review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, LYBALVI (olanzapine and samidorphan), which is indicated for the treatment of:

- Schizophrenia in adults
- Bipolar I disorder in adults
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

Subsequent to this approval, the USPTO received patent term restoration applications for LYBALVI (U.S. Patent Nos. 7,262,298; 9,119,848; 9,126,977; 10,300,054; and 10,716,785) from Alkermes Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 28, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of LYBALVI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LYBALVI is 4,564 days. Of this time, 4,003 days occurred during the testing phase of the regulatory review period, while 561 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* November 30, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 30, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* November 15, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for LYBALVI (NDA 213378) was initially submitted on November 15, 2019.

3. *The date the application was approved:* May 28, 2021. FDA has verified the applicant's claim that NDA 213378 was approved on May 28, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 311 days, 646 days, 1,325 days, 1,328 days, or 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28094 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4201]

Agency Information Collection Activities; Proposed Collection; Comment Request; Examination of Implied Claims in Direct-to-Consumer 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 a proposed study entitled ''Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion.''

DATES: Either electronic or written comments on the collection of information must be submitted by February 20, 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 February 20, 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–2023–N–4201 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Examination of Implied Claims in Direct-to-Consumer 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: Jonna 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.* 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.

Examination of Implied Claims in Direct-to-Consumer Prescription Drug Promotion

OMB Control Number 0910–NEW

I. Background

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 promotion may include truthful and non-misleading claims about the product. A particular claim may be direct (explicit) or indirect (implied or implicit). Some prior

research has shown that implied claims are misremembered as explicit claims (Ref. 1). Other research has shown that claims can result in a misleading impression of the product through implication, rather than literal interpretation (Ref. 2). Understanding how consumers who self-report having been diagnosed with a target condition interpret implied claims in DTC prescription drug promotion—and how their perceptions differ from those of consumers who have not been diagnosed with the target condition—will provide valuable insight into the relevance and impact of various product attributes and promotional claims on treatment decisions.

The current project will test the impact of several implied claims in DTC prescription drug advertising on consumer perceptions. The project has two phases: experimental and conjoint analysis. In the experimental phase, participants will view one version of a DTC television ad containing both explicit and one of four implicit product claims of interest or a control ad containing only explicit claims, and be asked their impressions of the product's risks, benefits, and other attributes. In the conjoint analysis phase, we will conduct a best-worst scaling (BWS) experiment to elicit the relative importance of various characteristics of immunotherapies indicated to treat patients with advanced melanoma, including several implied claims. For this study, we will use an object case design, which does not require us to manipulate different levels of the characteristics included in the design. Participants will be shown a series of choice tasks that are each made up of different subsets of an experiment-wide list of characteristics. Each participant will complete several tasks, and will be asked to first select which one they would care about the most if they were considering an immunotherapy, followed by the characteristic they would care about the least.

We are proposing to include 13 characteristics in our BWS experiment. Each task will include only four of those characteristics, the combination of which will be drawn from a balanced incomplete block design (BIBD; see Ref. 3). A BIBD ensures that (1) each task contains the same number of characteristics; (2) each characteristic occurs the same number of times across tasks; and (3) each pair of characteristics is shown to participants the same number of times over the entire experiment. These three properties are desirable for meeting estimation assumptions (*e.g.,* balance and orthogonality). An additional (and unique) favorable property of including 13 characteristics in the experiment is that BIBDs exist that yield 13 tasks with 4 characteristics per task. Thirteen is a manageable number of tasks for a single participant to complete, and as a result, the full experimental design will be replicated by each participant.

We estimate that participation in the study will take approximately 20 minutes. Adult voluntary participants aged 18 years or older 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 work in healthcare settings, employees of the Department of Health and Human Services, or individuals who work in the marketing, advertising, or pharmaceutical industries. Half the sample will consist of individuals who self-identify as cancer survivors, excluding survivors of certain nonmelanoma skin cancers.

The target sample size for the experimental phase is 1,030 adults and the target sample size for the conjoint analysis phase is 800 adults. Prior to conducting the main study for both the experimental phase and conjoint analysis phase, we will conduct at least one wave of pretests for each study phase: one before the experimental phase and one before the conjoint analysis phase. If the first pretest wave reveals that changes to the measurement instruments, stimuli, or procedures are required, a second pretest wave (for either the experimental phase, conjoint phase, or both) will be conducted with revised materials. The target sample size for each wave of pretests is 120 adults, split evenly between the experimental and conjoint analysis phases.

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 [2]	Total hours
Experimental phase Pretest 1 Screener [3]	132	1	132	0.08 (5 minutes)	11
Experimental Phase Pretest 1	66	1	66	0.33 (20 minutes)	22
Conjoint Analysis Phase Pretest 1 Screener [3]	132	1	132	0.08 (5 minutes)	11
Conjoint Analysis Phase Pretest 1	66	1	66	0.33 (20 minutes)	22
Experimental Phase Pretest 2 Screener [3 4]	132	1	132	0.08 (5 minutes)	11
Experimental Phase Pretest 2 [4]	66	1	66	0.33 (20 minutes)	22
Conjoint Analysis Phase Pretest 2 Screener [3 4]	132	1	132	0.08 (5 minutes)	11
Conjoint Analysis Phase Pretest 2 [4]	66	1	66	0.33 (20 minutes)	22
Experimental Phase Screener [3]	2,266	1	2,266	0.08 (5 minutes)	181
Experimental Phase Main Study	1,133	1	1,133	0.33 (20 minutes)	374
Conjoint Analysis Phase Screener [3]	1,760	1	1,760	0.08 (5 minutes)	141
Conjoint Analysis Phase Main Study	880	1	880	0.33 (20 minutes)	290
Total			6,831		1,118

[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 for the respective study phase are made in response to the findings of Pretest 1 for that phase.

As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for

samples in the pretest and main study of the experimental phase and conjoint analysis phase.

II. References

The following references are on display with 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. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register,** but websites are subject to change over time.

1. Harris, R.J., M.L. Trusty, J.I. Bechtold, et al. ''Memory for Implied Versus Directly Stated Advertising Claims,'' *Psychology & Marketing,* vol. 6, issue 2, pp. 87–96, 1989, *https://doi.org/10.1002/mar.4220060202.*
2. Burke, R.R., W.S. DeSarbo, R.L. Oliver, et al. ''Deception By Implication: An Experimental Investigation,'' *Journal of Consumer Research,* vol. 14, issue 4, pp. 483–494, 1988, *https://doi.org/10.1086/209130.*
3. Louviere, J.J., T.N. Flynn, and A.A.J. Marley, *Best-Worst Scaling: Theory, Methods, and Applications.* Cambridge: Cambridge University Press, 2015.

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28093 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1136]

Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization; 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 final guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' This guidance provides recommendations to sponsors on the development of monoclonal antibody products targeting SARS–CoV–2 intended for the prevention or treatment of COVID–19, including addressing the impact of emerging variants. The recommendations focus on the data and information that may be used to support a request for emergency use authorization (EUA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance supersedes the guidance entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2, Including Addressing the Impact of Emerging Variants, During the COVID–19 Public Health Emergency'' issued on February 22, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on December 21, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2020–D–1136 for ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' 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.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.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building,