

notice is not significant pursuant to section 3(f)(1) of Executive Order 12866. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget. In accordance with Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this notice does not meet the criteria for a major rule as defined in 5 U.S.C. 804(2).

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the RFA provisions at 5 U.S.C. 604. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This notice is primarily applicable to DMEPOS suppliers, not rural hospitals. Therefore, the Secretary has certified that this notice will not have a significant economic impact on the operations of small rural hospitals.

We expect savings to the Medicare program from the reduction in the number of newly enrolling medical supply companies. However, we do not have data upon which to base an estimate of the amount of savings.

C. Regulatory Flexibility Analysis (RFA)

1. Small Business Impact

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organization, and small governmental jurisdictions. Most entities and most other providers and suppliers are small entities, either by nonprofit status or by having revenues less than \$37.5 million to \$41 million in any 1 year. Individuals and states are not included in the definition of a small entity. For several reasons, we do not believe that our DMEPOS moratorium will have a significant economic impact on a substantial number of small businesses.

First, in 2025 there were 79,360 approved DMEPOS supplier Medicare enrollments, representing an 8.3 percent decrease since 2023. This reflects a consolidating but mature market. The consolidation of the DMEPOS marketplace reflects a certain level of saturation, whereby the number of currently enrolled DMEPOS suppliers can meet the demand for items/supplies from the Medicare beneficiary

population. As of October 2025, over 6,000 of the nearly 80,000 approved DMEPOS suppliers are medical supply companies. We believe that most small medical supply companies in this sector are already enrolled. Hence, the moratorium would not directly harm their ongoing operations. All currently enrolled medical supply companies could continue billing Medicare and operating normally. Once the medical supply company moratorium is in effect, we anticipate that small businesses hoping to establish themselves as medical supply companies will be able to pivot to other sectors.

Second, even though some small businesses hoping to enroll in Medicare as medical supply companies will be impacted, many other small businesses can still enroll as a different type of DMEPOS supplier; for example, over 30 percent of all retail pharmacies in the United States are believed to be independent community pharmacies. While not necessarily purely equivalent to small businesses, independent pharmacies stand as a sound proxy for the concept of a small business in the pharmacy space. Moreover, the number of potentially impacted medical supply companies is miniscule—very far from substantial—when compared to the well over 2 million Medicare providers and suppliers, many of which are small businesses.

Third, even though some small businesses will be impacted by the moratorium, the risk to the Medicare Trust Funds and Medicare beneficiaries by nefarious medical supply companies, small or large, is too great to warrant refraining from this moratorium. The negative effect on some small businesses that seek to enter the program as a medical supply company is outweighed by the benefit of protecting the Trust Funds, beneficiaries, and the taxpayers from substantial fraud, waste, and abuse.

2. Alternatives Considered

There are three principal alternatives we considered in preparing this notice. First, we considered forgoing a moratorium entirely. Yet the ongoing, serious problem of DMEPOS fraud, waste, and abuse requires measures beyond those that CMS currently utilizes; indeed, while these measures have certainly been helpful, the issue of DMEPOS program integrity remains. Second, we contemplated a moratorium on all DMEPOS supplier types. We chose not to because this could unnecessarily impact certain DMEPOS supplier types that are not typically among the highest risk sub-types. Third,

we considered limiting the moratorium to certain states. We believe, though, that the problems the moratorium seeks to address are nationwide rather than restricted to particular geographic areas.

D. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA of 1995 UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately \$187 million. This notice will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$187 million in any one year.

E. State and Local Costs

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026-03971 Filed 2-25-26; 4:15 pm]

BILLING CODE 4120-01-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, Agency, or we) 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 entitled “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 the draft guidance by April 28, 2026 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-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. 3623A, Silver Spring, MD 20993-0002, 240-402-1062, 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 entitled “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 December 5, 2025 (90 FR 56161). 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)
Aceclidine hydrochloride.
Acetaminophen.
Acoltremon.
Alpelisib (multiple reference listed drugs).
Apixaban.
Avacincaptad pegol sodium.
Bisoprolol fumarate.
Buprenorphine.
Cephalexin.
Dabrafenib mesylate.
Dexamethasone.
Diazoxide choline.
Entrectinib.
Foscarbidopa; Foslevodopa.
Glecaprevir; Pibrentasvir.
Imatinib mesylate.
Landioliol hydrochloride.
Letermovir.
Meloxicam; Rizatriptan benzoate.
Mometasone furoate.
Paliperidone palmitate.
Phenylephrine hydrochloride; Tropicamide.
Ribavirin.
Rilpivirine hydrochloride.
Semaglutide.
Sofosbuvir; Velpatasvir.
Tadalafil.
Testosterone cypionate (multiple reference listed drugs).
Tolmetin sodium (multiple reference listed drugs).

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)
Acetaminophen; Ibuprofen.
Alpelisib.
Amoxicillin; Omeprazole magnesium; Rifabutin.
Apixaban.
Asenapine.
Baclofen.
Baloxavir marboxil.
Barium sulfate (multiple reference listed drugs).
Buprenorphine (multiple reference listed drugs).
Buspiron hydrochloride.
Capsaicin.
Chlorthalidone.
Clonidine.
Clozapine (multiple reference listed drugs).
Cobicistat; Darunavir.
Dasatinib.
Dextroamphetamine.

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

Active ingredient(s)
Diclofenac epolamine.
Donepezil hydrochloride.
Duloxetine hydrochloride (multiple reference listed drugs).
Estradiol (multiple reference listed drugs).
Estradiol; Levonorgestrel.
Estradiol; Norethindrone acetate.
Ethinyl estradiol; Levonorgestrel.
Ethinyl estradiol; Norelgestromin.
Fentanyl.
Ferric derisomaltose.
Formoterol fumarate.
Granisetron.
Imatinib mesylate.
Ketocanazole (multiple reference listed drugs).
Lidocaine (multiple reference listed drugs).
Lorazepam.
Lorlatinib.
Loxapine.
Menthol; Methyl salicylate.
Metformin hydrochloride.
Methylphenidate.
Nicotine.
Nitroglycerin (multiple reference listed drugs).
Octreotide acetate.
Oxybutynin (multiple reference listed drugs).
Paliperidone palmitate.
Perfluorohexyloctane.
Rivastigmine.
Rotigotine.
Sacubitril; Valsartan.
Scopolamine.
Selegiline.
Selinexor.
Testosterone.
Testosterone undecanoate (multiple reference listed drugs).
Tiopronin.
Tizanidine hydrochloride.
Venlafaxine besylate.
Venlafaxine hydrochloride.

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 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1486]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; ZYCUBO (Copper Histidinate)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ZYCUBO (copper histidinate), approved January 12, 2026, manufactured by Sentyln Therapeutics Inc., meets the criteria for a priority review voucher.