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.*

Integrity (ORI) has taken final action in the following case:

Ozgur Tataroglu, Ph.D., University of Massachusetts Medical School: Based on the report of an investigation conducted by UMMS and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Ozgur Tataroglu, former postdoctoral fellow, Department of Neurobiology, UMMS, engaged in research misconduct in research supported by PHS funds, specifically NIGMS, NIH, grants R01 GM066777 and R01 GM079182.

Respondent neither admits nor denies ORI's findings of research misconduct. The settlement is not an admission of liability on the part of the Respondent. The parties entered into a Voluntary Settlement Agreement (Agreement) to conclude this matter without further expenditure of time, finances, or other resources.

ORI found that Respondent engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying data included in the following one (1) paper and two (2) grant applications submitted to NIGMS, NIH:

- Calcium and SOL Protease Mediate Temperature Resetting of Circadian Clocks. *Cell* 2015 Nov 19;163(5):1214–1224 (hereafter referred to as ''*Cell* 2015''). Retracted in: *Cell* 2017 Sep 21;171(1):256.
- R01 GM079182–05A1, ''Synchronization of *Drosophila* Circadian Rhythms by Temperature Cycles,'' submitted to NIGMS, NIH, on July 18, 2014.
- R35 GM118087–01, ''Molecular and neural mechanisms generating and synchronizing circadian rhythms,'' submitted to NIGMS, NIH, on May 19, 2015.

Specifically, ORI found that Respondent engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying data in bar graphs representing phase shift of circadian clock activity between *Drosophila* without and with heat pulse (HP) treatment in: Figures 1G, 2F, 3C, and 4C of *Cell* 2015; Figures 7D, 8G, and 9C in grant application R01 GM079182–05A1; Figures 3C and 4 in grant application R35 GM118087–01; and two (2) figures recorded in his unpublished data files, by selectively altering the original *Drosophila* behavior locomotor data in his primary data files. The data manipulations resulted in the creation or exaggeration of phase shifts caused by either HP treatment or over-expression of the calpain protease SOL, to support the hypothesis that temperature phase shifts the *Drosophila* circadian clock through the regulated degradation of the pacemaker protein TIMELESS mediated by SOL.

Dr. Tataroglu entered into an Agreement and voluntarily agreed:

(1) To have his research supervised for a period of three (3) years beginning on December 30, 2019; Respondent agreed that prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed supervision plan;

(2) that the requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for three (3) years beginning on December 30, 2019; the committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates, Respondent's compliance with appropriate research standards, and confirming the integrity of Respondent's research; and

ii. the committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts; the review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application/publication is supported by the research record;

(3) that for a period of three (3) years beginning on December 30, 2019, any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(4) that if no supervisory plan is provided to ORI, Respondent shall provide certification to ORI at the conclusion of the supervision period that he has not engaged in, applied for, or had his name included on any application, proposal, or other request for PHS funds without prior notification to ORI; and

(5) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years beginning on December 30, 2019.

Elisabeth A. Handley,

Interim Director, Office of Research Integrity.

[FR Doc. 2020–00874 Filed 1–17–20; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a two-day meeting in-person meeting. The meeting will be open to the public and public comment sessions will be held during the meeting.

DATES: The meeting will be held on Tuesday and Wednesday, February 13–14, 2020. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html* at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in one of the public comment sessions. Please register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious