4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6702]

The Least Burdensome Provisions: Concept and Principles; 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 or Agency) is announcing the availability of a final guidance entitled "The Least Burdensome Provisions: Concept and Principles." FDA utilizes a least burdensome approach to medical device regulation to eliminate unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. This document describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-6702 for "The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 "The Least Burdensome Provisions: Concept and Principles" 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: Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993-0002, 301-796-5155; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by the Food and Drug Administration Modernization Act of 1997, the FDA Safety and Innovation Act (FDASIA), and the 21st Century Cures Act (Cures

Act), includes least burdensome provisions that direct FDA to take a least burdensome approach to medical device evaluation in a manner that eliminates unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. The updates to the least burdensome provisions in FDASIA and the Cures Act clarified the original least burdensome provisions and further recognized the role of postmarket activities as they relate to premarket decisions. FDA believes, as a matter of policy, that least burdensome principles should be consistently and widely applied to all activities in the premarket and postmarket settings to remove or reduce unnecessary burdens so that patients can have earlier and continued access to high quality, safe, and effective devices. This guidance, therefore, reflects FDA's belief that least burdensome principles should be applied throughout the medical device total product lifecycle.

For the purposes of this guidance, FDA defines "least burdensome" as the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time. This guidance describes the least burdensome guiding principles and recommended approach for FDA staff and industry to ensure consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the FD&C Act.

FDA considered comments received on the draft guidance that appeared in the *Federal Register* of December 15, 2017 (82 FR 59623). FDA revised the guidance as appropriate in response to the comments. Among the comments that FDA received were those regarding metrics assessing the application of least burdensome principles and internal training on least burdensome principles. FDA issued a Report to Congress entitled "Least Burdensome Training Audit" pursuant to section 513(j) of the FD&C Act (21 U.S.C. 360c(j)), as added by the Cures

Act.[1] This report summarizes the mandatory training on least burdensome requirements for device review staff and supervisors and outcome of an audit of such training.

This guidance document replaces the 2002 Least Burdensome Guidance entitled "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles" (October 4, 2002).

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 "The Least Burdensome Provisions: Concept and Principles." 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. This guidance is not subject to Executive Order 12866.

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 https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. This guidance document is also available at https://www.regulations.gov or https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. Persons unable to download an electronic copy of "The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and Food and Drug Administration Staff" may

[1] FDA Report to Congress, "Least Burdensome Training Audit," June 8, 2018, available at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM610577.pdf.

send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1332 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations, guidance, form, and statutory provision have been approved by OMB as listed in the following table:

21 CFR Part or Section; Guidance; FDA Form; or Statute	Topic	OMB Control No.
820	Quality System Regulation	0910-0073
812	Investigational Device Exemption	0910-0078
807, subpart E	Premarket Notification	0910-0120
860.123	Reclassification Petition	0910-0138
814, subparts A through E	Premarket Approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
806	Medical Devices; Reports of Corrections and Removals	0910-0359
803	Medical Device Reporting	0910-0437
822	Postmarket Surveillance	0910-0449
Form FDA 3670	Adverse Event Reports/MedSun Program	0910-0471
801 and 809	Labeling	0910-0485
"Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices"	CLIA Waiver	0910-0598
807, subparts A through D	Registration and Listing	0910-0625
807, 812, and 814	Human Subject Protection; Acceptance of Data from Clinical Studies for Medical Devices	0910-0741
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"	Q-Submissions	0910-0756
42 U.S.C. 241	Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices	0910-0769
830	Unique Device Identification System	0910-0720
"De Novo Classification Process	De Novo Classification Process	0910-0844

(Evaluation of Automatic Class III Designation)"		

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

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