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List of Subjects in 21 CFR Part 317

Antibiotics, Communicable diseases, Drugs, Health, Health care, Immunization, Prescription drugs, Public health.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 317 is proposed to be added to read as follows:

PART 317—QUALIFYING PATHOGENS

Sec.
317.1 [Reserved]
317.2 List of qualifying pathogens that have the potential to pose a serious threat to public health.

Authority: 21 U.S.C. 355E, 371.

§ 317.2 List of qualifying pathogens that have the potential to pose a serious threat to public health.

The term ''qualifying pathogen'' in section 505E(f) of the Federal Food, Drug, and Cosmetic Act is defined to mean any of the following:

(a) *Acinetobacter* species.
(b) *Aspergillus* species.
(c) *Burkholderia cepacia* complex.
(d) *Campylobacter* species.
(e) *Candida* species.
(f) *Clostridium difficile.*
(g) *Enterobacteriaceae.*
(h) *Enterococcus* species.
(i) *Mycobacterium tuberculosis* complex.
(j) *Neisseria gonorrhoeae.*
(k) *Neisseria meningitidis.*
(l) Non-tuberculous mycobacteria species.
(m) *Pseudomonas* species.
(n) *Staphylococcus aureus.*
(o) *Streptococcus agalactiae.*
(p) *Streptococcus pneumoniae.*
(q) *Streptococcus pyogenes.*
(r) *Vibrio cholerae.*

Dated: June 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13865 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2013–N–0568]

Physical Medicine Devices; Reclassification of Stair-Climbing Wheelchairs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to reclassify stair-climbing wheelchairs, a class III device, into class II (special controls) based on new information and subject to premarket notification, and to further clarify the identification.

DATES: Submit either electronic or written comments on this proposed order or on the draft guideline by September 10, 2013. See section XII for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0568 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *Mail/Hand Delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0568. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), 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: Rebecca Nipper, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993, 301–796–6527.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established 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) established three categories (classes) of devices, reflecting 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).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Devices that were not in commercial distribution prior to May 28, 1976, (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

The Safe Medical Devices Act of 1990 (Pub. L. 101–629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended the device reclassification procedures under section 513(e) of the FD&C Act, changing the process from rulemaking to an administrative order. Prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. The proposed reclassification order must set forth the proposed reclassification and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risk of the device. (See section 513(e)(1)(A)(i) of the FD&C Act.) As required by section 513(b) of the FD&C Act, FDA intends to schedule a panel meeting to discuss the proposed reclassification prior to issuing a final order.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, *e.g., Holland-Rantos Co.* v. *United States Dep't of Health, Educ., & Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn* v. *Finch,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Association* v. *FDA,* 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1985).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides

that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This can include information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

FDAMA added section 510(m) to the FD&C Act (21 U.S.C. 360(m)). Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Regulatory History of the Device

On August 28, 1979 (44 FR 50497), FDA published a document proposing to classify stair-climbing wheelchair devices as class III requiring premarket approval. The Physical Medicine Device Classification Panel (Panel) recommended class III because the Panel believed that satisfactory performance of this device had not been demonstrated and, therefore, that it was not possible to establish an adequate performance standard for the device. The Panel said the design of the device was experimental and data to support its safe and effective use was not available. The Panel said the device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness. No comments were received on the proposed rule. On November 23, 1983 (48 FR 53032), FDA published a document classifying stair-climbing wheelchairs as class III devices. On May 11, 1987 (52 FR 17732 at 17741), FDA published a document amending the codified language for stair-climbing wheelchairs to clarify that no effective date had been established for the requirement for premarket approval.

On August 18, 1998 (63 FR 44177), FDA published a document proposing to require the filing of a PMA or a notice of competition of a product development protocol (PDP) for stair-climbing wheelchair devices under section 515(b) of the FD&C Act. FDA received no comments on the document but received one citizen petition requesting a change in the classification of the stair-climbing wheelchair from class III to class II. FDA reviewed the petition and determined that there was not sufficient information to establish special controls to reasonably assure the safety and effectiveness of the device. FDA informed the petitioner in a letter dated May 10, 1999, that if additional information was submitted under section 513(e) of the FD&C Act within 30 days to support the reclassification of the device, FDA would review the information. FDA also stated that if the petitioner did not submit additional information within 30 days to show that sufficient information was available to establish special controls to reasonably assure the safety and effectiveness of the device, FDA would deem the reclassification petition withdrawn. FDA did not receive any new information from the petitioner and deemed the reclassification petition withdrawn. On April 13, 2000 (65 FR 19833), FDA published a document that retained in class III stair-climbing wheelchair devices and that required the filing of PMAs or PDPs on or before July 12, 2000.

On November 20, 2012, a reclassification petition was filed with FDA, requesting FDA to reclassify stair-climbing wheelchairs from class III to class II. In accordance with section 513(e) of the FD&C Act and § 860.130(b)(3), based on new information regarding the device, FDA is now proposing to reclassify the stair-climbing wheelchair device from class III to class II.

III. Device Description

A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position and is intended to climb stairs while the patient remains in the chair. Characteristics of the device enabling this capability may include two endless belt tracks that adjust to the angle of the stairs. This may also include a balancing mechanism to steady the chair as it ascends/descends the staircase.

FDA is proposing in this order to slightly modify the identification language from how it is presently written in § 890.3890(a) (21 CFR 890.3890(a)) for a more accurate description of devices in this classification.

IV. Proposed Reclassification

FDA is proposing that stair-climbing wheelchairs be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls (including prescription use restrictions) applicable to the devices, would provide reasonable assurance of their safety and effectiveness. FDA believes that the identified special controls in this proposed order, if finalized, together with general controls applicable to the device, would provide reasonable assurance of safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, in accordance with sections 513(e) of the FD&C Act and § 860.130, based on new information with respect to the devices and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA is proposing to reclassify this preamendments class III device into class II. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for stair-climbing wheelchairs.

Section 510(m) of the FD&C Act authorizes the Agency to exempt class II devices from premarket notification (510(k)) submission. FDA has considered stair-climbing wheelchairs in accordance with the reserved criteria set forth in section 513(a) of the FD&C Act and determined that these devices require premarket notification. Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (section 510(k) of the FD&C Act) submission as provided for under section 510(m) of the FD&C Act.

V. Risks to Health

After considering the information from the reports and recommendations of the Panel for the classification of these devices, along with information in the petition submitted under section 513(e) of the FD&C Act and any additional information that FDA has at its disposal, FDA has identified and evaluated the risks to health associated with the use of stair-climbing wheelchairs. The petition dated October 22, 2012 (Ref. 1), identified risks to health for all stair-climbing wheelchairs; FDA found these risks to be applicable and identified additional risks to health that apply to stair-climbing wheelchair devices:

- *Instability:* Instability of the device could result in the device tipping over, slipping off an edge (*e.g.,* curb or stair), or sliding down stairs, or use in certain environmental conditions that minimizes frictional coefficient, may result in injury to the user.

- *Entrapment:* The device may entrap a user or a body part if it moves unintentionally, shifts the user into a position from which they are unable to extricate themselves, or pinches a body part against a solid object.
- *Use Error:* A stair-climbing wheelchair may be misused if the user is not properly secured within the seat or if the device is used outside of certain environmental conditions or prescribed step dimensions, structural characteristics.
- *Falls/Fractures:* The device is physically heavy and if the device falls or rolls over a body part of the user or another individual (*e.g.,* caregiver), it can result in serious injury, including fracture.
- *Battery/electrical/mechanical failure:* The device may fail and place the user in an unsafe position (*e.g.,* middle of a street intersection, on stairs). This may result from failure of device critical device components (electronics, battery, brakes) or the device changing operational modes unexpectedly.
- *Pressure sores:* Pressure sores or bruising may result from the user experiencing jarring forces when transitioning over different surfaces or from colliding with solid objects.
- *Burns:* As a result of battery overheating, electrical failure, or ignition of flammable materials, the user may sustain burns.
- *Electric shock:* The user may experience electric shock as a result of battery or electrical failure.
- *Electromagnetic interference:* The device may interfere with the operation of other electrical devices or be susceptible to interference from other electrical devices.

VI. Summary of Reasons for Reclassification

If properly manufactured and used, FDA believes that these devices can be utilized to provide mobility over a variety of terrains and obstacles encountered in everyday life, specifically climbing stairs. Many of these environments would not be accessible and many tasks could not be completed without the availability of a stair-climbing wheelchair. FDA believes that stair-climbing wheelchairs should be reclassified from class III to class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the devices, and because general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. In addition, there is now adequate information sufficient to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with section 513(e) of the FD&C Act and § 860.130, based on new information with respect to the device, FDA, in response to the petition dated October 22, 2012, and submitted under section 513(e), is proposing to reclassify this preamendments class III device into class II. Since the time of the original panel recommendation and device classification, sufficient evidence has been developed to support a reclassification of stair-climbing wheelchairs from class III to class II with special controls. The petitioner cites the petitioner's own history of use, the petitioner's own preclinical testing, and the development of relevant consensus standards that provide sufficient evidence that stair-climbing wheelchairs can be effective for providing mobility over a variety of terrains and obstacles that are encountered in everyday life. Specifically, the petitioner notes that these devices need to comply with the following consensus standards:

- ''American National Standards Institute (ANSI)/Rehabilitative Engineering & Assistive Technology Society (RESNA) American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters),'' sections 1, 5, 7, 8, 11, 13, 15, 16, 22, and 26. These are consensus standards applicable to both powered and mechanical wheelchairs to ensure proper performance regarding static stability, endurance/fatigue testing, and flammability as well as characterization of measurements and dimensions.
- ''ANSI/RESNA American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems,'' sections 2, 3, 4, 6, 9, 10, 14, and 21. These are consensus standards applicable to powered wheelchairs to ensure proper performance regarding dynamic stability, brake effectiveness, curb climbing ability, electrical safety testing and electromagnetic compatibility testing as well as characterization of speed/acceleration, battery longevity, and environmental testing.
- ''International Standards Organization (ISO) 7176 Wheelchairs,'' parts 1 to 6, 9 to 11, 13 to 16, and 21. These consensus standards address the same testing and attributes noted in the previously noted volumes of the ANSI/RESNA standards.

FDA believes that this information constitutes sufficient evidence to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V of this document, and that these special controls in addition to the general controls will provide a reasonable assurance of safety and effectiveness for stair-climbing wheelchairs.

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls (including applicable prescription-use restrictions), are sufficient to mitigate the risks to health described in section V of this document:

- The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.
- Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:
  - Fatigue testing;
  - Endurance testing;
  - Resistance to dynamic loads (impact testing);
  - Effective use of the braking mechanism and how the device stops in case of an electrical brake failure;
  - Demonstration of adequate stability of the device on inclined planes (forward, backward, and lateral);
  - Demonstration of the ability of the device to safely ascend and descend obstacles (*e.g.,* stairs, curb); and
  - Demonstration of ability to effectively use the device during adverse temperatures and following storage in adverse temperatures and humidity conditions.
- The skin-contacting components of the device must be demonstrated to be biocompatible.
- Software design, verification, and validation must demonstrate that the device controls, alarms, and user interfaces function as intended.
- Appropriate analysis and performance testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.
- Performance testing must demonstrate battery safety and evaluate longevity.
- Performance testing must evaluate the flammability of device components.
- Patient labeling must bear all information required for the safe and

effective use of the device, specifically including the following:

- A clear description of the technological features of the device and the principles of how the device works;
- A clear description of the appropriate use environments/conditions, including prohibited environments;
- Preventive maintenance recommendations;
- Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and
- A detailed summary of the device-related adverse events and how to report any complications.

• Clinician labeling must include all the information in the patient labeling noted previously but must also include the following:

- Identification of patients who can effectively operate the device; and
- Instructions how to fit, modify, or calibrate the device.

• Usability studies of the device must demonstrate that the device can be used by the patient in the intended use environment with the instructions for use and user training.

Stair-climbing wheelchairs are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed § 890.3890(a) (21 CFR 870.3890(a)); see section 520(e) of the FD&C Act and 21 CFR 801.109 (Prescription devices)). Prescription-use requirements are a type of general control authorized under section 520(e) of the FD&C Act and defined as a general control in section 513(a)(1)(A)(i) of the FD&C Act; and under § 807.81, the device would continue to be subject to 510(k) notification requirements.

IX. 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.

X. Paperwork Reduction Act of 1995

This proposed order 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) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XI. References

The following reference has 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 is available electronically at *http://www.regulations.gov*.

1. Petition from Deka Research & Development Corp., October 22, 2013 (Docket No. FDA–2012–P–1155).

XII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

XIII. Comments

Interested persons may submit either electronic comments regarding this document or the associated petition to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

XIV. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in this proposed order, we are proposing to revoke the requirements in § 890.3890 related to the classification of stair-climbing wheelchairs as class III devices and to codify the reclassification of stair-climbing wheelchairs into class II.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine 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 890 be amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

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

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

■ 2. Section 890.3890 is revised to read as follows:

§ 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position and is intended to climb stairs while the patient remains in the chair. Characteristics of the device enabling this capability may include two endless belt tracks that adjust to the angle of the stairs. This may also include a balancing mechanism to steady the chair as it ascends/descends the staircase.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:

(i) Fatigue testing;

(ii) Endurance testing;

(iii) Resistance to dynamic loads (impact testing);

(iv) Effective use of the braking mechanism and how the device stops in case of an electrical brake failure;

(v) Demonstration of adequate stability of the device on inclined planes (forward, backward and lateral);

(vi) Demonstration of the ability of the device to safely ascend and descend obstacles (*e.g.,* stairs, curb); and

(vii) Demonstration of ability to effectively use the device during adverse temperatures and following storage in adverse temperatures and humidity conditions.

(3) The skin-contacting components of the device must be demonstrated to be biocompatible.

(4) Software design, verification, and validation must demonstrate that the device controls, alarms, and user interfaces function as intended.

(5) Appropriate analysis and performance testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

(6) Performance testing must demonstrate battery safety and evaluate longevity.

(7) Performance testing must evaluate the flammability of device components.

(8) Patient labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device and the principles of how the device works;

(ii) A clear description of the appropriate use environments/conditions, including prohibited environments;

(iii) Preventive maintenance recommendations;

(iv) Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and

(v) A detailed summary of the device-related adverse events and how to report any complications.

(9) Clinician labeling must include all the information noted previously in the patient labeling but must also include the following:

(i) Identification of patients who can effectively operate the device; and

(ii) Instructions how to fit, modify, or calibrate the device.

(10) Usability studies of the device must demonstrate that the device can be used by the patient in the intended use environment with the instructions for use and user training.

Dated: June 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13864 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 1000

[Docket No. FR–5650–N–03]

Indian Housing Block Grant Allocation Formula: Notice of Proposed Negotiated Rulemaking Committee Membership

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of proposed negotiated rulemaking committee membership.

SUMMARY: On September 18, 2012, HUD published a document in the **Federal Register** requesting nominations for membership on the negotiated rulemaking committee that will develop regulatory changes to the funding formula for the Indian Housing Block Grant program authorized by the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA). In accordance with section 564 of the Negotiated Rulemaking Act, this document establishes the committee, announces the names and affiliations of the committee's proposed members, requests public comment on the committee and its proposed membership, explains how additional nominations for committee membership may be submitted, and provides other information regarding the negotiated rulemaking process.

DATES: *Comment Due Date:* July 12, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable. Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Rodger Boyd, Deputy Assistant Secretary for Native American Programs, Room 4126, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone number: 202–401–7914 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4101 *et seq.*) (NAHASDA) changed the way that housing assistance is provided to Native Americans. NAHASDA eliminated several separate assistance programs and replaced them with a single block grant program, known as the Indian Housing Block Grant (IHBG) program. In addition, title VI of NAHASDA authorizes federal guarantees for financing of certain tribal activities (Title VI Loan Guarantee program). The