wholesalers, flower, nursery stock, and florist's supplies wholesalers, state government, other chemical and allied product merchant wholesalers, exterminating and pest control service, management, scientific, and technical consulting services. North American Industrial Classification System (NAICS) codes identified in question 12 of the ICR.

Respondent's obligation to respond: Mandatory. FIFRA and FFDCA.

Estimated number of potential respondents: 15,023.

Frequency of response: On occasion.

Total estimated average number of responses for each respondent: Between 1 to 74.

Total estimated burden: 2,234,433 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated costs: $172,873,497 (per year), includes $0 annualized capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an increase of 59,385 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects EPA's updating of burden estimates for this collection based upon historical information on the number of responses anticipated for some ICs and the inclusion of an additional prior ICR titled, ''Exemptions of Certain Plant Incorporated Protectants (PIPs) Derived from Newer Technologies'' (OMB Control No. 2070–0214; Rulemaking RIN–2070–AK54). Based upon revised estimates and the inclusion of an additional IC, the total number of responses anticipated across categories has increased by 32,627 with a corresponding increase in the associated burden hours. While burden hours increased, the annual total costs to respondents have decreased due to a program change to reflect updated guidance on the calculation of overhead in fully loaded wages. This change is the result of a program change.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 27, 2025.

Nancy B. Beck,

Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2025–21758 Filed 12–1–25; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

[Docket No. 25–07]

PKDC, LLC, Complainant v. COSCO Shipping Lines Co., Ltd., Respondent; Notice of Filing of Amended Complaint

Notice is given that an amended complaint has been filed with the Federal Maritime Commission (the ''Commission'') by PKDC, LLC (the ''Complainant'') against COSCO Shipping Lines Co., Ltd. (the ''Respondent''). Complainant states that the Commission has subject-matter jurisdiction over this complaint pursuant to 46 U.S.C. 40101 *et seq.,* and personal jurisdiction over Respondent as an ocean common carrier, as defined in 46 U.S.C. 40102(7), (9), and (18).

Complainant is a limited liability company existing under the laws of the state of Colorado with its principal place of business in Denver, Colorado.

Complainant identifies Respondent as a corporation organized under the laws of the People's Republic of China with its corporate headquarters in Shanghai, China, whose agent in the United States is COSCO Shipping Lines (North America) Inc. with its principal place of business in Secaucus, New Jersey.

Complainant alleges that Respondent violated 46 U.S.C. 41102(c) and 46 CFR 545.5. Complainant alleges these violations arose from the assessment of unjust and unreasonable demurrage and detention charges due to circumstances outside the control of Complainant, and other acts or omissions of Respondent.

An answer to the amended complaint must be filed with the Commission within 25 days after the date of service.

The full text of the amended complaint can be found in the Commission's electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/25-07/.* This proceeding has been assigned to the Office of Administrative Law Judges. The initial decision of the presiding judge shall be issued by May 6, 2026, and the final decision of the Commission shall be issued by November 20, 2026.

(Authority: 46 U.S.C. 41301; 46 CFR 502.61(c))

Served: November 28, 2025.

David Eng,

Secretary.

[FR Doc. 2025–21770 Filed 12–1–25; 8:45 am]

BILLING CODE 6730–02–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 February 2, 2026.

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 February 2, 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–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 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

[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.

[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.*

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?
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 12–1–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Medical Student Education Program Non-Competitive Supplement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of class deviation from competition requirements.

SUMMARY: HRSA provides grants to public institutions of higher education to expand or support graduate education for medical students preparing to become physicians in states with a projected primary care provider shortage. This supplemental funding is for the 12 Medical Student Education (MSE) Program award recipients from cohort fiscal year 2023, HRSA–23–124, to expand scholarships and faculty, preceptor, and curriculum development activities.

FOR FURTHER INFORMATION CONTACT: Andrea Knox, Acting Chief, Medical Training and Geriatrics Branch, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, MD 20852, email: *aknox@hrsa.gov,* phone: 301–443–4170.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: MSE Program award recipients, as listed in Table 1.

Amount of Non-Competitive Supplement Award(s): $14.1 million; $1.175 million to each for fiscal year 2026.

Project Period: July 1, 2026, to June 30, 2027.

Assistance Listing Number: 93.680.

Award Instrument: Non-competitive supplement for MSE.

Authority: Consolidated Appropriations Act, 2022 (Pub. L. 117–103); Consolidated Appropriations Act, 2023 (Pub. L. 117–328); Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 118–4).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Original award amount
T99HP52105	University of Arkansas for Medical Sciences	Little Rock, AR	$4,000,000
T99HP52104	University of Alabama at Birmingham	Birmingham, AL	3,999,999
T99HP52110	University of Missouri System	Columbia, MO	4,000,000
T99HP52113	University of Utah	Salt Lake City, UT	3,999,999
T99HP52111	University of Oklahoma	Oklahoma City, OK	3,999,999
T99HP52106	The University of Kentucky Research Foundation	Lexington, KY	3,970,759
T99HP52109	University of Missouri System	Kansas City, MO	4,000,000
T99HP52112	University of South Alabama	Mobile, AL	4,000,000
T99HP52103	Trustees of Indiana University	Bloomington, IN	3,865,680
T99HP52108	University of Mississippi Medical Center	Jackson, MS	3,973,000
T99HP54245	Oklahoma State University	Tulsa, OK	4,000,000
T99HP52107	University of Louisville	Louisville, KY	4,000,000

Justification: HRSA is providing a $1.175 million supplement to each of the 12 MSE grant recipients from cohort 2023; HRSA–23–124. The supplement will provide scholarships to medical students in their 3rd or 4th year, who are applying to primary care residency programs in general internal medicine, general pediatrics, family medicine, or internal medicine/pediatrics. This core funding is designed to support students early in their training who are aligned with the MSE Program purpose, goals, and objectives. These years are critical in a student's educational journey, as they begin clinical rotations, choose and apply for residency training specialties, and make firm decisions about future practice locations. This supplement provides additional incentive and support at a time when long-term career intentions are being considered. In addition, the following activities are required under this supplement:

(1) Support the development of faculty in general internal medicine, general pediatrics, family medicine, or internal medicine/pediatrics.

(2) Support the training of general internal medicine, general pediatrics,