journals, including a major study funded by a Healthcare Innovation Award from the Center for Medicare and Medicaid Innovation (CMMI). This extensive research has shown that quality and safety are at least as high as that received by similar patients admitted to traditional brick and mortar hospitals.

This program clearly differentiates the delivery of acute hospital care at home from traditional home health services. Home health care provides important skilled nursing and other services, Acute Hospital Care at Home is for beneficiaries who require acute inpatient admission to a hospital and who require at least daily rounding by a physician and medical team monitoring their care needs on an ongoing basis. A minimum of two in-person visits will occur daily by either registered nurses or mobile integrated health paramedics, based on the patient's nursing plan and hospital policies. Hospitals may only treat patients with this waiver if they are admitted from their Emergency Department or if they are transferred from inpatient hospital beds. There is no payment change, and hospitals are not permitted to bill Medicare or its beneficiaries for any costs outside of a typical inpatient admission.

CMS is seeking to obtain continued OMB approval for information. All approved hospitals have submitted this information via an online portal at *CMS QualityNet* the previously mentioned website. To date, 433 hospitals individual hospitals/CCNs have submitted waiver requests and 396 of these hospitals have been approved. At this time, 65 hospitals have completed the online expedited waiver request, and 331 hospitals have completed the online detailed waiver request. When a hospital submits a waiver request, it completes one of two online forms found on the waiver landing page, depending on its level of experience with this type of care. Experienced hospitals, defined as treating at least 25 patients with acute hospital care at home previously, have an expedited submission that is based on a series of attestations. Additionally, all hospitals with an approved waiver are asked to submit data for patient admissions and discharges, escalations of care back to the brick-and-mortar hospital, and unexpected patient mortalities to CMS on a monthly (Tier 1) or weekly (Tier 2). This data is submitted voluntarily through the same online portal as the waiver submission and is not a requirement of ongoing participation in the Waiver. Of note, without further Congressional action, this waiver submission process will end September 30, 2030. *Form Number:* CMS–10950 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 1,947; *Total Annual Responses:* 1,947; *Total Annual Hours:* 1,947. (For policy questions regarding this collection, contact Danielle Adams at 410–786–8818.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–07583 Filed 4–17–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–6130]

Establishing Impurity Specifications for Antibiotics; Draft Guidance 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 a draft guidance for industry entitled ''Establishing Impurity Specifications for Antibiotics.'' The draft guidance provides recommendations regarding the establishment of specifications for organic impurities in antibiotics manufactured by fermentation and semi-synthesis. This draft guidance applies to antibiotic drugs subject to approval under new drug applications (NDAs) and abbreviated new drug applications (ANDAs) and associated type II drug substance drug master files (DMFs) referenced in antibiotic NDAs and ANDAs. This guidance also applies to nonprescription antibiotic drugs, often referred to as over-the-counter (OTC) monograph drugs. By providing these recommendations, FDA intends to clarify effective control strategies, support the development of high-quality antibiotic products, and promote consistency in quality standards.

DATES: Submit either electronic or written comments on the draft guidance by June 22, 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–2025–D–6130 for ''Establishing Impurity Specifications for Antibiotics.'' 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.gpo.gov/fdsys/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 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: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993–0002, 240–402–6341.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Establishing Impurity Specifications for Antibiotics.'' This draft guidance provides recommendations for establishing specifications for organic impurities in antibiotics manufactured by fermentation and semi-synthesis. These recommendations can be used to establish consistent standards for impurity testing and ensure that batches of antibiotic drug products meet appropriate impurity specifications.

This draft guidance applies to antibiotic drugs subject to approval under NDAs and ANDAs submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355), associated type II drug substance DMFs referenced in antibiotic NDAs and ANDAs, and nonprescription antibiotic drugs marketed pursuant to section 505G of the FD&C Act (21 U.S.C. 355h) (often referred to as OTC monograph drugs). INDs submitted under 21 CFR part 312 should follow the general principles outlined in the draft guidance.

The recommendations in the draft guidance are not intended to be applied retroactively (*i.e.,* to antibiotic drugs submitted in applications or their supplements, or antibiotic drugs marketed before finalization of this guidance). This is to prevent potential manufacturing discontinuances or interruptions of marketed antibiotic drugs that could lead to supply chain disruptions. However, applicants and manufacturers of marketed antibiotic drugs should consider updating impurity specifications in accordance with this draft guidance when making major changes, such as replacing a source of active ingredient(s), and to ensure the drugs are manufactured in compliance with Current Good Manufacturing Practice (CGMP) requirements.

The ICH guidances for industry *Q3A(R) Impurities in New Drug Substances* (June 2008) and *Q3B(R2) Impurities in New Drug Products* (August 2006) provide recommendations on thresholds for the identification, reporting, and qualification of impurities and degradation products in new drug substances and drug products using drug substances that are produced by chemical synthesis. However, current guidances do not provide recommendations for the control of impurities and degradation products in fermentation and semi-synthetic products, including certain antibiotics manufactured from these processes. Antibiotics manufactured by fermentation or semi-synthesis are typically more complex than those produced solely by chemical synthesis, often containing a mixture of the active ingredient and impurities. The active ingredient is generally not a single molecular entity but rather a collection of structurally related, biologically active analogs that together define the active ingredient. To address this gap, the draft guidance provides recommendations on the identification, qualification, and control of impurities and degradation products in fermentation-based and semi-synthetic antibiotics. The principles described in ICH Q3A(R), ICH Q3B(R2), and ICH M7(R2) should apply to antibiotics manufactured by fermentation and semi-synthesis. Antibiotic drugs that have United States Pharmacopeia (USP) monographs must meet the requirements outlined in the respective USP monographs for the drug substance and the drug product (section 501(b) of the FD&C Act).

The 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 ''Establishing Impurity Specifications for Antibiotics.'' 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.

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.

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 parts 210 and 211 pertaining to CGMP requirements have been approved under OMB control number 0910–0139. The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information pertaining to 21 CFR part 201 Subpart C pertaining to over-the-counter drug product labeling have been approved under OMB control number 0910–0340.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *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. 2026–07629 Filed 4–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6743]

Potential New Indication for Testosterone Replacement Therapy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that we have reviewed information in published literature that seems promising regarding the potential use of testosterone replacement therapy (TRT) in the treatment of low libido in men with decreased libido associated with idiopathic hypogonadism. We encourage holders of approved TRT new drug applications (NDAs) that are interested in seeking approval for this new indication to contact FDA for further information regarding submission of a supplemental NDA, including data needed to support an approval.

DATES: Holders of currently approved TRT NDAs interested in seeking approval for the treatment of low libido in men with decreased libido associated with idiopathic hypogonadism are encouraged to contact FDA (see **FOR FURTHER INFORMATION CONTACT**) by April 30, 2026, for further information regarding submission of a supplemental NDA, including data needed to support the new indication.

FOR FURTHER INFORMATION CONTACT: Dorsa Jalali, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5333, 240–402–0543, *dorsa.jalali@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Testosterone is the principal hormone secreted by the testes and is the main androgenic steroid in males. Endogenous androgens like testosterone are necessary and responsible for the normal growth and development of the male sex organs and for the development and maintenance of secondary sex characteristics. Approved TRT drug products have been used for decades in the United States for certain conditions associated with a deficiency or absence of endogenous testosterone. In general, the goal of TRT is to reliably and safely restore concentrations of testosterone and its major metabolites (*e.g.,* dihydrotestosterone, estradiol) to normal levels in men with low or absent testosterone levels from structural or genetic causes. FDA-approved TRTs include drug products that vary by dosage forms, strengths, and dosing regimens. These TRTs are currently indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, specifically primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). The approved TRTs also bear a limitation of use in the labeling to note that safety and efficacy of TRT in men with ''age-related hypogonadism'' have not been established.[1]

II. Potential New Indication for TRT

On December 10, 2025, FDA convened an expert panel, ''Expert Panel on Testosterone Replacement Therapy for Men'' (recording available at *https://www.fda.gov/patients/fda-expert-panels/fda-expert-panel-testosterone-replacement-therapy-men-12102025*), to discuss TRT, including the use of testosterone in men for signs and symptoms associated with idiopathic hypogonadism (*i.e.,* low testosterone levels from inadequate testicular stimulation or function without a known underlying cause).[2] The expert panel members discussed their individual views and available information on a range of topics related to the risks and benefits of testosterone therapy, including a potential broadening of the current approved indication for testosterone products to include treatment of men with symptomatic hypogonadism without known structural or genetic etiologies.

FDA has conducted a preliminary review of the published literature on possible use of TRT to treat men with symptomatic idiopathic hypogonadism. In evaluating symptomatic idiopathic hypogonadism, FDA reviewed articles meeting the following criteria: (1) the studies involved prospective, controlled trials; and (2) the articles contained information about the study protocol, endpoints, statistical methods, sample size, and blinding procedures. Our preliminary review of the literature suggests that TRT may be safe and effective in treating low libido in men with decreased libido associated with idiopathic hypogonadism. The published literature we reviewed regarding this potential indication for TRT is listed in the REFERENCES section.

We encourage holders of currently approved TRT NDAs interested in seeking approval for the treatment of low libido in men with decreased libido associated with idiopathic hypogonadism to contact FDA (see **FOR FURTHER INFORMATION CONTACT**) by April 30, 2026, for further information regarding submission of a supplemental NDA, including data needed to support the new indication.[3] Approval of any new indication will be based on rigorous scientific evidence and comprehensive risk-benefit analysis, consistent with applicable law.

III. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website addresses listed. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Pencina KM, Travison TG, Cunningham GR, Lincoff AM, Nissen SE, Khera M, et al., 2024, ''Effect of Testosterone Replacement Therapy on Sexual Function and Hypogonadal Symptoms in Men with Hypogonadism,'' *J Clin Endocrinol Metab,* 109(2):569–580. Available at *https://doi.org/10.1210/*

[1] See, *e.g.,* FDA-approved labeling for ANDROGEL (NDA 021015), ANDRODERM (NDA 020489), AVEED (NDA 022219), and JATENZO (NDA 206089) available at *https://www.accessdata.fda.gov/scripts/CDER/daf/*.

[2] In conjunction with the meeting of the expert panel, FDA announced a request for information regarding the scientific, regulatory, and practical considerations that shape TRT use (see 90 FR 57474, Dec. 11, 2025). FDA is in the process of reviewing the comments received.

[3] Drug products approved by FDA in supplemental NDAs (including new indications) may be protected by patents issued by the U.S. Patent and Trademark Office and/or by periods of exclusivity. Patent protections and exclusivities may have implications for the timing of approval of subsequent NDAs submitted pursuant to section 505(b)(2) of Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(2)) and abbreviated new drug applications (ANDAs), including supplemental 505(b)(2) NDAs and ANDAs. See, *e.g.,* sections 505(c)(3), 505(j)(5)(B), 505(j)(5)(F), 505A, and 527 of the FD&C Act (21 U.S.C. 355(c)(3), 355(j)(5)(B), 355(j)(5)(F), 355A, and 360cc); see also 21 CFR 314.107, 314.108, 316.31, and 316.34.