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)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Li You, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0828, *Li.You@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #116 (VICH GL23) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (Revision 2).'' This draft revised guidance recommends a Standard Battery of Tests that can be used for the evaluation of the genotoxicity of veterinary drug residues. The Standard Battery of Tests intends to achieve reasonable confidence in the assessment of the genotoxicity potential of veterinary drug residues and to be in harmony with the requirements of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use for testing human drugs for genotoxicity. This draft guidance also advises on modifications to the Standard Battery of Tests and on interpretation of test results. The objective of this guidance is to ensure international harmonization of genotoxicity testing of veterinary drug residues.

FDA has participated in efforts to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries. FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The goal of the VICH is to develop harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and receives input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency; AnimalhealthEurope; FDA—Center for Veterinary Medicine and U.S. Department of Agriculture—Center for Veterinary Biologics; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry and Fisheries; and the Japanese Veterinary Products Association. There are 10 observers to the VICH Steering Committee: 1 representative from government and 1 representative from industry of Australia, New Zealand, Canada, South Africa, and the United Kingdom. The World Organisation for Animal Health is an associate member of the VICH. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

This level 1 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 ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (Revision 2).'' 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032. The collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22301 Filed 9–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4168; FDA–2024–D–4169; FDA–2024–D–4170; and FDA–2024–D–4171]

Safety and Performance Based Pathway Device-Specific Guidances; 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 four final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and

Performance Based Pathway,'' ''Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway,'' and ''Dental Cements—Performance Criteria for Safety and Performance Based Pathway.'' The device-specific guidances identified in this notice were developed in accordance with the finalized *guidance* entitled ''Safety and Performance Based Pathway.''

DATES: The announcement of the guidances is published in the **Federal Register** on September 30, 2024.

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–2024–D–4168 for ''Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway,'' Docket No. FDA–2024–D–4169 for ''Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway,'' Docket No. FDA–2024–D–4170 for ''Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway,'' or Docket No. FDA–2024–D–4171 for ''Dental Cements—Performance Criteria for Safety and Performance Based Pathway.'' 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 ''Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway,'' or ''Dental Cements—Performance Criteria for Safety and Performance Based Pathway'' to the Office of Policy, 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

FDA is announcing the availability of four final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway,'' and ''Dental Cements—Performance Criteria for Safety and Performance Based Pathway.'' 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

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

rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act (FD&C 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 of air powered dental handpieces and air motors, or dental cement devices 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 relevant above-listed guidance rather than using direct predicate comparison testing for some of the performance characteristics.

These guidances are being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that these guidance documents present less burdensome policies that are consistent with public health. Although these guidances are being implemented immediately, FDA will consider all comments received and revise the guidance documents as appropriate.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the current thinking of FDA on ''Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway,'' and ''Dental Cements—Performance Criteria for Safety and Performance Based Pathway.'' 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 guidances 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 or https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway,'' ''Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway,'' or ''Dental Cements—Performance Criteria for Safety and Performance Based Pathway'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00021014 for ''Air Powered Dental Handpieces and Air Motors—Performance Criteria for Safety and Performance Based Pathway,'' document number GUI00007014 for ''Dental Ceramics—Performance Criteria for Safety and Performance Based Pathway,'' document number GUI00007013 for ''Dental Impression Materials—Performance Criteria for Safety and Performance Based Pathway,'' or document number GUI00021005 for ''Dental Cements—Performance Criteria for Safety and Performance Based Pathway'' to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions; pre-submissions.	0910–0756

Dated: September 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22309 Filed 9–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees