4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1039]

General Wellness: Policy for Low Risk Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "General Wellness: Policy for Low Risk Devices." The guidance is intended to provide clarity to industry and FDA staff on Center for Devices and Radiological Health's (CDRH) compliance policy for low-risk products that promote a healthy lifestyle (general wellness products). By clarifying the policy on general wellness products, we hope to improve the predictability, consistency, and transparency on CDRH's regulation of these products. For purposes of the guidance, CDRH defines "general wellness products" as products which meet the following factors: They are intended for only general wellness use as defined in the guidance and present a low risk to the safety of users and other persons.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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-2014-N-1039 for "General Wellness: Policy for Low Risk Devices." 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.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "General Wellness: Policy for Low Risk Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5458, Silver Spring, MD 20993-0002, 301-796-5528.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of section 201(h) (21 U.S.C. 321(h)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or, if they are devices, whether they comply with the premarket review and postmarket regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to: Registration and listing and premarket notification requirements (21 CFR part 807); labeling requirements (21 CFR part 801 and 21

CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR part 820); and Medical Device Reporting (MDR) requirements (21 CFR part 803).

For purposes of the guidance, CDRH defines "general wellness products" as products which meet the following factors: (1) Are intended for only general wellness use as defined in the guidance and (2) present a low risk to the safety of users and other persons. A general wellness product has an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or has an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

CDRH's general wellness policy applies only to general wellness products that are low risk. In order to be considered low risk for purposes of the guidance, the product must not: (1) Be invasive, (2) be implanted, or (3) involve an intervention or technology that may pose risk to the safety of users and other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure.

General wellness products may include exercise equipment, audio recordings, video games, software programs, and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded), when consistent with the factors outlined in the guidance.

The FDA published in the Federal Register of January 20, 2015 (80 FR 2712), the notice of availability for the draft guidance entitled "General Wellness: Policy for Low Risk Devices;

Draft Guidance for Industry and Food and Drug Administration Staff" and the comment period for the guidance closed on April 20, 2015.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on General Wellness: Policy for Low Risk Devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "General Wellness: Policy for Low Risk Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1300013 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance 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 part 807 (registration and listing and premarket notification (510(k))) have been approved under OMB control numbers 0910-0625 and 0910-0120,

respectively; the collections of information in part 801 and § 809.10 (labeling) have been approved under OMB control number 0910-0485; the collections of information in part 820 (good manufacturing practice requirements as set forth in the quality system regulation) have been approved under OMB control number 0910-0073; and the collections of information in part 803 (MDR requirements) have been approved under OMB control number 0910-0437.

Dated: July 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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