*Estimated Total Annual Burden Hours (State Agencies):* 1,245.

*Annual Burden Estimates: URM Provider Agencies.*

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|---|---|---|---|---|---|
| ORR–3 Unaccompanied Refugee Minors Placement Report | 24 | 270 | 0.50 | 3,240 | 1,080 |
| ORR–4 Unaccompanied Refugee Minors Outcomes Report | 24 | 162 | 1.0 | 3,888 | 1,296 |

*Estimated Total Annual Burden Hours (Provider Agencies):* 2,376.

*Annual Burden Estimates: Youth Participants.*

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|---|---|---|---|---|---|
| ORR–4 Unaccompanied Refugee Minors Outcomes Report | 1032 | 3 | 0.50 | 1,548 | 516 |

*Estimated Total Annual Burden Hours (Youth Participants):* 516.

*Total Estimated Annual Burden Hours:* 4,137.

**Authority:** 8 U.S.C. 1522(d).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020–27194 Filed 12–10–20; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2019–D–1647, FDA–2019–D–1652, and FDA–2019–D–1650]**

### Performance Criteria for Safety and Performance Based Pathway; Guidances 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 three device-specific final guidance documents for the Safety and Performance Based Pathway—specifically, ''Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' and ''Magnetic Resonance (MR) Receive-only Coil—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' The device-specific guidances identified in this notice were developed in accordance with the final guidance entitled ''Safety and Performance Based Pathway.''

**DATES:** The announcement of the guidances is published in the **Federal Register** on December 11, 2020.

**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–2019–D–1647 for ''Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' Docket No. FDA–2019–D–1652 for ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' and Docket No. FDA–2019–D–1650 for ''Magnetic Resonance (MR) Receive-only Coil—Performance Criteria for Safety and Performance Based Pathway; 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, 240–402–7500.

• 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 documents are available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidances. Submit written requests for a single hard copy of the guidance document entitled ''Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' or ''Magnetic Resonance (MR) Receive-only Coil—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' 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:** Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–4908.

**SUPPLEMENTARY INFORMATION:**

## I. Background

These device-specific guidance documents provide performance criteria for premarket notification (510(k)) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled ''Safety and Performance Based Pathway.'' [1] As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the above-listed guidances, rather than using direct predicate comparison testing for some of the performance characteristics.

A notice of availability of the draft guidances ''Spinal Plating Systems'' and ''Orthopedic Non-Spinal Metallic Bone Screws and Washers'' appeared in the **Federal Register** of September 20, 2019 (84 FR 49528). A notice of availability of the draft guidance ''Magnetic Resonance Coil'' appeared in the **Federal Register** of December 9, 2019 (84 FR 67272). FDA considered comments received on the ''Spinal Plating Systems'' guidance and revised the guidance as appropriate by clarifying the types of plates that are excluded from the scope of the guidance (*i.e.,* occipital plates) and the lack of a specified minimum plate thickness. FDA considered comments received on the ''Orthopedic Non-Spinal Metallic Bone Screws and Washers'' guidance and revised the guidance as appropriate by expanding the scope of appropriate materials, clarifying the type of appropriate screw and washer design features, and clarifying the expectations for performance test methods and criteria. FDA considered comments received on the ''Magnetic Resonance Coil'' guidance and revised the guidance as appropriate by clarifying that the guidance is intended for receive-only magnetic resonance coils, expanding performance test methods with applicable FDA-recognized consensus standards, and clarifying the relation between performance testing and evaluations of interoperability.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the current thinking of FDA on performance criteria for ''Spinal Plating Systems,'' ''Orthopedic Non-Spinal Metallic Bone Screws and Washers,'' and ''Magnetic Resonance Coil.'' They do not establish any rights for any person and are 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.* These guidance documents are also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of either ''Spinal Plating Systems—Performance Criteria for Safety and Performance Based

[1] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.*

Pathway; Guidance for Industry and Food and Drug Administration Staff'' (document number 19008), ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' (document number 19009), or ''Magnetic Resonance (MR) Receive-only Coil—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' (document number 19011) may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

### III. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. 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 |
| ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''. | Q-submissions | 0910–0756 |

Dated: December 7, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020–27248 Filed 12–10–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA- 2019–N–4203]**

### Advisory Committee; Bone, Reproductive and Urologic Drugs Advisory Committee; Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Bone, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 23, 2022, expiration date.

**DATES:** Authority for the Bone, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2022 unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Kalyani Bhatt, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *BRUDAC@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Bone, Reproductive and Urologic Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner.

Under its Charter, the Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/bone-reproductive-and-urologic-drugs-advisory-committee-formerly-reproductive-health-drugs-advisory* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the Committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: December 8, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020–27289 Filed 12–10–20; 8:45 am]

**BILLING CODE 4164–01–P**