DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0795]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 January 17, 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 title of this information collection is ''A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

A Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising

OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the 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.

Direct-to-consumer (DTC) prescription drug advertising may make quantitative claims about the drug's efficacy or risks (Ref. 1). Although there is research and FDA guidance (''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements,'' available at *https://www.fda.gov/media/169803/download*) that provides general guidelines for how to present quantitative information, it is not fully understood how consumers will interpret specific quantitative claims. We conducted a literature review and found that while some types of quantitative information are well-studied (*e.g.,* relative frequencies), many questions remain on how best to communicate certain quantitative information about prescription drugs. For example, we do not have sufficient information about how consumers interpret different claims describing medians (*e.g.,* ''People treated with Drug X lived for a median of 8 months'' alone or in combination with a definition such as ''In people receiving Drug X, this means that about half lived more than 8 months and about half lived less than 8 months'' or ''A median is the middle number in a group of numbers ordered from smallest to largest''). This study aims to survey U.S. adults about their interpretation of specific quantitative claims.

We plan to use an address-based, mixed-mode methodology that will direct one randomly chosen member of sampled households to complete a 20-minute online survey, with nonrespondents receiving a paper questionnaire. The sample will be representative of the U.S. population. A sample of U.S. households will be drawn from the U.S. Postal Service Computerized Delivery Sequence File. Adults aged 18 or over will be eligible for participation. Up to four contacts (mailings) will be sent to respondents by U.S. mail. The contacts will include the URL for the online survey and a unique survey login. This unique survey login will be used to track completed surveys without the use of personally identifying information. The contact method, based on recent recommendations (Ref. 2), includes a prenotification letter (week 1), a web survey invitation letter (soft launch in week 2, full launch in week 3), a reminder postcard sent to nonresponders (week 5), and a final mailing with the paper version of the survey sent to nonresponders (Week 7). We estimate a 40-percent response rate, based on recent experience with similar surveys. We estimate 1,100 respondents will complete the main study (see table 1).

Based on previous research (Refs. 3, 4, and 5), we plan to include a small prepaid incentive in the second mailing sent to the sampled addresses as a gesture to encourage response and maintain data quality. We expect that

approximately 5 percent of the sampled addresses will be postal non-deliverable returned letters from the first mailing (prenotification letter), so the second mailing is estimated to go out to the remaining addresses. We also will conduct an experiment to assess the efficacy of using a promised post-paid incentive. Seventy-five percent of the sample will be sent the promised incentive upon completion of the survey, and the remaining 25 percent of the sample will not be notified of or provided with any promised incentive. We opted to split the sample 75–25 rather than 50–50 because the initial evidence shows the benefits of including a promised incentive (Refs. 4, 6, and 7), and we aimed to maximize response rates.

The survey contains questions about respondents' perceptions and understanding of several quantitative claims drawn from DTC ads in the marketplace. We will also measure other potentially important variables, such as demographics and numeracy. The survey questions will be informed by consumer feedback elicited in one-on-one interviews (approved under OMB Control No. 0910–0847). The survey is available upon request from *DTCResearch@fda.hhs.gov.*

We will test whether any variables differed between modes (online versus mail survey) and will account for any mode effects in our analyses. We will examine the descriptive statistics for the survey items (*e.g.,* frequencies and percentages) and explore the relationship between the survey items and demographic and health characteristics. We will weigh the data to account for different probability of selection and nonresponse.

In the **Federal Register** of April 25, 2023 (88 FR 24997), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two submissions that were Paperwork Reduction Act (PRA) related. Within the submissions, FDA received multiple comments that the Agency has addressed in this notice. For brevity, some public comments are paraphrased and, therefore, may not state the exact language used by the commenter. All comments were considered even if not fully captured by our paraphrasing in this document. Comments and responses are numbered here for organizational purposes only.

(Comment 1) One comment suggested testing claims that are addressed by the guidance for industry entitled ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers.''

(Response 1) The focus of this study is not to test such claims. In addition, because these drugs are fictional, there is no label with which to compare the claims, which means that the guidance is not an applicable concept in this study. These study results could apply to any quantitative claims similar to those we will test.

(Comment 2) One comment suggested recruiting a sufficient number of individuals with a health condition or their caregivers because they may be more familiar with the quantitative information in the claims than the general population would be.

(Response 2) Our intent is to conduct a nationally representative sample to get a broad sense of how the public interprets quantitative claims that appear in prescription drug ads across drug classes. Moreover, the claims we are testing refer to several medical conditions (*i.e.,* colon cancer, arthritis, seizures, migraine, lung cancer, heart attack or stroke, eczema), which makes it impractical to recruit a sufficient number of patients and caregivers for each medical condition. However, in response to this comment, we have added an item to the survey to assess whether participants have these conditions or have cared for someone with these conditions. This will allow us to explore associations between survey responses and experiences with the medical conditions.

(Comment 3) One comment recommended determining participants' comprehension of information regarding relative risk, absolute risk, relative benefit, and absolute benefit.

(Response 3) There is a body of research on many of these topics; see, for example, the references section in the guidance for industry entitled ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements,'' available at *https://www.fda.gov/media/169803/download.* In this survey, we will examine participants' interpretations of relative benefit.

(Comment 4) One comment requested information on the number of and demographic diversity of the one-on-one interviews.

(Response 4) Since the 60-day **Federal Register** notice was published, we conducted 24 interviews (approved under OMB Control No. 0910–0847). We recruited with demographic diversity in mind. Half (50 percent) of the participants had some college or more education, and half (50 percent) had less education. Overall, 58 percent of the participants were women, 29 percent were non-Hispanic White, 29 percent were non-Hispanic Black, and 25 percent were Hispanic. We also recruited participants of different ages: 42 percent were between the ages of 18 and 39, 29 percent were between the ages of 40 and 59, and 29 percent were 60 and older.

FDA estimates 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	Total hours
Read prenotification letter	2,993	1	2,993	0.08 (5 min.)	239
Read web survey invitation letter [2]	2,843	1	2,843	0.08 (5 min.)	227
Read reminder postcard	2,585	1	2,585	0.03 (2 min.)	78
Respond to survey (web and paper)	1,100	1	1,100	0.33 (20 min.)	363
Total					907

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The numbers assume around 5 percent postal non-deliverables from the prenotification letter and estimates nonrespondents for the subsequent mailings.

References

The following references marked with an asterisk (*) 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; they also are available electronically at *https://*

www.regulations.gov. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

*1. Sullivan, H.W., K.J. Aikin, and L.B. Squiers, ''Quantitative Information on Oncology Prescription Drug websites,'' *Journal of Cancer Education,* vol. 33, Issue 2, pp. 371–374, 2018. (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5334459*)

2. Dillman, D.A., J.D. Smyth, and L.M. Christian, *internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method, 4th ed.,* John Wiley & Sons, Inc.: Hoboken, NJ, 2014.

*3. Cheung, Y.T.D., X. Weng, M.P. Wang, et al., ''Effect of Prepaid and Promised Financial Incentive on Follow-Up Survey Response in Cigarette Smokers: A Randomized Controlled Trial,'' *BMC Medical Research Methodology,* vol. 19, Article 138, 2019. (*https://link.springer.com/article/10.1186/s12874-019-0786-9*)

4. Mercer, A., A. Caporaso, D. Cantor, et al., ''How Much Gets You How Much? Monetary Incentives and Response Rates in Household Surveys,'' *Public Opinion Quarterly,* vol. 79, pp. 105–129, 2015.

5. Sun, H., J. Newsome, J. McNulty, et al., ''What Works, What Doesn't? Three Studies Designed to Improve Survey Response,'' *Field Methods,* vol. 32, Issue 3, pp. 235–252, 2020. (*https://doi.org/10.1177/1525822X20915464*)

6. Ellis, J., J. Charbonnier, C. Lowenstein, et al., ''Assessing the Impacts of Different Incentives and Use of Postal Mail on Response Rates,'' *American Association for Public Opinion Research (AAPOR) Conference,* Chicago, IL, 2022, May.

*7. Yu, S., H.E. Alper, A.M. Nguyen, et al., ''The Effectiveness of a Monetary Incentive Offer on Survey Response Rates and Response Completeness in a Longitudinal Study,'' *BMC Medical Research Methodology,* vol. 17, Article 77, 2017. (*https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-017-0353-1*)

Dated: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27652 Filed 12–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5323]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of two new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 17, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 021455	Boniva (ibandronate sodium) Tablets, equivalent to (EQ) 2.5 milligrams (mg) base and EQ 150 mg base.	Hoffmann-La Roche, Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080–4990.
NDA 022424	Flowtuss (guaifenesin 200 mg/5 milliliters (mL) and hydrocodone bitartrate 2.5 mg/5 mL) Oral Solution.	Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 17, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on January 17, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27661 Filed 12–15–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3740]

Priority Zoonotic Animal Drug Designation and Review Process; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #283 entitled ''Priority Zoonotic Animal Drug Designation and Review Process.'' This draft guidance is intended to assist sponsors pursuing priority zoonotic animal drug (PZAD) designation for a new animal drug. This draft guidance is intended to provide the eligibility criteria for PZAD designation, the process for requesting PZAD designation, and enhancements in the FDA review process for PZADs.

DATES: Submit either electronic or written comments on the draft guidance by February 16, 2024 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: