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.
Landiolol 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).
Buspirone hydrochloride.
Capsaicin.
Chlorthalidone.
Clonidine.
Clozapine (multiple reference listed drugs).
Cobicistat; Darunavir.
Dasatinib.
Dextroamphetamine.
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.
Ketoconazole (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.

[FR Doc. 2026–03963 Filed 2–26–26; 8:45 am]

BILLING CODE 4164–01–P

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 Sentynl Therapeutics Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993–0002, 301–796–2771, *Quyen.Tran1@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined ZYCUBO (copper histidinate), manufactured by Sentynl Therapeutics Inc., meets the criteria for a priority review voucher. ZYCUBO (copper histidinate) injection is indicated for treatment of Menkes disease in pediatric patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about ZYCUBO (copper histidinate), go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03925 Filed 2–26–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1628]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Scheduling Recommendations; N-Pyrrolidino Isotonitazene; N-Desethyl Etonitazene; Coca Leaf; MDMB-FUBINACA; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is providing interested persons with the opportunity to submit written comments concerning recommendations to impose international manufacturing and distributing restrictions on certain drug substances, under international drug control treaties. The comments received in response to this notice will be considered in preparing the United States' position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, in March 9–13, 2026. This notice is issued under the Controlled Substances Act (CSA).

DATES: Submit either electronic or written comments by March 5, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 5, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 5, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2026–N–1628 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Scheduling Recommendations; *N*-Pyrrolidino isotonitazene; *N*-Desethyl etonitazene; Coca leaf; MDMB-FUBINACA; Request for Comments.'' Received comments, those filed in a timely manner (see), 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