;” youth beds to either 21 CFR 880.5100, “AC powered adjustable hospital bed,” or 21 CFR 880.5120, “Manual adjustable hospital bed,” depending on whether they are powered or not; pediatric stretchers to 21 CFR 880.6910, “Wheeled stretchers;” and crib enclosure beds to 21 CFR 880.6760, “Protective restraint.” This action would not have any substantive effect on the current marketing status of the devices. However, manufacturers of these devices would need to refer to the new regulation classification and product code provided by the Agency in future interactions with FDA.

As discussed in section IV, an analysis of Medical Device Reports (MDRs) submitted to the Manufacturer and User Facility Device Experience (MAUDE) database from January 1, 2005, to September 1, 2015, indicated 516 adverse events associated with pediatric medical cribs including 15 serious injuries. The adverse events associated with pediatric medical cribs were assessed to better understand the risks and establish the proposed special controls for this device. FDA believes that sufficient information is available to establish special controls to provide a reasonable assurance of the safety and effectiveness of the device.

As discussed further in section VI, FDA believes risks to health resulting from use of these cribs would be effectively mitigated by the special controls proposed in this rule, and that these controls, in combination with the general controls, would provide a reasonable assurance of safety and effectiveness for pediatric medical cribs for their intended use. Therefore, FDA is proposing new safety requirements and allowing medical cribs in homes and day cares only when medically necessary.

FDA is also taking this opportunity to address adverse event reports pertaining

to medical bassinets by proposing to establish special controls for these devices to provide a reasonable assurance of safety and effectiveness. FDA has received adverse events 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. The Agency is proposing to separate medical bassinets from other types of pediatric hospital beds to allow for more targeted postmarket surveillance of these devices. FDA believes the special controls it is proposing here, in combination with the general controls, would provide a reasonable assurance of safety and effectiveness for medical bassinets.

#### IV. Risks to Health

##### A. Pediatric Medical Crib

Between January 1, 2005, and September 1, 2015, FDA received 516 adverse event reports, or MDRs, associated with open pediatric medical cribs, through the Agency’s MAUDE database. There were 15 adverse event reports of serious injuries including 6 reports of entrapment, which were predominantly extremity entrapments of 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. These malfunctions (501 reports) were not associated with any adverse health effects. After considering available information, FDA determined that the following risks to health are associated with the use of pediatric medical cribs:

- *Injury resulting from mechanical or structural failure of the device*—

Mechanical or structural failure of the crib can result in failure of load-bearing components such as the wheels or casters, or failure of the latches or other locking mechanisms that secure the sides of the crib. These failures can result in injuries, as demonstrated by the MDRs received in FDA’s database.

- *Pinching, laceration, splinters, and foreign body ingestion*—Depending on the material of the pediatric crib, certain cribs may peel or crack and may expose pediatric patients to substances or materials that may be toxic or may cause abrasions or lacerations if the surface of the crib material is compromised.

- *Entrapment, falls, and strangulation*—Pediatric medical cribs may cause entrapment of patient limbs if the width of the side rails are not correct and if there are gaps between the mattress and crib frame that are larger

than the width of two fingers. Depending on the height requirements of the rails a pediatric patient may escape or fall from the crib. The term “entrapment” refers to circumstances where a patient is caught, trapped, or entangled in the space in or about the bed rail, mattress, or hospital bed frame.

- **Burns**—Certain flammable materials used in the construction of pediatric medical cribs may allow for the spread of fire, which may result in serious injuries. Fires can spread easily in hospital rooms with a patient using oxygen. The free-flowing oxygen can intensify a fire, which can rapidly spread to flammable objects in the room, including crib mattresses.

- **Use error**—Use error may contribute to or exacerbate any of the previously mentioned adverse events. For example, a user may be unaware that a side rail did not latch, or may fail to properly maintain a pediatric medical crib. Therefore, adequate instructions for use and user education are essential to safe device operation.

**B. Medical Bassinet**

Between January 1, 2005, and September 1, 2015, FDA received 40 adverse event reports associated with this device type. The most common MDRs for medical bassinets include reports of malfunctions such as casters or wheels not working, which have caused tipping, and broken bassinet base components, such as doors and drawers, or collapse or breakage of utility shelves or chart holders. There are also reports of the plastic sleep basket or bed component crazing (cracking), resulting in sharp edges and cuts to hospital personnel.

FDA has considered the available information and determined that the following risks to health are associated with medical bassinets:

- **Injury resulting from mechanical or structural failure of the device**—Mechanical or structural failure of the bassinet can result in failure of load-bearing components such as the wheels

or casters, or failure of the latches or other locking mechanisms that secure the drawers of the bassinet. These failures can result in injuries, particularly if the bassinet tips over, as demonstrated by the MDRs received in FDA’s database.

- **Burns**—Certain flammable materials used in the construction of pediatric medical bassinets may allow for the spread of fire, which may result in serious injuries. Fires can spread easily in hospital rooms with a patient using oxygen. The free-flowing oxygen can intensify a fire, which can rapidly spread to flammable objects in the room, including bassinet mattresses.

- **Crazing or cracking of basket or bed component**—The basket or bed component of the bassinet that the pediatric patient is placed in may craze or crack due to improper care or handling, such as cleaning the plastic material of the basket or bed component with inappropriate cleaning solutions. Crazing or cracking may result in injuries such as cuts.

- **Use error**—Use error may contribute to, or exacerbate, any of the previously mentioned risks. For example, a user may accidentally leave a door or drawer in the base component of the bassinet open or place too much weight in a drawer or on a shelf, which may present a tipping hazard. Also, a user may fail to properly maintain a medical bassinet.

**V. Establishment of Special Controls**

Under section 513(a)(1)(B) of the FD&C Act, as amended by the SMDA, class II devices are defined as devices for which general controls 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. Special controls may include the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines,

recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (see also § 860.3(c)(2)).

Under this authority, FDA is proposing to establish special controls for pediatric medical cribs (§ 880.5140) and pediatric medical bassinets (§ 880.5145). The Agency believes that the applicable special controls, together with the general controls, would provide reasonable assurance of the safety and effectiveness of these devices.

**VI. Proposed Special Controls**

**A. Pediatric Medical Crib**

FDA consulted with health care providers in children’s hospitals, registered nurses in pediatric units, biomedical engineers, and technicians, and analyzed the associated adverse events with pediatric medical cribs. Specifically, FDA consulted with MedSun hospitals regarding their 2011 survey on clinicians’ experiences with pediatric medical cribs with drop-side rails used in MedSun’s hospitals (Ref. 1). The MedSun survey summary highlights the clinical perspective and the importance of this device in medical and health care settings. The most common issues and concerns in the survey were the lack of understanding of side rail operation and the need for reinforcing patient safety when the side rails are raised or lowered. Many respondents of the survey suggested further improvements for pediatric medical cribs, for instance, improved labeling, specific distance between slats and emergency releases on side rails for faster access to pediatric patients. The adverse events identified in the MedSun survey are similar to the MDRs FDA has received on this device. FDA believes that the special controls proposed in this proposed rule, in combination with the general controls, would provide a reasonable assurance of safety and effectiveness for pediatric medical cribs their intended use.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR PEDIATRIC MEDICAL CRIB

Identified risks to health	Mitigation measures
Injury Resulting from Mechanical or Structural Failure of the Device .....	Performance Testing. Design Testing.
Pinching, Lacerations, Splinters, and Foreign Body Ingestion .....	Appropriate Materials Free From Surface Defects. Labeling.
Entrapment, Falls, and Strangulation .....	Performance Testing. Rail and End Panel Design. Side Rail Spacing and Safety Features. Appropriate Fitting of Mattress.
Burns .....	CPSC’s Mattress Flammability Standard.
Use Error .....	Labeling.

As provided in Table 1, the Agency believes the following special controls, in combination with the general controls, would effectively mitigate the identified risks to health and provide reasonable assurance of the safety and effectiveness of the device:

1. Design and performance testing must be conducted to ensure the mechanical and structural stability of the crib under expected conditions of use, including the security of latches and other locking mechanisms when engaged. These requirements are derived from sections 6.2 and 6.3 of ASTM (formerly the American Society for Testing and Materials) International Standard F1169–13, entitled “Standard Consumer Safety Specification for Full-Size Baby Cribs” (Ref. 2) and sections 5.7 and 6.3 of ASTM International Standard F2710–13, entitled “Standard Consumer Safety Performance Specification for Commercial Cribs” (Ref. 3), which was developed with input from crib manufacturers.

2. To reduce possible injury of pinching, lacerations, and crushing, the crib shall be designed and constructed in a manner that eliminates hardware accessible to a child within the crib. This requirement is derived from section 5.10 of ASTM International Standard F1169–13, entitled “Standard Consumer Safety Specification for Full-Size Baby Cribs” (Ref. 2), which was developed with input from crib manufacturers. Also, materials used shall be appropriate for the conditions of use, allow for proper sanitation, and free from surface defects of the device that could result in injuries.

3. To reduce the risk of head and limb entrapment, the distance between side rail components (such as slats, spindles, corner posts, and rods) shall be designed to reduce potential entrapment of pediatric patients and the distance between such components shall not exceed 2 3/8 inches (6 centimeters) apart. In addition, the rails and end panels of a crib must be of a height to mitigate the possibility of falls and/or escapes by the patient. These requirements are derived from sections 5.7.2 and 5.8.1 of ASTM International Standard F1169–13, entitled “Standard Consumer Safety Specification for Full-Size Baby Cribs” (Ref. 2), which was developed with input from crib manufacturers.

4. To reduce the risk of head and limb entrapment, no gap shall exist between the edge of the bottom rail and the top of the mattress surface and the mattress must fit tightly around all four sides of the crib. These requirements are derived from section 5.9 of ASTM International Standard F1169–13, entitled “Standard Consumer Safety Specification for Full-Size Baby Cribs” (Ref. 2), which was developed with input from crib manufacturers.

5. To reduce flammability and the risk of burns, the mattress for the crib shall meet the CPSC Standard for the Flammability of Mattresses and Mattress Pads and its Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR parts 1632 and 1633, respectively. This proposed special control would clarify for manufacturers the standards necessary for mattresses intended to be used with pediatric medical cribs to prevent the spread of fires that can easily occur in hospital rooms with a patient using oxygen. The free-flowing oxygen can intensify a fire, which can rapidly spread to most of the flammable objects in the room especially mattresses. The consumer standards for flammability of mattresses in 16 CFR parts 1632 and 1633 are also accepted by the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations). CPSC’s mattress and mattress pad flammability standard under 16 CFR part 1632 addresses mattress fires ignited by open flame sources, including matches, candles, lighters, and other related scenarios. It prescribes a test to determine the ignition resistance of a mattress or a mattress pad when exposed to a lighted cigarette. CPSC’s standard for the flammability of mattress sets under 16 CFR part 1633 is a broader standard designed to reduce deaths and injuries caused by mattress fires, particularly those fires ignited by, among others things, oxygen use or electrical equipment sources that may occur in a patient’s room. In addition, CPSC’s regulations require that manufacturers meet an established fire safety performance standard, based on ASTM E2187–09, entitled “International’s Standard Test Method for Measuring the Ignition Strength of Cigarettes” (Ref. 4), which was developed with input from crib manufacturers.

6. To reduce flammability and the risk of burns, the labeling must bear all information required pursuant to the CPSC Standard for the Flammability of Mattresses and Mattress Pads and its Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR parts 1632 and 1633, respectively.

7. To reduce the risk of use error, which may result in mechanical or structural failure of the crib due to inadequate care or maintenance, pediatric medical crib labeling must include adequate instructions for users to care for and maintain their crib. These requirements are derived from sections 5.18 of ASTM International Standard F1169–13, entitled “Standard Consumer Safety Specification for Full-Size Baby Cribs” (Ref. 2).

FDA believes that the special controls proposed in this rule would provide a reasonable assurance of safety and effectiveness of pediatric medical cribs in their intended use. The ASTM and CPSC standards noted above apply to all mattresses and mattress pads intended or promoted for sleeping upon, as defined in 16 CFR 1632.1(a), including medical mattresses that are regulated by FDA as an accessory to medical beds. Therefore, FDA anticipates that manufacturers would be able to meet the requirements imposed by the proposed special controls in this proposed rule without undue burden. FDA invites comments on this conclusion, including comments regarding the types of performance testing manufacturers conduct for pediatric medical cribs, particularly to ensure the performance of medical crib latches on drop-side rails.

In addition, FDA is proposing to restrict these devices to prescription use under section 520(e) of the FD&C Act (see § 801.109 (prescription devices)). In order to use or administer use of pediatric medical cribs, authorization must be made by a practitioner licensed by law.

*B. Medical Bassinet*

Table 2 lists the risks to health FDA has identified for Medical Bassinets, as described in the Risks to Health, section IV of this proposed rule, along with the corresponding proposed mitigation measures for each risk.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR MEDICAL BASSINET

Identified risks to health	Mitigation measures
Injury Resulting from Mechanical or Structural Failure of the Device .....	Performance Testing. Labeling.
Burns .....	CPSC’s Mattress Flammability Standard.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR MEDICAL BASSINET—Continued

Identified risks to health	Mitigation measures
Crazing or Cracking of Basket or Bed Component .....	Performance Testing.
Use Error .....	Labeling. Labeling.

The Agency believes the following special controls, in combination with the general controls, would effectively mitigate the identified risks to health and provide reasonable assurance of the safety and effectiveness of medical bassinets:

1. To mitigate crazing, cracking, and deterioration of the basket or bed component of the device, the manufacturer must conduct performance testing to determine material compatibility with cleansing products labeled to clean the device.

2. To reduce flammability and the risk of burns, the bassinet shall meet CPSC’s Standard for the Flammability of Mattresses and Mattress Pads and its Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR parts 1632 and 1633, respectively.

3. To reduce the risk of injury resulting from mechanical or structural failure of the device, and particularly, device tipping that can result from those failures; manufacturers shall conduct performance testing to ensure the mechanical and structural stability of the bassinet under expected use conditions, including transport of patients in the bassinet.

4. To reduce the risk of use error, specifically error that may result in bassinet tipping, FDA proposes that manufacturers shall have a label on the front of the bassinet cabinet with the following warning statement:

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.

The label must be affixed to the front of the bassinet base cabinet and the text shall be in letters not less than 10 millimeters in height.

FDA believes this warning is necessary because even if performance testing demonstrates that a bassinet does not present a tipping hazard under expected use conditions, users may exceed these expected use conditions, particularly during transport of a patient in the bassinet.

5. To reduce the risk of use error, which may result in mechanical or structural failure of the bassinet due to inadequate care or maintenance, medical bassinet labeling must include adequate instructions for users to care for and maintain the bassinet.

FDA believes that the special controls proposed in this rule would provide a reasonable assurance of safety and effectiveness of medical bassinets in their intended use. The CPSC standards noted previously apply to all mattresses and mattress pads intended or promoted for sleeping upon, as defined in 16 CFR 1632.1(a), including medical mattresses that are regulated by FDA as an accessory to medical beds. Therefore, FDA believes most manufacturers are already complying with the proposed special control for mattress flammability set forth in this proposed rule. FDA invites comments on the types of performance testing manufacturers conduct for medical bassinets.

In addition, FDA is proposing to restrict these devices to prescription use under section 520(e) of the FD&C Act (see § 801.109 (Prescription devices)). In order to use or administer use of medical bassinets, authorization must be made by a practitioner licensed by law.

**VII. Proposed Effective Date**

FDA proposes that any final rule based on this proposal become effective 60 days after its publication in the **Federal Register**.

**VIII. Environmental Impact, No Significant 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.

**IX. Economic Analysis of Impacts**

FDA has examined the impacts of the proposed 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 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 proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies 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 propose to certify that this rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “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 \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

*A. Objective of the Rule*

Pediatric hospital beds are classified as class II, 510(k) exempt medical devices intended for the treatment, care, or diagnosis of diseases or illnesses of pediatric patients. In this proposed rule, FDA proposes to amend § 880.5140 by revising the identification and establishing special controls for pediatric medical cribs. This rule would also change the name of the classification regulation from “pediatric hospital bed” to “pediatric medical crib,” and place medical bassinets, previously under the pediatric hospital beds classification regulation, as a separate class II, 510(k) exempt device, subject to its own special controls.

Pediatric medical cribs used in health care settings contain a drop-side rail design that includes movable and latchable side and end rails. As stated previously, 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 (December 28, 2010, 75 FR 81766). CPSC's rule establishes new standards for full-size and non-full-size cribs used for non-medical purposes, which effectively prohibit the manufacture or sale of cribs for non-medical purposes with a drop-side rail design in households, child care facilities, family child care homes, and places of public accommodation. The compliance date for this same rule for child care facilities, family child care homes, and places of public accommodation was December 28, 2012 (75 FR 81766). CPSC's rule was established in response to infant deaths that occurred when the side rail of a crib used for non-medical purposes detached or disengaged. In contrast, there have been no deaths and a few serious injuries reported to FDA associated with pediatric medical cribs, which are made of more durable materials and construction in comparison to cribs used for non-medical purposes. Additionally, FDA has determined that drop-side rails are essential for patient care in hospital settings and even outside of traditional health care settings to allow parents and care givers easy access to their patients in order to perform both routine and emergency medical procedures. To address concerns raised by CPSC's reports on consumer drop-side rail cribs and account for the medical need of this device, FDA is proposing to establish special controls and require a prescription for this device when used outside of traditional health care setting. Thus, FDA has determined that cribs with drop-side rail designs may remain on the market when intended for medical use, and can be used outside of traditional health care settings through prescription use only. In addition, this proposed rule adds specific special controls for medical bassinets to mitigate health risks such as tipping of the device and crazing of the plastic basket or bed component. Regulation of this device under a separate regulation would also allow for more targeted post market surveillance for this device.

#### *B. Benefits*

FDA's Registration and Listing database identifies 38 manufacturers of medical cribs and bassinets. FDA has reviewed the safety standards of several large pediatric crib and bassinet manufacturers in order to determine the compliance burden associated with the proposed special controls. The Agency concludes that many of the special controls proposed by this rule are consistent with current industry practice among many medical crib and bassinet manufacturers. The proposed special control that is not currently

practiced is the warning labeling requirements for medical bassinets. For new pediatric medical crib and bassinet manufacturers entering the market or manufacturers that may not be currently following the practices required by the proposed special controls, if this proposed rule is finalized, its special controls will clarify safety standards and minimize the risk of injury to pediatric patients.

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 baby from all sides. The proposed special controls would require bassinet manufacturers to place labels on their devices warning against device tipping. This requirement would apply to new bassinets; bassinets that have already been sold would not be required to add the new labels to their devices. The warning label is intended to prevent tipping of the device, which may be caused by unlatched drawers, dislodged wheels, or too much weight on the shelves. The Agency has not received any reports of death or serious injury related to medical bassinets, although there have been a small number of reports of malfunctioning casters, which may cause device tipping. The benefits of the new warning label are not readily quantifiable, but it is expected to reduce the risk of the bassinet from tipping and thus, reduce potential injury to pediatric patients.

The provision allowing for the medical cribs outside of traditional health care settings would benefit pediatric patients who require the specialized care provided by these devices outside of traditional health care settings. Due to the CPSC rule regarding cribs used for non-medical purposes, discussed previously, consumers and child care facilities are restricted from using cribs with a drop-side rail design. If this proposed rule is finalized, it will allow consumers and child care facilities to utilize the pediatric medical cribs if they are prescribed by a health care professional.

The special controls regarding the mechanical structure of pediatric medical cribs are intended to minimize the risk of injury, including entrapment or strangulation of pediatric patients. The spacing specifications of the side rail components are designed to prevent head or neck entrapment and strangulation incidents in which infants may slip between the openings of the slats, and the performance testing requirements are designed to ensure the side rail latches of pediatric medical cribs will perform as intended and remain secure when the latches are

engaged. The special control requiring specific height of the rails and end panels may prevent falls and/or escapes by the patient. Also, by having pediatric medical crib manufacturers use materials that are appropriate for the conditions of use and allow for proper sanitation, these special controls may help mitigate surface defects that can cause injury to the patient.

Additionally, the mattress size standards for cribs and bassinets are intended to reduce the risk of significant gaps between the mattress and the device structure, which could potentially create an entrapment hazard. The flammability standard is intended to reduce deaths and injuries related to mattress fires, particularly those initially ignited by open flame sources such as lighters, candles, and matches. Although the practices proposed in these special controls are believed to be followed by almost all manufacturers of products currently on the market, the proposed special controls would reinforce safety standards for such manufacturers and ensure that other manufacturers and manufacturers of new products adhere to the same safety standards.

#### *C. Costs*

The economic impact of the proposed regulation is determined primarily by whether manufacturers currently comply with the proposed special controls. As stated previously, the special controls that are not currently practiced by industry, of which FDA is aware, are the bassinet warning labeling and the performance testing requirements. FDA is also aware that many manufacturers of pediatric medical cribs and medical bassinets registered with the FDA currently conform to the risk mitigations and structural requirements that are being proposed as special controls, and thus conforming to these special controls, if finalized, would not result in an increase in cost to pediatric medical crib manufacturers and only cause a small increase in cost for medical bassinet manufacturers. Additionally, the renaming of pediatric medical cribs and redesignation in the CFR for medical bassinets and the remaining devices under the pediatric hospital bed classification are administrative in nature, and are not expected to result in any cost burdens.

The new warning labeling requirements for medical bassinets will apply to manufacturers of new bassinets only. FDA does not expect bassinets that are currently on the market to be relabeled. If manufacturers of new bassinets add labels to the devices at the



time of production, the cost burden to manufacturers would be minimized. Although we do not have direct estimates of labeling costs for these devices, the best estimate of these costs is derived from FDA's labeling cost model. Because FDA would require specific language and format of the labels, we consider this to be a minor labeling change that would not require label design, market tests, or analytical tests. Labeling costs would include labor and material, and are estimated to be, on average, approximately \$140 per unit. Then we use the number of live births per year as reported by the Center for Disease Control and Prevention in order to determine the number of bassinets produced per year for medical use (Ref. 5). Using an estimate of 4 million births per year and 11,000 births per day, we estimate that each birth requires an average hospital stay of 3 days. This yields a total supply of approximately 33,000 medical bassinets in the United States. Given an average yearly replacement rate of 20 percent for all medical bassinets, we estimate that approximately 6,600 new bassinets will be produced annually. Applying the \$140 per unit labeling cost yields a total yearly cost of \$924,000 associated with the new bassinet warning label requirement.

The special controls require performance testing for medical bassinets to reduce the risk of crazing of the plastic basket or bed component. We assume that the performance testing may be conducted as an extension to current product testing and may be performed at the same testing facilities currently utilized by bassinet manufacturers. FDA projects that a maximum of an additional week of testing would be required. The costs associated with the performance testing include the labor costs of mechanical engineers, who typically perform these tests. The mean 2012 hourly wage for mechanical engineers is \$40.75, as reported by the Occupational Employment Statistics provided by the Bureau of Labor Statistics (Ref. 6). Applying a multiplier of 1.45 to adjust for benefits, hourly labor costs are estimated to be approximately \$59. Assuming a 40-hour work week, the total maximum estimated cost for each manufacturer to perform these additional tests is approximately \$2,360. It is uncertain the exact number of manufacturers that do not currently conduct performance testing and would therefore be required to extend current testing practices. However, given the relatively small number of medical bassinet manufacturers, FDA anticipates

that even the upper-bound total cost would be modest.

The prescription use of pediatric medical cribs outside of traditional health care settings may potentially increase Medicaid spending for eligible pediatric patients. According to our review of Healthcare Common Procedure Coding System billing codes for the Medicaid program, currently, States typically offer Medicaid coverage for prescribed rental or purchase of hospital beds and pediatric cribs (Ref. 7). We estimate the number of additional prescriptions for pediatric medical cribs to be filled annually as a result of this proposed rule would be less than 100. Medicaid expenditure on pediatric medical cribs is estimated to be on average \$2,500 per device. This yields a maximum annual total cost of \$250,000.

Although it is unlikely that these devices would require physical modification to meet the standards proposed by the special controls in this proposed rule, there may be manufacturers on the market of which we are unaware that do not conform to the requirements proposed in the special controls. The proposed special controls could have a significant impact on firms that are not currently in compliance with the special controls, as their products may require modifications. The special control that may cause additional costs for manufacturers is the special control concerning the mechanical structure of pediatric medical cribs. We are not able to estimate the actual compliance costs for manufacturers of pediatric medical cribs because such costs may vary by firm size and the amount of modification required. Alternatively, we provide an estimate of the modification cost by using aggregate industry market price information and cost data. The costs associated with these modifications may include the costs associated with product design and testing, labor, material, and production. We use data from the Annual Survey of Manufacturers to calculate aggregate labor and materials costs as a percentage of total sales for manufacturers represented by North American Industry Classification System code 339113 (Ref. 8). The data indicate that labor and materials represent approximately 45 percent of total sales. Allowing market price to represent per unit revenue at the firm level, we estimate the cost of modification to be approximately 45 percent of the average price of a pediatric medical crib. After surveying market prices of pediatric medical cribs, we estimate an average per unit price of \$2,500. This yields an average cost of

approximately \$1,125 to modify a pediatric medical crib to be in compliance with the proposed special controls.

FDA invites comments on the compliance of manufacturers with the special controls, including the performance testing, mechanical structure, flammability requirements, and bassinet labeling requirements, as well as cost information if modifications are required.

#### X. Paperwork Reduction Act of 1995

The proposed 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 Budget (OMB) and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information, regarding premarket notification submissions (21 CFR 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 proposed § 880.5140(b)(1) and proposed § 880.5145(b)(1) and (b)(3) of this document), are approved under OMB control number 0910–0073. The collections of information in 16 CFR 1632 and 1633, regarding mattress flammability, are approved under OMB control number 3041–0014.

In addition, FDA concludes that the warning label for bassinets does not constitute a “collection of information” under the PRA. Rather, the labeling statement is “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)).

#### XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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. ASTM International (formerly the American Society for Testing and Materials), "Standard Consumer Safety Specifications for Full-Size Baby Cribs," Designation: F1169-13, available at <http://www.astm.org/Standards/F1169.htm>, 2013.
3. ASTM International (formerly the American Society for Testing and Materials), "Standard Consumer Safety Performance Specification for Commercial Cribs," Designation: F2710-13, available at <http://www.astm.org/Standards/F2710.htm>, 2013.
4. ASTM International, "Standard Test Method for Measuring the Ignition Strength of Cigarettes," Designation: E2187-09 Standard, available at <http://www.astm.org/Standards/E2187.htm>.
5. Centers for Disease Control and Prevention (CDC), National Vital Statistics System, Birth Data, available at <http://www.cdc.gov/nchs/births.htm>.
6. Occupational Employment Statistics provided by the Bureau of Labor Statistics, May 2012 Occupational Employment Statistics, available at [http://www.bls.gov/oes/2012/may/oes\\_stru.htm](http://www.bls.gov/oes/2012/may/oes_stru.htm).
7. Centers for Medicare & Medicaid Services, HCPCS 2015 Code: E0300, available at <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html?redirect=/medhcpcsgeninfo/>.
8. U.S. Census Bureau, 2013 Annual Survey of Manufacturers, available at <http://www.census.gov/manufacturing/asm/index.html>.

#### 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, it is proposed that 21 CFR part 880 be 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:** 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 free from surface defects that could result in injuries;

(3) Rails and end panels shall be designed taking into account the crib's height at its lowest point to the top of the mattress to prevent patient falls and/or escape. Hardware and fasteners shall be designed and constructed to eliminate mechanical hazards to the patient;

(4) The distance between components of the side rail (such as slats, spindles, and corner posts) shall not be greater than  $2\frac{3}{8}$  inches (6 centimeters (cm)) apart at any point. Side rails shall contain safety features for locking and adjust the lowest position of the crib to a height that shall be 20 inches (51 cm) above the top of the mattress;

(5) The device shall not have a gap between the bottom of the rail and the top surface of the mattress and the mattress pad must fit tightly around all four sides of the crib;

(6) The mattress for the crib shall meet the Consumer Product Safety Commission (CPSC) Standard for the Flammability of Mattresses and Mattress Pads and Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR parts 1632 and 1633, respectively;

(7) The labeling must bear all information required pursuant to the CPSC Standard for the Flammability of Mattresses and Mattress Pads and Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR parts 1632 and 1633, respectively; and

(8) Pediatric medical crib labeling must include adequate instructions for users to care for and maintain their crib.

- 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 baby care items. The wheels or casters allow the bassinet to transport the baby 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) The mattress for the device shall meet the Consumer Product Safety Commission Standard for the Flammability of Mattresses and Mattress Pads and Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR parts 1632 and 1633, respectively;

(3) Manufacturers shall conduct performance testing to ensure the mechanical and structural stability of the bassinet under expected use conditions, 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 use conditions;

(4) Each device must have affixed a label on the front of the bassinet cabinet with the following language in text of at least 10 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.

(5) Labeling must include adequate instructions for users to care for and maintain their bassinet.

Dated: October 2, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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