remove from the list of drug products published in the Orange Book, those drug products in ANDAs that used NDA 019537 CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base as their reference listed drug; these are Amneal Pharmaceuticals, LLC's ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075939; Dr. Reddy's Laboratories' ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075593; Watson Laboratories, Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076794; Rising Pharma Holdings, Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075817; Taro Pharmaceutical Industries Ltd.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076912; and Pliva Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076426.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17650 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2603]

Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Provider Survey of Topics Related to Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with a proposed study entitled ''Healthcare Provider Survey of Topics Related to Prescription Drug Promotion.''

DATES: Either electronic or written comments on the collection of information must be submitted by October 7, 2024.

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 October 7, 2024. 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–2024–N–2603 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Provider Survey of Topics Related to Prescription Drug Promotion.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

The draft survey instrument is available upon request from *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined

in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Healthcare Provider Survey of Topics Related to Prescription Drug Promotion

OMB Control Number 0910—NEW

I. Background

This information collection request supports Agency research authorized by section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) and section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)).

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area: advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research,* which includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

This current project will be a survey with a selection of prescribers examining a variety of topics of interest to OPDP. The prescriber sample will be primary care physicians (PCPs) (in family practice, general practice, or internal medicine), nurse practitioners and physician assistants (NP/PAs), and specialists (cardiology, dermatology, endocrinology, neurology, obstetrics/gynecology, oncology, ophthalmology, psychiatry, rheumatology, and urology). Topics we plan to assess include, but are not limited to, awareness and use of the Bad Ad program (Refs. 1 and 2), understanding of quantitative data displays that may appear in prescription drug promotion (Refs. 3 and 4), perceptions of trust in FDA, perceptions of medical misinformation (Refs. 5 and 6), and attitudes about prescription drug promotion on social media (Refs. 7 and 8). These topics were selected to extend previous FDA work on healthcare provider understanding of quantitative data displays, provide an updated snapshot of social media attitudes and Bad Ad program awareness, and help inform FDA's role in addressing medical misinformation (Ref. 9).

We estimate that participation in the survey will take approximately 20 minutes. Our target respondents are adult voluntary participants who are PCPs, NP/PAs, or specialists engaging in patient care at least half time, with a range of gender, race and ethnicity, and ages that reflects the composition of the American Medical Association. Participants will be recruited by email through an internet panel, and participant eligibility will be determined with a screener at the beginning of the online survey. We will exclude individuals who are employees of the Department of Health and Human Services and individuals who work for a marketing, advertising, or pharmaceutical firm.

The target sample size for the survey is 2,410 respondents. Before conducting the survey, we will conduct up to two pretests. If the first pretest wave reveals that changes to the measurement instruments, stimuli, or procedures are required, a second pretest wave will be conducted with revised materials. The target sample size for Pretest 1 is 75 respondents and for Pretest 2 is 50 respondents.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Pretest 1 Screener [3]	150	1	150	0.08 (5 minutes)	12
Pretest 1	75	1	75	0.33 (20 minutes)	25
Pretest 2 Screener [3 4]	100	1	100	0.08 (5 minutes)	8
Pretest 2 [4]	50	1	50	0.33 (20 minutes)	17
Survey Screener [3]	4,820	1	4,820	0.08 (5 minutes)	386
Survey [5]	2,410	1	2,410	0.33 (20 minutes)	795

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Total	5,070				1,243

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.
[3] Number of screener respondents assumes a 50 percent eligibility rate with targeted recruitment.
[4] Pretest 2 will be conducted only if changes to study materials are made in response to the findings of Pretest 1.
[5] Sample size is based on power analysis and designed to accommodate a within-survey test of recruitment language.

II. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) 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 address, if listed. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. O'Donoghue, A.C., V. Boudewyns, K.J. Aikin, et al., ''Awareness of the Food and Drug Administration's Bad Ad Program and Education Regarding Pharmaceutical Advertising: A National Survey of Prescribers in Ambulatory Care Settings,'' *Journal of Health Communication,* vol. 20, issue 11, pp. 1330–1336, 2015, doi:10.1080/10810730.2015.1018649.

2. Betts, K.R., A.C. O'Donoghue, M. Johnson, et al., ''Detecting and Reporting Deceptive Prescription Drug Promotion: Differences Across Consumer and Physician Audiences and by Number and Type of Deceptive Claims and Tactics,'' *Health Communication,* vol. 37, issue 13, pp. 1609–1621, 2022, doi:10.1080/10410236.2021.1909264.

3. Thompson, J., M. Lynch, H.W. Sullivan, et al., ''Complexity of Data Displays in Prescription Drug Advertisements for Healthcare Providers,'' *Therapeutic Innovation & Regulatory Science,* vol. 57, issue 4, pp. 712–716, 2023, doi:10.1007/s43441–023–00523–3.

4. Thompson, J., R.C. Wines, M. Brewington, et al., ''Healthcare Providers' Understanding of Data Displays of Clinical Trial Information: A Scoping Review of the Literature,'' *Journal of Communication in Healthcare,* vol. 16, issue 3, pp. 260–267, 2023, doi:10.1080/17538068.2022.2150236.

5. Goldwire, M.A., S.T. Johnson, M. Abdalla, et al., ''Medical Misinformation: A Primer and Recommendations for Pharmacists,'' *Journal of the American College of Clinical Pharmacy,* vol. 6, issue 5, pp. 497–511, 2023, doi:10.1002/jac5.1760.

6. Boudewyns, V., B.G. Southwell, K.R. Betts, et al., ''Awareness of Misinformation in Health-Related Advertising: A Narrative Review of the Literature,'' *Misinformation and Mass Audiences,* edited by B.G. Southwell, E.A. Thorson, and L. Sheble, University of Texas Press, 2018.

7. Campbell, B.C. and C.M. Craig, ''Social Media and Health: Current and Future Healthcare Provider Perspectives,'' *Journal of Contemporary Medical Education,* vol. 2, issue 2, pp. 128–133, 2014, doi:10.5455/jcme.20140515123200.

8. Betts, K.R., A.C. O'Donoghue, K.J. Aikin, et al., ''Professional Online Community Membership and Participation Among Healthcare Providers: An Extension to Nurse Practitioners and Physician Assistants,'' *Journal of the American Association of Nurse Practitioners,* vol. 28, issue 12, pp. 639–645, 2016, doi:10.1002/2327–6924.12383.

9. Califf, R.M., ''Speech by Commissioner Robert M. Califf to the House of Medicine,'' June 16, 2023, *https://www.fda.gov/news-events/speeches-fda-officials/speech-commissioner-robert-m-califf-house-medicine-06162023.*

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17646 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Cosmetic Export Certificate Application Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 9, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0793. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Cosmetic Export Certificate Application Process

OMB Control Number 0910–0793—Revision

This information collection helps support implementation of statutory and regulatory authorities governing the export of certain FDA-regulated products found in section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), and in 21 CFR part 1, subpart E—Imports and Exports, of Agency regulations. Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a ''certificate.'' In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that