DEPARTMENT OF HEALTH & HUMAN SERVICES

DEC 19 2013

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Michael A. Carome, M.D.
Deputy Director
Public Citizen Health Research Group
1600 20th Street, NW
Washington, DC 20009

Re: Citizen Petition Docket Number FDA-2011-P-0438

Dear Dr. Carome:

This letter is in response to the above referenced citizen petition dated May 4, 2011, and filed by the Food and Drug Administration (FDA or "agency") on May 31, 2011. In the petition, you request that FDA take the following actions:

> (1) ban the marketing of Bedside Assistant bed handles, model numbers BA10W and BA10W-6, manufactured by Bed Handles, Inc., because these devices have directly caused the deaths of at least four patients through entrapment and subsequent strangulation or positional asphyxia and therefore present "an unreasonable and substantial risk of illness or injury;"
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> (2) order Bed Handles, Inc. to recall all Bedside Assistant bed handles, model numbers BA10W and BA10W-6, that have been sold or distributed; and
>
> (3) investigate thoroughly the association between (a) the design and use of all similar bed handle or bed rail devices manufactured by Bed Handles, Inc. or any other manufacturer and (b) the risk of death due to entrapment and subsequent strangulation or positional asphyxia, and as appropriate, based on the result of this investigation, take action to ban the marketing of, and to recall, those devices that pose a risk of death and injury similar to that seen with Bedside Assistant bed handles.

We have carefully considered your petition. For the reasons described below, your petition is granted in part and denied in part.

A. Request to ban the marketing of Bedside Assistant bed handles, model numbers BA10W and BA10W-6, manufactured by Bed Handles, Inc.

Your request that FDA ban the marketing of Bedside Assistant bed handles, models BA10W and BA10W-6, manufactured by Bed Handles, Inc., is denied because these bed handles are not medical devices, as defined by section 201(h) of the Federal, Food Drug and Cosmetic Act

(FD&C Act) [21 U.S.C. 321(h)], and, therefore, are not under FDA's regulatory jurisdiction. Rather, these bed handles are consumer products under the jurisdiction of the Consumer Product Safety Commission (CPSC).

The determination of whether a product is a medical device under section 201(h) of the FD&C Act [21 U.S.C. 321(h)] depends on the product's intended use, including any indications for use, which can be evidenced by statements in or on the product's label, accompanying labeling, promotional material, advertising, and any other relevant source. [See 21 CFR 801.4].

In your petition, you assert that Bedside Assistant bed handles are medical devices because they are intended for medical purposes to assist patients getting into and out of bed, sitting up in bed, and rolling over in bed. Your petition quotes the following claims for Bedside Assistant bed handles that appeared on the website of Bed Handles, Inc.:

- "Makes any bed a safer bed…Especially for anyone who uses a cane or walker or who feels dizzy or unsteady as they get in and out of bed."
- "Designed by an engineer for his wife who has [multiple sclerosis], the Bedside Assistant was tested by people with weakness from Parkinson's (sic), injury, medication, hypertension, chemotherapy and stroke."

Following submission of your petition, FDA contacted Bed Handles, Inc. regarding the claims on its website for Bedside Assistant bed handles. Bed Handles, Inc. subsequently revised the claims on its website, which currently read:

- "Makes any bed a safer bed…Especially for anyone who simply needs something to hold on to as they get in and out of bed."
- "Designed by an engineer for his wife who was weak and unsteady, the Bedside Assistant has been used by many that need a little extra help to be more independent."

After reviewing the current claims on the website of Bed Handles, Inc., FDA concludes that Bedside Assistant bed handles are not intended for use in the mitigation of disease and are not medical devices within FDA's regulatory jurisdiction. Rather, such bed handles are consumer products subject to the jurisdiction of CPSC. The FDA has made CPSC aware of your concerns regarding Bedside Assistant bed handles. You can contact CPSC to report an unsafe product as follows: online at (www.saferproducts.gov), by e-mail (hazard@cpsc.gov), phone (800)/638-2772), fax (800/809-0924) or letter (U.S. Consumer Product Safety Commission, Injury Report, Washington, DC 20207). As noted in your petition, CPSC has taken certain steps with respect to drop-side baby cribs that posed a risk of death or suffocation to infants and toddlers and may have authority to take similar steps with respect to adult bed handles and bed rails that are consumer products within its jurisdiction.

Although the specific products mentioned in your petition are not within FDA's jurisdiction, FDA appreciates your concern regarding the safety of bed handles and bed rails. We take this

concern seriously, and as discussed in further detail below, we are working with CPSC on efforts to reduce bed handle and bed rail related injuries and deaths.

B. Request to order Bed Handles, Inc. to recall all Bedside Assistant bed handles, model number BA10W and BA10W-6, that have been sold or distributed

Your request that FDA direct Bed Handles, Inc. to recall all Bedside Assistant bed handles, model numbers BA10W and BA10W-6 is denied because, as explained above, these bed handles are not medical devices. Therefore, FDA lacks jurisdiction to order Bed Handles, Inc. to recall its bed handles. You may contact CPSC using the methods described above to report your concerns regarding this consumer product. FDA will continue collaborating with CPSC on efforts to reduce bed handle and bed rail related injuries and deaths.

C. Request to investigate thoroughly the association between (a) the design and use of all similar bed handle or bed rail devices manufactured by Bed Handles, Inc. or any other manufacturer and (b) the risk of death due to entrapment and subsequent strangulation or positional asphyxia, and as appropriate, based on the result of this investigation, take action to ban the marketing of, and to recall, those devices that pose a risk of death and injury similar to that seen with Bedside Assistant® bed handles

Your request that FDA investigate the association between the design and use of all similar bed handles or bed rails manufactured by Bed Handles, Inc. or any other manufacturer and the risk of death due to entrapment and subsequent strangulation or positional asphyxia is granted, as described below.

Because bed handles and bed rails can be regulated as either medical devices or consumer products, depending on the specific product's intended use, the FDA and CPSC are working together on efforts to reduce bed handle and bed rail related injuries and deaths, to improve regulatory coordination on bed handle and bed rail issues between the two agencies, and to explore additional ways to mitigate bed handle and bed rail-related risks.

Following receipt of your petition, FDA and CPSC reached out to ASTM International, a standards development organization, and requested the formation of a committee to develop a new voluntary standard for adult portable bed rails.[1] The first committee meeting was held on June 19, 2013, and the goal is to create a voluntary consensus standard that could be recognized by both FDA and CPSC so that bed rails could satisfy the same safety parameters regardless of whether they fall under CPSC's or FDA's regulatory jurisdiction.

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[1] http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/UCM356991.pdf

Additionally, FDA is an active participant in a newly developed Bed Rails Communications Interagency Working Group with CPSC, FTC, and the Administration on Aging. The interagency working group is developing a communication that the agencies intend to post on their respective websites[2] to alert consumers, caregivers, and health care providers about the risks associated with bed rails and to provide recommendations for the safe use of bed rails, including alternatives to bed rails. As part of these efforts, FDA will be examining the association between the design and use of bed handles and bed rails with the risk of death or injury.

Finally, FDA will continue to monitor and evaluate bed handles and bed rails determined to be medical devices under FDA's jurisdiction for safety and regulatory compliance and will refer deceptive advertising claims to FTC as part of its ongoing coordination and collaboration with FTC.

Conclusion

For the reasons discussed above, we grant your petition in part and deny it in part.

If you have any questions about this petition response, please contact Jean Olson of our Regulations Staff at (301) 796-6579.

Sincerely,

Leslie Kux, J.D.
Assistant Commissioner for Policy
Office of the Commissioner

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2 http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/default.htm