explaining that Librax is not subject to review under DESI because a new drug application for Librax was approved by the Agency on September 1, 1966, and at that time the Agency determined that Librax was safe and effective for the indications set forth in its labeling, (consistent with the Stipulation for Dismissal in *Hoffman-La Roche, Inc.* v. *Richardson, et al.,* Civil Action 11–73 (D.N.J. August 2, 1973)). On June 2, 2016, Valeant responded by withdrawing its hearing request.

There are no longer outstanding hearing requests pertaining to drug products containing an anticholinergic or antispasmodic in combination with a sedative, and single-entity antispasmodic drug products, in oral dosage form under Docket No. FDA–1975–N–0336, DESI 10837. Shipment in interstate commerce of any drug product identified in this docket under DESI 10837, or any IRS product, that is not the subject of an approved NDA or ANDA is unlawful as of the applicable date of this notice (see **DATES**). Any person who wishes to determine whether a specific product is covered by this notice should write to Jeffrey Trunzo (see **FOR FURTHER INFORMATION CONTACT**). Firms should be aware that, after the applicable date of this notice (see **DATES**), FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

III. Discontinued Products

Firms must notify the Agency of certain product discontinuations in writing under section 506C(a) of the FD&C Act (21 U.S.C. 356c) (see *https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm*). Some firms may have previously discontinued manufacturing or distributing products covered by this notice without discontinuing the listing as required under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or distributing listed products in response to this notice. All firms are required to electronically update the listing of their products under 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this notice (21 CFR 207.57(b)). Questions on electronic drug listing updates should be sent to *eDRLS@fda.hhs.gov.* In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the discontinued product(s), including the product National Drug Code (NDC) number(s), and stating that the manufacturing and/or distribution of the product(s) have been discontinued. The letter should be sent electronically to Jeffrey Trunzo (see **FOR FURTHER INFORMATION CONTACT**). FDA plans to rely on its existing records, including its drug listing records, the results of any future inspections, or other available information, when it identifies violative products for enforcement action.

IV. Reformulated Products

FDA cautions firms against reformulating products and marketing under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combinations of active ingredients have the potential to confuse healthcare practitioners and harm patients.

Dated: April 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08740 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0081]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 research entitled ''Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion.''

DATES: Submit either electronic or written comments on the collection of information by June 24, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 24, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 24, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2022–N–0081 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tradeoff Analysis of Prescription Drug Product

Claims in Direct-to-Consumer and Healthcare Provider 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: *Regarding the information collection:* 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. For copies of the questionnaire:* Office of Prescription Drug Promotion (OPDP) Research Team, *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.

Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider 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 Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. 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. Our research focuses 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 disease and product characteristics 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, and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first and second topic areas, advertising features and target populations.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved by using 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 home page, which can be found at: *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

The proposed research examines the relative importance of prescription drug product information such as prescription drug efficacy, risk, adherence, and patient preference claims in two medical conditions (type 2 diabetes and psoriasis) in consumer and physician samples. When confronted with an important decision, people tend to make choices that reflect a series of tradeoffs between certain desirable and undesirable attributes of a product, service, or experience. Pharmaceutical manufacturers provide information about prescription drug products, including side effects, contraindications, and effectiveness through product labeling and promotional materials (21 CFR 202.1(e)).

The treatment preferences of diagnosed consumers and treating physicians have been shown to be influenced by certain characteristics, such as the perceived drug's impact on quality of life, complexity of dosage regimens, mode of administration, cost to family and self, and marketing claims unrelated to medicinal properties (Refs. 1 to 5). Although diagnosed consumers may weigh the risks, benefits, or other salient characteristics of prescription drug products differently than physicians, little research directly compares the treatment preferences of these two groups (Ref. 6). Understanding the tradeoffs among drug product characteristics diagnosed consumers make—and how the tradeoffs could potentially differ from the tradeoffs made by physicians—will provide valuable insight into the relevance and impact of various product attributes and promotional claims on informed choices and treatment decisions.

We intend to examine these tradeoffs using a choice-based conjoint analysis, also known as a discrete choice experiment. Conjoint analysis is a broad class of survey-based techniques used to estimate how attractive or influential different features of choice options or product attributes are in determining purchase behavior or treatment choices (Ref. 7). Conjoint analysis can be used to examine the joint effects and tradeoffs of multiple variables or product attributes on decisions. A choice-based conjoint analysis is based on the principle that products are composed of a set of attributes, and each attribute can be described using a finite number of levels. In the proposed research, participants will be shown a carefully designed sequence of choice tasks containing up to five hypothetical product attributes—in this case, profiles describing fictitious prescription drug products for either type 2 diabetes or psoriasis. Using data from the choices that participants make across these tasks, we can use statistical techniques to draw inferences about the relative value they place on different product attributes, estimate the relative importance of different attributes, explore the tradeoffs that consumers and physicians are willing to make to avoid or accept specific attribute levels, and compare the preferences of these two groups (Ref. 8).

We estimate that participation in the study will take approximately 20 minutes. Adult 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. The consumer sample will consist of adults who self-report as having been diagnosed by a healthcare provider with either psoriasis or type 2 diabetes. For the consumer sample, we will exclude individuals who work in healthcare settings because their knowledge and experiences may not reflect those of the average consumer. The physician sample will consist of primary care physicians and specialists who report treating patients with psoriasis or type 2 diabetes. For the physician sample, we will exclude individuals who spend less than 50 percent of their time on direct patient care. Department of Health and Human Services employees and individuals who work in the marketing, advertising, or pharmaceutical industries will be excluded from both respondent groups. Respondents will receive a survey invitation with a unique password protected link. All panel members are recruited following a double opt-in process. Sample sizes were estimated by combining approaches for conjoint analysis suggested by Orme (Ref. 9) and Johnson et al. (Ref. 10).

The target sample size for the main study is 800 physicians and 800 consumers, with half of each cohort focusing on treatments for psoriasis and the other half focusing on treatments for type 2 diabetes. Prior to conducting the main study, we will conduct at least one pretest. If the first pretest reveals that changes to the measurement instruments, stimuli, or procedures are required, a second pretest will be conducted with revised materials. The target sample size for each wave of pretests is 60 physicians and 60 consumers.

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 [2]	Total annual responses	Average burden per response [3]	Total hours
Pretest 1 Screener, Physicians [4]	95	1	95	0.08 (5 minutes)	8
Pretest 1 Screener, Consumers [4]	95	1	95	0.08 (5 minutes)	8
Physician Pretest 1	66	1	66	0.33 (20 minutes)	22
Consumer Pretest 1	66	1	66	0.33 (20 minutes)	22
Pretest 2 Screener, Physicians [4 5]	95	1	95	0.08 (5 minutes)	8
Pretest 2 Screener, Consumers [4 5]	95	1	95	0.08 (5 minutes)	8
Physician Pretest 2 [4]	66	1	66	0.33 (20 minutes)	22
Consumer Pretest 2 [4]	66	1	66	0.33 (20 minutes)	22
Physician Main Study Screener [4]	1,258	1	1,258	0.08 (5 minutes)	101
Physician Main Study	880	1	880	0.33 (20 minutes)	290
Consumer Main Study Screener [4]	1,258	1	1,258	0.08 (5 minutes)	101
Consumer Main Study	880	1	880	0.33 (20 minutes)	290
Total			4,920		902

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] 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 both samples in the study.

[3] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

[4] Number of screener respondents assumes a 70 percent eligibility rate with targeted recruitment.

[5] Pretest 2 will be conducted only if changes to study materials are made in response to the findings of Pretest 1.

II. 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. 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. Aikin, K.J., K.R. Betts, K.S. Ziemer, et al. (2019). ''Consumer Tradeoff of Advertising Claim Versus Efficacy Information in Direct-to-Consumer Prescription Drug Ads.'' *Research in Social and Administrative Pharmacy,* 15(12), 1484–1488. *https://doi.org/10.1016/j.sapharm.2019.01.012.*

*2. Arroyo, R., A.P. Sempere, E. Ruiz-Beato, et al. (2017). ''Conjoint Analysis to Understand Preferences of Patients With Multiple Sclerosis for Disease-Modifying Therapy Attributes in Spain: A Cross-Sectional Observational Study.'' *BMJ Open,* 7(3), e014433. *https://doi.org/10.1136/bmjopen-2016-014433.*

3. Fraenkel, L., L. Suter, C.E. Cunningham, et al, (2014). ''Understanding Preferences for Disease-Modifying Drugs in Osteoarthritis.'' *Arthritis Care & Research,* 66(8), 1186–1192. *https://pubmed.ncbi.nlm.nih.gov/24470354/.*

4. Katz, D.A., C. Hamlin, M.W. Vander Weg, et al. (2020). ''Veterans' Preferences for Tobacco Treatment in Primary Care: A Discrete Choice Experiment.'' *Patient Education and Counseling,* 103(3), 652–660. *https://doi.org/10.1016/j.pec.2019.10.002.*

5. Wouters, H., G.A. Maatman, L. Van Dijk, et al. (2013). ''Trade-Off Preferences Regarding Adjuvant Endocrine Therapy Among Women With Estrogen Receptor-Positive Breast Cancer.'' *Annals of Oncology,* 24(9), 2324–2329. *https://doi.org/10.1093/annonc/mdt195.*

6. Gregorian, Jr., R.S., A. Gasik, W.J. Kwong, et al. (2010). ''Importance of Side Effects in Opioid Treatment: A Trade-Off Analysis With Patients and Physicians.'' *The Journal of Pain,* 11(11), 1095–1108. *https://doi.org/10.1016/j.jpain.2010.02.007.*

7. Johnson, FR, E. Lancsar, D. Marshall, et al. (2013). ''Constructing Experimental Designs for Discrete-Choice Experiments: Report of the ISPOR Conjoint Analysis Experimental Design Good Research Practices Task Force.'' *Value in Health,* 16(1), 3–13. *https://doi.org/10.1016/j.jval.2012.08.2223.*

8. Bridges, J.F.P., A.B. Hauber, D. Marshall, et al. (2011). ''Conjoint Analysis Applications in Health—A Checklist: A Report of the ISPOR Good Research Practices for Conjoint Analysis Task Force.'' *Value in Health,* 14(4), 403–413. *https://doi.org/10.1016/j.jval.2010.11.013.*

9. Orme, B. (2019). *Getting Started With Conjoint Analysis: Strategies for Product Design and Pricing Research* (Fourth ed.). Madison, WI: Research Publishers LLC.

10. Johnson, F., B. Kanninen, M. Bingham, et al. (2006). ''Experimental Design for Stated-Choice Studies.'' In: *Valuing Environmental Amenities Using Stated Choice Studies* (pp. 159–202). B.J. Kanninen (Ed.). Dordrecht: Springer.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08728 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0559]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation

AGENCY: Food and Drug Administration, Health and Human Services (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 May 25, 2022.

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 0910–0456. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation

OMB Control Number 0910–0456—Extension

This information collection helps support implementation of the Department of Health and Human Services' ''PHS Guideline on Infectious Disease Issues in Xenotransplantation'' dated January 19, 2001, available at: *https://www.fda.gov/media/73803/download.* FDA is authorized to collect this information under sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264) and provisions of the Federal Food, Drug, and Cosmetic Act that apply to drugs (21 U.S.C. 321 *et seq.*). The guideline was developed by the PHS to identify general principles for the prevention and control of infectious diseases associated with xenotransplantation that may pose a risk to public health. The PHS guideline recommends procedures to diminish the risk of transmission of infectious agents to the xenotransplantation product recipient and to the general public. The PHS guideline is intended to address public health issues raised by xenotransplantation, through identification of general principles of prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to the public health. The collection of information described in this guideline is intended to provide general guidance on the following topics: (1) The development of xenotransplantation clinical protocols; (2) the preparation of submissions to FDA; and (3) the conduct of xenotransplantation clinical trials. Also, the collection of information will help ensure that the sponsor maintains important information in a cross-referenced system that links the relevant records of the xenotransplantation product recipient, xenotransplantation product, source animal(s), animal procurement center, and significant nosocomial exposures. The PHS guideline also describes an occupational health service program for the protection of health care workers involved in xenotransplantation