(R) TDS products using an appropriately designed skin I/S study with human subjects to demonstrate that the potential for a skin irritation or sensitization reaction with the T TDS is no worse than the reaction observed with the R TDS.

This revised draft guidance provides the following updates to the original draft guidance:

(1) Clarifies recommendations for the design and conduct of studies to evaluate the in vivo skin I/S potential of a proposed TDS.

(2) Clarifies when an in vivo study to assess the sensitization potential of a TDS product may not be needed.

(3) Provides guidance to applicants intending to utilize alternative scoring scales or alternative approaches to compare irritation and sensitization between the T and R TDS.

The recommendations in this revised draft guidance relate to studies submitted in support of an ANDA. The Agency is seeking comments on the recommendations reflected in the revised draft guidance announced in this notice. In addition, FDA invites comments on the scoring scales and any alternative approaches, including those recommended by international regulatory agencies, that may have been used for the comparative assessment of the I/S potential for proposed generic TDS products. FDA also specifically invites comments regarding the comparative assessment of sensitization itself, *i.e.,* whether there are clinical scenarios where a comparative sensitization assessment may be uninformative when conducted in addition to a comparative irritation assessment.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this revised draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 relating to the submission of abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information relating to good clinical practice have been approved under OMB control number 0910–0843.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07769 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0379 Revision]

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Questionnaire and Data Collection Testing, Evaluation, and Research for the Health Resources and Services Administration

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 12, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at (301) 594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Questionnaire and Data Collection Testing, Evaluation, and Research for HRSA—OMB No. 0915–0379—Revision

Abstract: The purpose of information collections under this generic umbrella ICR package is to allow HRSA to continue collecting feedback from members of the public for HRSA to use when developing new questions, questionnaires, and tools; pilot/pre-test instruments to be deployed by HRSA; and to identify problems in instruments currently in use.

This generic clearance is limited to data collection for the development or revision of HRSA tools and data collection instruments, as well as reports for internal decision-making and development purposes. Information collected under this generic clearance will not be used for data collection, reports, or policy documents to be released to the public. It is anticipated that data collection approved under this generic clearance will rely heavily on qualitative techniques and not the collection of numerical data. In general, these activities are not designed to yield results that meet generally accepted standards of statistical rigor but designed to obtain information to develop clearer and more effective and efficient data collection tools that will yield more accurate results and decrease public non-response. The forms submitted under this generic clearance will be voluntary, low-burden, and uncontroversial.

HRSA originally developed this generic umbrella ICR to support similar needs across HRSA's bureaus and offices as reflected in their specific activities informed by their specific authorizing statutes. The purpose is to collect qualitative data from small groups of people in response to short questionnaires, using questions posed on HRSA's website, through focus groups and individual interviews of HRSA staff and members of the public. The abbreviated clearance process of the generic clearance helps ensure timely data gathering on current issues HRSA is addressing (*e.g.,* allows program offices to gather a suitable pool of

candidates for piloting future instruments).

HRSA seeks to extend OMB approval of this ICR and existing ICRs that fall under it while including a slight increase in the burden estimate to account for HRSA's implementation of Executive Order 13985, which calls on agencies to advance racial equity and support for underserved communities through identifying and addressing barriers to equal opportunity that underserved communities may face; HRSA will likely conduct additional information collection requests so that HRSA may effectively implement this Executive Order.

Need and Proposed Use of the Information: HRSA conducts interviews, focus groups, usability tests, and field tests/pilot interviews for data collection instrument development and evaluation (including assessment of response errors in data collection instruments). HRSA staff use various techniques to evaluate interviewer-administered, self-administered, telephone, Computer Assisted Personal Interviewing, Computer Assisted Self-Interviewing, Audio Computer-Assisted Self-Interviewing, and web-based questionnaires.

Each information collection under this generic clearance will specify the specific testing and evaluation procedures to be used. Participation will be fully voluntary, and non-participation will not affect eligibility for, or receipt of, future HRSA health services research activities or grant awards, recruitment, or participation. Appropriate consent procedures will be customized and used for each information collection activity and any collection of personal, privacy-protected information will be handled in accordance with all applicable federal requirements. If HRSA wishes to record the encounter, the respondent's permission to record will be obtained before beginning the interview. If consent is not provided, the interview either will not be recorded or not be conducted. When screening is used (*e.g.,* quota sampling), the screening will be as brief as possible, and the screening questionnaire will be provided to OMB for review.

Collection methods—The particular information collection methods used will vary, but may include the following:

- Individual in-depth interviews—In-depth interviews will commonly be used to ensure that the respondent understands the meaning of a questionnaire or strategy. When in-depth interviewing is used, the interview guide will be provided to OMB for review.
- Focus groups—Focus groups will be used to obtain insights into beliefs and understandings of the target audience early in the development of a questionnaire or tool. When focus groups are used, the focus group discussion guide will be provided to OMB for review.
- Expert/Gatekeeper review of tools—In some instances, medical providers or other gatekeepers may review tools to provide feedback on the acceptability and usability of a particular tool. This will usually be in addition to an individual user pretesting the tool.
- Record abstractions—On occasion, the development of a tool or other information collection requires review and interaction with records, rather than individuals.
- ''Dress rehearsal'' of a specific protocol—In some instances, the proposed pre-testing will constitute a walkthrough of the intended data collection procedure. In these cases, the request will mirror what is expected to occur for the larger scale data collection.

Professionally recognized procedures are followed in each information collection activity to ensure collection of high-quality information. Examples of these procedures could include the following:

- Monitoring by supervisory staff of some telephone interviews;
- Conducting interviews using methods including ''think-aloud'' techniques and debriefings;
- Computerizing data-entry from mail or paper-and-pencil surveys using scannable forms or double-key entry (*i.e.,* two people input the data from mail or paper-and-pencil surveys into an electronic format, and then comparing the two sets of entries for anomalies);
- Monitoring by observers of focus groups and recording (*e.g.,* video recording, audio recording) of focus group proceedings (subject to participant consent); and
- Employing commonly used statistical validation techniques to ensure accuracy (such as disallowing out-of-range values) of data submitted through on-line surveys.

HRSA is requesting approval for generic information collections previously approved by OMB. These include:

- Health Center Workforce Well-Being Survey: Listening Sessions
- Health Center Workforce Well-Being Survey: Cognitive Sessions
- Health Center Workforce Well-Being Survey: Pilot Testing
- Health Center Workforce Survey Evaluation and Technical Assistance: Pilot Survey
- Fast Track Interviews with National Hypertension Control Initiative Group 2 Participants.

HRSA notes that the previously approved collections are mostly unchanged, except that they may have updates to include any advances in burden estimation or information collection protocols. HRSA also anticipates conducting additional collections as the agency implements Executive Order 13985. To identify areas for improvement, HRSA anticipates collecting and aggregating data by race, ethnicity, gender, disability, income, veteran status, or other key demographic variables, while protecting individual privacy, so that HRSA can use the information to help increase equity in its programs for people from a robust range of demographic groups.

Likely Respondents: Participation in any collections under this clearance will be entirely voluntary, and the privacy of respondents will be preserved to the extent requested by participants and as permitted by law.

Respondents will be recruited by means of advertisements in public venues or through techniques that replicate prospective data collection activities that are the focus of the project. For instance, a survey on physician communication, designed to be administered following an office visit, might be pretested using the same procedure. Each ICR will specify the recruitment procedure to be used.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. HRSA anticipates that the total burden of collections under this generic package will be slightly greater than under the prior approval, due to HRSA's efforts to comply with Executive Order 13985. HRSA also reduced the number of hours for in-person testing as it has become a less popular option among prospective survey participants. The total annual

burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Type of information collection	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Mail/email [1]	1,000	1	1,000	0.26	260
Telephone	1,000	1	1,000	0.26	260
Web-based	1,200	1	1,200	0.25	300
Focus Groups	925	1	925	1.00	925
In-person	250	1	250	1.00	250
Automated [2]	500	1	500	1.00	500
Cognitive Testing	700	1	700	1.41	987
Total	5,575		5,575		3482

[1] May include telephone non-response follow-up in which case the burden will not change.
[2] May include testing of database software, Computer Assisted Personal Interviewing software, or other automated technologies.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–07774 Filed 4–12–23; 8:45 am]

BILLING CODE 4165–15–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 Carlo Spirli, Ph.D. (Respondent), who was an Assistant Professor of Medicine, Department of Digestive Diseases, Yale University (YU). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants R01 DK079005 and P30 DK034989. The administrative actions, including debarment for a period of four (4) years, were implemented beginning on March 28, 2023, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, 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 Integrity (ORI) has taken final action in the following case:

Carlo Spirli, Ph.D., Yale University: Based on the report of an investigation conducted by YU and additional analysis conducted by ORI in its oversight review, ORI found that Carlo Spirli, Ph.D., former Assistant Professor of Medicine, Department of Digestive Diseases, YU, engaged in research misconduct in research supported by PHS funds, specifically NIDDK, NIH, grants R01 DK079005 and P30 DK034989.

ORI found that Respondent engaged in research misconduct by knowingly, intentionally, or recklessly falsifying and/or fabricating data included in the following four (4) published papers, two (2) presentations, and three (3) grant applications submitted for PHS funds:

- Cyclic AMP/PKA-dependent Paradoxical Activation of Raf/MEK/ERK Signaling in Polycystin-2 Defective Mice Treated with Sorafenib. *Hepatology.* 2012 Dec;56(6):2363–74. doi: 10.1002/hep.25872 (hereafter referred to as ''*Hepatology* 2012a'').
- Altered Store Operated Calcium Entry Increases Cyclic 3′,5′-Adenosine Monophosphate Production and Extracellular Signal-Regulated Kinases 1 and 2 Phosphorylation in Polycystin-2-Defective Cholangiocytes. *Hepatology.* 2012 Mar;55(3):856–68. doi: 10.1002/hep.24723 (hereafter referred to as ''*Hepatology* 2012b'').
- Protein Kinase A-Dependent pSer(675)-β-catenin, a Novel Signaling Defect in a Mouse Model of Congenital Hepatic Fibrosis. *Hepatology.* 2013 Nov;58(5):1713–23. doi:10.1002/hep.26554 (hereafter referred to as ''*Hepatology* 2013'').
- Posttranslational Regulation of Polycystin-2 Protein Expression as a Novel Mechanism of Cholangiocyte Reaction and Repair from Biliary Damage. *Hepatology.* 2015 Dec; 62(6):1828–39. doi: 10.1002/hep.28138 (hereafter referred to as ''*Hepatology* 2015''). Retraction in: *Hepatology.* 2022 Dec;76(6):1904. doi: 10.1002/hep.32595.
- PKA-Dependent p-SER675-b-Catenin Phosphorylation Increases Cholangiocyte Motility in Pkhd1del4/del4 Mouse, a Model of Fibropolycystic Liver Diseases Caused by Defective Fibrocystin Function. Presented at the European Association for the Study of the Liver (EASL) (hereafter referred to as ''EASL Presentation 2011'').
- Cyclic-AMP-Dependent, Rac1-Mediated Nuclear Translocation Of P-Ser-675β-Catenin, A Novel Signaling Defect in Congenital Hepatic Fibrosis (CHF) and Caroli's Disease (CD). Presented at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting, Boston, MA, in November 2012 (hereafter referred to as ''AASLD Presentation 2011'').
- R01 DK079005–11A1, ''Epithelial Angiogenic Signaling in Biliary Pathophysiology and in Polycystic Disease,'' submitted to NIDDK, NIH, on December 13, 2018. Administratively withdrawn by the funding agency on March 1, 2021.
- R01 DK090021–01 ''Mechanisms of fibrosis in fibrocystin-deficiency associated cholangiopathies'' submitted to NIDDK, NIH, on February 2, 2010. Administratively withdrawn by the funding agency on July 1, 2012.
- R01 DK090021–01A1 ''Mechanisms of fibrosis in fibrocystin-deficiency associated cholangiopathies'' submitted to NIDDK, NIH, on November 11, 2010.