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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan Hughes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, 240–702–3970, *Jonathan.Hughes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry titled ''Evaluation of Therapeutic Equivalence.'' This guidance explains FDA's current thinking on therapeutic equivalence evaluations, including the assignment of TE codes, and addresses frequently asked questions regarding therapeutic equivalence. FDA's therapeutic equivalence evaluations are listed for multisource prescription drug products approved under the FD&C Act in the Active section of the Orange Book. As FDA explained when it first proposed to make available a list of all approved drug products, together with therapeutic evaluations of listed products that are available from more than one manufacturer, therapeutic equivalence evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs (see, *e.g.,* 44 FR 2932 (January 12, 1979) and 45 FR 72582 (October 31, 1980)).

This guidance finalizes the draft guidance titled ''Evaluation of Therapeutic Equivalence'' issued on July 21, 2022 (87 FR 43529). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include revisions to reflect an additional process by which applicants of certain 505(b)(2) applications may request TE codes. In addition, minor changes were made to improve clarity and to update the 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 ''Evaluation of Therapeutic Equivalence.'' 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 10.30 relating to the submission of a citizen petition have been approved under OMB control number 0910–0191. The collections of information in 21 CFR 201.56 and 201.57 relating to the content and format requirements of labeling for prescription drug products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 314 relating to the content and format of new drug applications and abbreviated new drug applications, including the results of safety and effectiveness studies, have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17215 Filed 8–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; 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 additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry titled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The draft guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on these draft guidances by October 23, 2026 to ensure that the Agency considers your comment on these draft guidances before it begins work on the final version of these guidances.

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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. 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: Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–3400, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry titled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on May 22, 2026 (91 FR 30307). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Avatrombopag maleate
Benzoyl peroxide
Benzoyl peroxide; Tretinoin
Bimatoprost
Bosutinib monohydrate
Brensocatib
Epinephrine
Epinephrine bitartrate
Fluvoxamine maleate
Hydrocortisone
Lidocaine
Lisdexamfetamine dimesylate
Maralixibat chloride
Meloxicam (multiple reference listed drugs)
Miglustat
Mitomycin
Nimodipine
Olezarsen sodium
Rilzabrutinib
Sebetralstat
Sunvozertinib
Taletrectinib adipate
Vimseltinib

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Amphetamine
Amphetamine; Amphetamine aspartate/dextroamphetamine sulfate (multiple reference listed drugs)
Baricitinib
Brimonidine tartrate; Brinzolamide
Brinzolamide
Buprenorphine
Cariprazine hydrochloride
Clindamycin phosphate
Ferric carboxymaltose
Ferumoxytol
Glimepiride
Latanoprost
Letermovir
Leuprolide acetate (multiple reference listed drugs)
Levothyroxine sodium
Lisdexamfetamine dimesylate
Maralixibat chloride
Mirtazapine
Octreotide acetate
Olaparib
Ondansetron
Pitolisant hydrochloride
Sodium phenylbutyrate (multiple reference listed drugs)
Tenapanor hydrochloride
Zolpidem tartrate (multiple reference listed drugs)

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

IV. Paperwork Reduction Act of 1995

While these guidances contain no 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17222 Filed 8–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Docket No. HHS–OS–2026–0332]

RIN: 0991–ZA62

Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: The Department of Health and Human Services (HHS or the Department), in support of the Task Force on Safer Childhood Vaccines and in furtherance of the Executive Order of August 10, 2026, ''Delivering Gold Standard Childhood Vaccine Recommendations for Americans,'' seeks public comment on whether the categories currently used in Federal vaccine recommendations are adequate. Those categories are routine (universal) recommendations, risk-based recommendations, and recommendations based on shared clinical decision-making, also referred to as individual-based decision-making. The Department seeks comment on these categories and whether additional or different categories should be adopted. The Department further seeks comment on the considerations that should be relied upon in setting vaccine recommendations, including the availability and strength of available scientific evidence, the appropriate approach when randomized controlled trial evidence is limited or absent, a presumption in favor of individual autonomy and religious freedom, the downstream legal and programmatic consequences of category assignment, and the communication practices necessary to earn and maintain public trust.

DATES: To be assured consideration, comments must be received at the address provided below no later than September 20, 2026.

ADDRESSES: Interested persons are invited to submit written comments identified by Docket No. HHS–OS–2026–0332 by either of the following methods: (1) Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the instructions for submitting comments; or (2) Mail: Cynthia Goss, 200 Independence Ave SW, Washington, DC 20201. All submissions received must include the agency name and docket number. Comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Cynthia Goss, Deputy Assistant Secretary for Planning and Evaluation (Health Policy), Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation, Office of the Secretary, Department of Health and Human Services, (202) 690–7858 or by email at: *osaspeinfo@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. The Federal Vaccine Recommendation Framework and its Categories

Federal vaccine recommendations are developed principally through the Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP), and are reflected in the child and adolescent and adult immunization schedules. Current recommendations fall into three principal categories. Under a *routine* (universal) recommendation, the default is to vaccinate all persons in an age group absent contraindications. A *risk-based* recommendation is directed to persons with specified medical, occupational, behavioral, or other risk factors. A recommendation based on *shared clinical decision-making* (SCDM) is individually based and informed by a decision process between the health care provider and the patient or parent/guardian. CDC guidance explains that