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

21 CFR part or section; activity	Number of respondents	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
Guidance Recommendations: Meeting requests to OOPD and related submission packages	807	1.5	1,211	4	4,842
Total			5,613		174,289

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

Our burden estimate includes those activities related to: (1) requesting orphan drug designation; (2) responding to deficiencies letters with submissions of amendments; (3) keeping files current with contact information for agents and transfer of ownership, when applicable; (4) submitting annual reports while products have designation status; and (5) requesting and preparing for both informal and formal meetings. Because the PRA defines a recordkeeping requirement to include reporting those records to the Federal government, we account for these activities cumulatively in table 1 above. Upon a recent evaluation of the information collection, we adjusted our burden estimate to reflect an overall increase of 50,616 hours and an increase of 766 records annually. We attribute this adjustment to an increase in the number of submissions, amendments, and annual reports.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12547 Filed 6–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1083]

Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination.'' The draft guidance, when finalized, will provide our current view of insanitary conditions of tattoo ink preparation, packaging, or holding that may render the inks injurious to health because of microbial contamination.

DATES: Submit either electronic or written comments on the draft guidance by September 11, 2023 to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2023–D–1083 for ''Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination.'' 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.'' FDA 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 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Colors and Cosmetics, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Elizabeth Anderson, Office of Colors and Cosmetics, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1130; or Deirdre Jurand, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

Tattooing has become increasingly popular in the United States: about 30 percent of all Americans, and 40 percent of those aged 18 to 34 years, have at least one tattoo (Refs. 1 and 2). State and local jurisdictions generally regulate the practice of intradermal tattooing, including permanent makeup. FDA regulates, among other things, the inks used in that practice. These inks are cosmetics as defined by section 201(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(i)) because they are articles intended to be introduced into or otherwise applied to the human body for beautifying, promoting attractiveness, or altering the appearance. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction, or delivery for introduction, into interstate commerce of cosmetics that are adulterated or misbranded. Cosmetics are adulterated within the meaning of section 601(c) of the FD&C Act (21 U.S.C. 361(c)) if they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

Microbes normally regarded as nonpathogenic when introduced in certain ways (*e.g.,* topically) may become opportunistically pathogenic and virulent when introduced in other ways (*e.g.,* in wounds, or via cosmetics introduced into or through the skin). Tattoo inks bypass the body's primary physical barrier against pathogens because they are inserted below the epidermis. We have received multiple reports of illness caused by microbially contaminated tattoo inks, and subsequent testing has found many sealed tattoo inks in the United States with microbial contamination. Among other things, between 2003 and 2019, tattoo ink firms conducted 15 ink recalls, 14 of which resulted from findings of microbial contamination. Eight of these recalls (Refs. 3 to 7) occurred after FDA conducted multiple surveys of tattoo inks available in the U.S. market and tested them for microbial contamination. Many of these inks were heavily contaminated with a variety of microorganisms, some of which can cause serious infections (Refs. 8 and 9).

This draft guidance, when finalized, will help tattoo ink manufacturers and distributors understand examples of what could adulterate a tattoo ink because it has been prepared, packed, or held under insanitary conditions that could render it injurious to health. We also recommend certain steps that manufacturers and distributors could take to help prevent the occurrence of these conditions, or to identify and remediate insanitary conditions that already exist during manufacturing and distribution.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/CosmeticGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. 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. Giulbudagian, M., I. Schreiver, A.V. Singh, et al., ''Safety of Tattoos and Permanent Make-up: A Regulatory View.'' *Archives of Toxicology,* 94: 357–369 (2020).
2. Ipsos poll. ''More Americans Have Tattoos Today than Seven Years Ago,'' August 29, 2019. Available at: *https://www.ipsos.com/en-us/news-polls/more-americans-have-tattoos-today* (accessed January 19, 2023).
* 3. Food and Drug Administration, ''Fusion Ink'': Recall, posted November 30, 2017; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=158974* (accessed January 19, 2023).
* 4. Food and Drug Administration, ''Radiant Colors'': Recall, posted December 21, 2017; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=160130* (accessed January 19, 2023).
* 5. Food and Drug Administration, ''Solid Ink'': Recall, posted June 20, 2018; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=164628* (accessed January 19, 2023).
* 6. Food and Drug Administration, ''Intenze Ink'': Recall, posted July 31, 2018; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=165649* (accessed January 19, 2023).
* 7. Food and Drug Administration, ''Eternal Ink'': Recall, posted October 24, 2018; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=167698* (accessed

January 19, 2023).
* 8. Nho, SW, S-J. Kim, O. Kweon, et al. ''Microbiological Survey of Commercial Tattoo and Permanent Makeup Inks Available in the United States.'' *Journal of Applied Microbiology,* 124: 1294–1302 (2018).
* 9. Food and Drug Administration, ''FDA Advises Consumers, Tattoo Artists, and Retailers to Avoid Using or Selling Certain Tattoo Inks Contaminated with Microorganisms''; available at *https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-tattoo-artists-and-retailers-avoid-using-or-selling-certain-tattoo-inks* (accessed January 19, 2023).

Dated: June 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12380 Filed 6–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request: Information Collection Request Title: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915–0335–Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 13, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, contact Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call 301–443–3938.

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

Information Collection Request Title: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915–0335—Revision.

Abstract: HRSA's Maternal and Child Health Bureau (MCHB) provides funds to support several programs related to autism, as authorized by 42 U.S.C. 280i–1 (title III, section 399BB of the Public Health Service Act), as amended by the Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2019 (Pub. L. 116–60). The Autism CARES Act of 2019 emphasizes improving health outcomes and the well-being of individuals with Autism Spectrum Disorder and Developmental Disabilities across the lifespan.

MCHB's programs related to autism fall within three distinct but complementary areas—research, state systems, and training. The awards advance research on early screening and interventions for autism and developmental disabilities; improve the capacity of state public health agencies to build and maintain coordinated systems of services for individuals with autism and developmental disabilities; and train the health care workforce to screen, refer, and provide services for children and youth with autism and developmental disabilities. MCHB currently funds 12 programs and 95 awardees. HRSA seeks to implement annual comprehensive evaluations of MCHB's Autism CARES Initiative investments.

This ICR is a revision to an existing package; this study is the fifth evaluation of HRSA's autism activities and employs similar data collection methodologies as the prior studies. Grantee interviews remain the primary form of data collection. Minor proposed revisions to the data collection process include modifications to the interview questions and grantee survey based on current legislation and HRSA's Notices of Funding Opportunity for programs authorized under the Autism CARES Act. In addition, the previous data collection compiled survey responses from all grantees, whereas this revised data collection will only seek survey responses from the Research and State Systems grantees. The previous data collection also included a quantitative data collection form for the Research grantees that the current data collection will not collect. These changes result in fewer burden hours estimated across all primary data collection activities.

A 60-day notice published in the **Federal Register** on March 21, 2023, vol. 88, No. 54; pp. 16995–16996. There were no public comments.

Need and Proposed Use of the Information: The purpose of this data collection is to implement a comprehensive evaluation that describes the activities, accomplishments, outcomes, barriers, and challenges of the grant programs in implementing the provisions of the Autism CARES Act. The data will be used to (1) conduct performance monitoring of the programs; (2) provide credible and rigorous evidence of program effectiveness; (3) meet program needs for accountability, decision-making, and quality assurance; and (4) strengthen the evidence base for best practices.

Likely Respondents: The survey respondents will include Principal Investigators/Project Directors from the research programs and networks (Autism Intervention Research Network on Physical Health, Autism Intervention Research Network on Behavioral Health, MCHB Secondary Data Analysis Research Program, Autism Field-Initiated Innovative Research Studies Program, Autism Single Investigator Innovation Program, the Developmental-Behavioral Pediatrics Research Network, and the Healthy Weight Research Network for Children with Autism and Other Developmental Disabilities); and state systems programs (State Innovations) and coordinating center (State Public Health Coordinating Center for Autism). The respondents for the interviews will include Principal Investigators/Project Directors from the research and state systems programs above, and the training programs (Leadership Education in Neurodevelopmental and Related Disabilities program, the Developmental Behavioral Pediatrics program, and the National Interdisciplinary Training Resource Center).

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