the complex thermomechanical behavior of nitinol, there are unique considerations when assessing the safety and performance of nitinol devices.

The Agency has developed this guidance to provide FDA's current thinking on technical considerations specific to devices using nitinol. These recommendations are intended to be general and apply to medical devices that have at least one patient contacting component comprised of nitinol. The following technical areas are covered by this guidance: general information, mechanical testing, corrosion, biocompatibility, and labeling of nitinol devices.

A notice of availability of the draft guidance appeared in the **Federal Register** of April 19, 2019 (84 FR 16516). FDA considered comments received and revised the guidance as appropriate in response to the comments, including minor technical clarifications.

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 technical considerations for non-clinical assessment of medical devices containing nitinol. 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.

II. 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17013 and the complete guidance title to identify the guidance you are requesting.

III. 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. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) Request for Information	0910–0705
''Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
801	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice; Quality System Regulation.	0910–0073

Dated: October 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22877 Filed 10–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0350]

Select Updates for Biocompatibility of Certain Devices in Contact With Intact Skin; Draft 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 the draft guidance entitled ''Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin.'' FDA has developed this draft guidance to propose select updates to FDA's current thinking regarding the type of biocompatibility information that should be provided in a premarket submission for certain devices made from common polymers and fabrics that are in contact with intact skin. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 14, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2013–D–0350 for ''Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin.'' 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.govinfo.gov/content/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, 240–402–7500.

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 draft guidance document entitled ''Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin'' to the Office of Policy, 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: Jennifer Goode, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1656, Silver Spring, MD 20993–0002, 301–796–5701.

SUPPLEMENTARY INFORMATION:

I. Background

Many devices have intact skin contacting component materials that are made from polymers and fabrics. FDA believes these materials pose a very low biocompatibility risk because they have a long history of safe use in medical devices that contact intact skin. For such devices, significant FDA review resources are expended to obtain sufficient rationales to justify omission of biocompatibility testing for frequently used intact skin contacting medical devices, consistent with FDA's recommendations in the FDA guidance ''Use of International Standard ISO 10993–1, 'Biological evaluation of Medical Devices—Part 1: Evaluation and testing within a risk management process' '' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and*).

This select update describes a least burdensome approach for these devices that recommends specific material information in a premarket submission in lieu of biocompatibility testing. This approach also supports the principles of the ''3Rs,'' to reduce, refine, and replace animal use in testing when feasible. This approach is partially based on FDA's experience with these common polymers and fabrics. This approach also relies on certain parts of the Quality System Regulation (21 CFR part 820) and other postmarket controls that already require compliance (*e.g.,* 21 CFR part 803) to identify potential biocompatibility-related issues.

After FDA finalizes this guidance, FDA intends to periodically reassess the list of component materials and exclusion characteristics identified in this guidance. FDA requests that external stakeholders submit comments to the docket to suggest the addition or removal of component materials or exclusion characteristics from this policy, including a rationale. FDA intends to review comments received in the docket and periodically assess whether any changes to this policy are warranted. When FDA believes changes are warranted, FDA will issue updated guidance in accordance with the procedures in the Good Guidance Practices Regulation (21 CFR 10.115).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin.'' 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.

II. Electronic Access

Persons interested in obtaining a copy of the draft 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Select Updates for Biocompatibility of Certain Devices in Contact with Intact

Skin'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19007 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This draft 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. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

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807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
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812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: October 8, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22876 Filed 10–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3926]

Request for Nominations for Voting Members on Public Advisory Panels or Committees; Device Good Manufacturing Practice Advisory Committee and the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) and the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. This annual notice is also in accordance with the 21st Century Cures Act, which requires the Secretary of Health and Human Services (the Secretary) to provide an annual opportunity for patients, representatives of patients, and sponsors of medical devices that may be specifically the subject of a review by a classification panel to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before December 14, 2020 will be given first consideration for membership on the DGMPAC and Panels of the MDAC. Nominations received after December 14, 2020 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, contact the following persons listed in table 1:

TABLE 1—PRIMARY CONTACT AND COMMITTEE OR PANEL

Primary contact person	Committee or panel
Joannie Adams-White, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5561, Silver Spring, MD 20993, 301–796–5421, email: *Joannie.Adams-White@fda.hhs.gov*.	Medical Devices Dispute Resolution Panel
Aden S. Asefa, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993, 301–796–0400, email: *Aden.Asefa@fda.hhs.gov*.	Dental Products Panel, Immunology Devices Panel, Microbiology Devices Panel, Neurological Devices Panel, Ophthalmic Devices Panel, DGMPAC.