DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–N–0783 and FDA–2024–N–0021]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices	0910–0052	9/30/2027
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types	0910–0744	10/31/2027

Dated: October 21, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24822 Filed 10–24–24; 8:45 am]

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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; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination.'' The final guidance provides 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. This guidance finalizes the draft guidance of the same title issued on June 13, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on October 25, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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.'' 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.

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 guidance to Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave WO1, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–4880 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination.''

Tattooing has become increasingly popular in the United States. Polling and data suggest that about 30 percent of all Americans, and 40 percent of those aged 18–34, have at least one tattoo (Refs. 1 and 2). State and local jurisdictions generally regulate the practice of intradermal tattooing, including permanent makeup and microblading. FDA regulates, among other things, the inks used in that practice. Tattoo 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.

Microorganisms normally regarded as nonpathogenic when applied 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 8) 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 guidance 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.

This guidance finalizes the draft guidance entitled ''Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination'' issued on June 13, 2023 (88 FR 38516). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include addition of a definition of injection for purposes of this guidance. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination.'' 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

This 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 guidance at *https://www.fda.gov/CosmeticGuidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

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. Although FDA verified the website addresses in this document, please note that 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, July 22, 2024).
*3. FDA, ''Fusion Ink'': Recall, posted November 30, 2017; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=158974* (accessed January 19, 2023, July 22, 2024).
*4. FDA, ''Radiant Colors'': Recall, posted December 21, 2017; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=160130* (accessed January 19, 2023, July 22, 2024).
*5. FDA, ''Solid Ink'': Recall, posted June 20, 2018; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=164628* (accessed

January 19, 2023, July 22, 2024).
*6. FDA, ''Intenze Ink'': Recall, posted July 31, 2018; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=165649* (accessed January 19, 2023, July 22, 2024).
*7. FDA, ''Eternal Ink'': Recall, posted October 24, 2018; available at *https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=167698* (accessed January 19, 2023, July 22, 2024).
*8. FDA, ''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, July 22, 2024).
*9. 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).

Dated: October 21, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–24841 Filed 10–24–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4777]

Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmacy Compounding Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on December 4, 2024, from 8 a.m. to 3 p.m. Eastern Time.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–4777. The docket will close on December 3, 2024. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on December 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before November 19, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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'').

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- 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–2024–N–4777 for ''Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List.'' 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.'' 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 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 the 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