4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-4731]

Increasing Access to Nonprescription Drugs; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a request for information from interested parties and the public to share their perspectives with FDA on how to increase access to nonprescription drugs. The Agency intends to use the information submitted to inform plans for a public meeting intended to be held in calendar year 2026.

DATES: Either electronic or written comments on the notice must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2025-N-4731 for "Increasing Access to Nonprescription Drugs; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), 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.

FOR FURTHER INFORMATION CONTACT: Nikia Morris, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., White Oak Building 22, Room 5134, Silver Spring, MD 20993, 240-402-6625, Nikia.Morris@fda.hhs.gov with the subject line "Increasing Access to Nonprescription Drugs CDER".

SUPPLEMENTARY INFORMATION:

I. Background

Nonprescription drug products are important for the treatment of many conditions and diseases. Unlike prescription drug products, nonprescription drug products are accessible to

consumers without a prescription and may be accessed and used safely and effectively by consumers without the supervision of a practitioner licensed by law to administer such drugs for their intended use. At present, the majority of nonprescription drug products are intended to provide temporary relief of minor symptoms or to treat self-limited conditions and diseases. Nonprescription drug products are usually accessible to consumers to purchase at pharmacies, supermarkets, or other retail locations, and from online retailers.

FDA approves drugs as either prescription or nonprescription drug products under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355). A drug must be dispensed by prescription when it is not safe for use except under the supervision of a practitioner licensed by law to administer such drug product because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use (see section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1))).

If the drug does not meet the criteria for prescription-only dispensing, it may be marketed as nonprescription. There are two regulatory pathways to bring a nonprescription drug product to market in the United States.[1] This request for information is focused on the new drug application (NDA) process under section 505 of the FD&C Act. An applicant seeking to market a nonprescription drug under an NDA must submit data to satisfy the applicable statutory and regulatory requirements for approval of an NDA. Among other things, an NDA must include adequate tests to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling,[2] and there must be substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.[3] Often, consumer studies are required to demonstrate that products can be used safely and effectively in a nonprescription setting. Label

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[1] The two regulatory pathways to bring a nonprescription drug product to market in the United States are: (1) the over-the-counter (OTC) monograph drug review process under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h); and (2) the application process under section 505 of the FD&C Act.
[2] See section 505(d)(l) and (2) of the FD&C Act.
[3] See section 505(d)(5) of the FD&C Act.

comprehension studies, self-selection studies, actual use studies, human factors studies, and other types of studies may be required to evaluate proposed nonprescription drug product labeling and to demonstrate that the drug is safe and effective for use in self-medication, as directed in proposed labeling as required under 21 CFR 310.200(b).[4] The less that is known about the use of a medication without the intervention of a health care practitioner, the more data that typically will be required.

II. Purpose of Request for Information

This request for information provides an opportunity for interested parties and the public--including commercial drug developers, health care providers, consumers, and other relevant groups--to share their perspectives with FDA on increasing access to nonprescription drugs. Specifically, FDA is interested in perspectives on the scientific, regulatory, and practical considerations that shape nonprescription drug access. The collected input will help inform topics for a public meeting planned for calendar year 2026.

III. Questions for Consideration

We seek input on the questions presented below. While the questions are aimed at gathering information most pertinent to increasing access to nonprescription drugs, we welcome any additional data and information regarding access to nonprescription drugs that may improve our understanding and advance our public health mission. To help FDA review comments efficiently, please identify the question to which you are responding by its associated category and number. If you are responding to more than one question, please identify each question to which you are responding, and categorize each response by question.

General:

1. What are challenges faced in the development of drugs for nonprescription use?
2. What are the biggest opportunities to improve access to nonprescription drugs?

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[4] See, for example, the guidance for industry "Self-Selection Studies for Nonprescription Drug Products," available at https://www.fda.gov/media/81141/download; and
the guidance for industry "Label Comprehension Studies for Nonprescription Drug Products," available at https://www.fda.gov/media/75626/download.

3. How could interested parties--including, but not limited to, drug developers, health care providers, patients, consumers, and retailers--work together to increase access to safe and effective nonprescription drugs?
4. Looking ahead to a 2026 public meeting, what specific topics or questions would you like to see on the agenda for public discussion?

Scientific Considerations:

5. What scientific barriers most limit progress in increasing access to nonprescription drugs?
6. What additional scientific tools, technologies, or data sources could support access to nonprescription drugs?
7. Are there specific diseases or conditions that have not, traditionally, been treated with nonprescription drugs for which nonprescription drugs could be safely and effectively used without the supervision of a licensed healthcare practitioner? If so, what information would support such use under the applicable statutory and regulatory requirements for nonprescription drugs?

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-21728 Filed: 12/1/2025 8:45 am; Publication Date: 12/2/2025]