regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson or chairpersons of each individual RDRC, investigators, and participants in the studies. The burden estimates are based on our experience with these reporting and recordkeeping requirements and the number of submissions we received under the regulations over the past 3 years.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR Section and applicable form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 361.1(c)(3) reports and (c)(4) approval (Form FDA 2914: Membership Summary) [3].	62	1	62	1	62
§ 361.1(c)(3) reports (Form FDA 2915: Study Summary) [4].	40	10	434	3.5 (3 hours, 30 minutes)	1,519
§ 361.1(d)(8) adverse events	10	1	10	.5 (30 minutes)	5
Total			506		1,586

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.
[3] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094979.pdf.*
[4] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074720.pdf.*

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR Section	Number of recordkeepers	Number of records per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
§ 361.1(c)(2) RDRC	62	4	248	10	2,480
§ 361.1(d)(5) human research subjects.	40	10	434	.75 (45 minutes)	326
Total			682		2,806

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.

We have adjusted our estimate for the information collection to reflect an annual decrease of 525 hours and 147 responses since last OMB review. This adjustment corresponds to fewer submissions we have received under the information collection over the last few years.

Dated: January 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00873 Filed 1–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5666]

Agency Information Collection Activities; Proposed Collection; Comment Request; Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

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 ''Empirical Study of Promotional Implications of Proprietary Prescription Drug Names.''

DATES: Submit either electronic or written comments on the collection of information by March 23, 2020.

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 March 23, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 23, 2020. 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–2019–N–5666 for ''Empirical Study of Promotional Implications of Proprietary Prescription Drug Names.'' 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.

• 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@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.

Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

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 promotional material is truthful, balanced, and accurately communicated, so that patients and healthcare providers (HCPs) 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 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 two topic areas.

Because we recognize the strength of data and the confidence in the robust nature of the findings is 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, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a direct-to-consumer (DTC) survey conducted in 1999.

During the prescription drug approval process, sponsors propose proprietary names for their products. These names undergo a proprietary name review that involves the Office of Drug Safety, the relevant medical office, and the OPDP. OPDP reviews names to assess for alignment with the FD&C Act, which provides that labeling or advertising can misbrand a product if misleading representations are made (see 21 U.S.C. 321(n)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading. OPDP focuses its misbranding review on identifying names that overstate the efficacy or safety of the drug, expand drug indications, suggest superiority without substantiation, or are of a fanciful nature that misleadingly implies unique effectiveness or composition. While there are several ways proprietary names can be misleading, this research will primarily focus on overstatement of the efficacy of the drug product.

The proposed study is designed to provide systematic, empirical evidence to answer two research questions:

- Primary research question: How, if at all, do names that suggest the drug's indication affect consumers' and/or healthcare providers' perceptions of the prescription drug?
- Secondary research question: How, if at all, do names that suggest an overstatement of the efficacy of the drug affect consumers' and/or healthcare providers' perceptions of prescription drugs?

The ideas generated in the Prescription Drug User Fee Amendments pilot project proprietary name review concept paper of 2008 [1] provided a starting point for the study. Based on ideas from that document, a review of the linguistics and social sciences literature, and an environmental scan, FDA developed and pretested an extreme, explicitly suggestive name (*e.g.,* CureAll) and a neutral name for two indications, high cholesterol and gastroesophageal reflux disease (OMB control number 0910–0695). In the proposed main study, approximately 500 consumers from the general population and 500 HCPs (including physicians, nurse practitioners, and physician assistants) will see these pretested extreme and neutral names plus five target (to be tested) names per indication and answer questions about the names, before and after they have been told what each drug's indication is. Target names will vary such that some efficacy implications are more apparent than others and some will more clearly imply indication or benefits than others. Dependent variables will include indication identification, efficacy, and perceptions.

To our knowledge, this study is the first to provide a systemic investigation of a variety of proprietary prescription drug names.

The questionnaire is available upon request from *DTCResearch@fda.hhs.gov.*

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
Consumer Screener	1,233	1	1,233	0.08 (5 minutes)	99
HCP Screener	1,233	1	1,233	0.08 (5 minutes)	99
Consumer Study	493	1	493	0.33 (20 minutes)	163
HCP Study	493	1	493	0.33 (20 minutes)	163
Total					524

[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.

Dated: January 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00823 Filed 1–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Ozgur Tataroglu, Ph.D. (Respondent), former postdoctoral fellow, Department of Neurobiology, University of Massachusetts Medical School (UMMS). Dr. Tataroglu engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants R01 GM066777 and R01 GM079182. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on December 30, 2019, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research

[1] *https://www.regulations.gov/docket?D=FDA-2008-N-0281.*