intentionally introduced to foods, including by acts of terrorism, with the intent to cause widespread harm to public health. Under the regulations, domestic and foreign food facilities that are required to register under the FD&C Act are required to identify and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

In an effort to reduce burden and assist respondents, FDA offers tools and educational materials related to protecting food from intentional adulteration, including the FDA Food Defense Plan Builder, a user-friendly tool designed to help owners and operators of food facilities develop a personalized food defense plan, and the Mitigation Strategies Database, a database for the food industry providing a range of preventative measures that firms may choose to implement. These and other informational resources are available at *https://www.fda.gov/food/food-defense/food-defense-tools-educational-materials.* FDA also offers a small entity compliance guide titled ''Mitigation Strategies to Protect Food Against Intentional Adulteration'' (August 2017) to inform domestic and foreign food facilities about compliance with regulations to protect against intentional adulteration. Further, FDA developed two draft guidance documents titled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry'' (March 2019) and ''Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration'' (February 2020). Once finalized, the draft guidance documents would assist the food industry in developing and implementing the elements of a food defense plan. These guidance documents are available at *https://www.fda.gov/food/food-defense.* All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Description of Respondents: The respondents to this information collection are manufacturers, processors, packers, and holders of retail food products marketed in the United States.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food from very small businesses; 21 CFR 121.5	18,080	1	18,080	0.5 (30 minutes)	9,040

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

Certain facilities may qualify for an exemption under the regulations. Because these facilities must provide documentation upon request to verify their exempt status, we have characterized this as a reporting burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Food Defense Plan; § 121.126	3,247	1	3,247	23	74,681
Actionable Process Steps; § 121.130	9,759	1	9,759	20	195,180
Mitigation Strategies; § 121.135(b)	9,759	1	9,759	20	195,180
Monitoring Corrective Actions, Verification; §§ 121.140(a), 121.145(a)(1), and 121.150(c)	9,759	1	9,759	175	1,707,825
Training; § 121.160	367,203	1	367,203	0.67 (40 minutes)	246,026
Records; §§ 121.305 and 121.310	9,759	1	9,759	10	97,590
Total					2,516,482

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments other than to increase the burden estimate by 1,224 hours due to a corrected calculation for the estimate related to training (§ 121.160).

Dated: December 10, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27285 Filed 12–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0241]

Inspection of Injectable Products for Visible Particulates; Draft 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 draft guidance for industry entitled ''Inspection of Injectable Products for Visible Particulates.'' Visible particulates in injectable products can jeopardize patient safety. This draft guidance addresses the development and implementation of a holistic, risk-based approach to visible particulate control that incorporates product development, manufacturing controls, visual inspection techniques, particulate identification, investigation, and

corrective actions designed to assess, correct, and prevent the risk of visible particulate contamination. The draft guidance also clarifies that meeting an applicable U.S. Pharmacopeia (USP) compendial standard alone is not generally sufficient for meeting the current good manufacturing practice (CGMP) requirements for the manufacture of injectable products.

DATES: Submit either electronic or written comments on the draft guidance by February 15, 2022 to ensure that the Agency considers your comment on this 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–2021–D–0241 for ''Inspection of Injectable Products for Visible Particulates.'' 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Eric Dong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6652, Silver Spring, MD 20993–0002, 240–402–4172; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Laura Huffman, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, Metro Park North 2 (MPN2), Rm. Hotel CVM, 7500 Standish Pl., Rockville, MD 20855, 240–402–0664.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Inspection of Injectable Products for Visible Particulates.'' Visible particulates in injectable products can jeopardize patient safety. The draft guidance addresses a holistic approach to visible particulate control that incorporates risk assessment, prevention, inspection, identification, and remediation of visible particulates in injectable products.

Adherence to FDA's CGMP requirements. as set forth in section 501 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351) and 21 CFR parts 210 and 211 for drug, animal drug, and biological products; 21 CFR 600.10 through 600.15 for biological products; and 21 CFR part 4 for combination products, is essential for the control of visible particulates in injectable products. Adherence to compendial standards can also assist manufacturers in complying with CGMP requirements. USP General Chapter <1> *Injections and Implanted Drug Products (Parenterals)—Product Quality Tests* states that ''[t]he inspection process should be designed and qualified to ensure that every lot of all parenteral preparations is essentially free from visible particulates'' as defined in USP General Chapter <790> *Visible Particulates in Injections.* Injectable

products with a USP monograph are required to meet the applicable criteria from these USP General Chapters (see section 501(b) of the FD&C Act). Noncompendial products should also be ''essentially free from visible particulates'' as defined in USP General Chapter <790>.

Applying acceptance criteria, such as the criterion outlined in USP General Chapter <790>, is an important component of the overall visible particulate control program, but meeting these acceptance criteria alone is not sufficient to ensure compliance with the applicable CGMP requirements identified above, which cover a broader array of manufacturing practices than product inspection. Full compliance with CGMP requirements is needed to ensure the continued supply of pure, safe, and effective injectable products.

This 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 ''Inspection of Injectable Products for Visible Particulates.'' 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 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 parts 211, 314, and 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0308, respectively.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 14, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27351 Filed 12–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFAs (EB–19–002; EB–20–001) Review SEP.

Date: February 11, 2022.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Songtao Liu, MD, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892, (301) 827–3025, *songtao.liu@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, HHS)

Dated: December 10, 2021.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27340 Filed 12–16–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee CIDR Member Conflict Meeting.

Date: January 14, 2022.

Time: 12:00 p.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Room 3184, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rudy Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, Bldg. 6700B Rockledge Dr., Rm. 3184, 6700B Rockledge Dr., Bethesda, MD 20817, (301) 402–0838, *pozzattr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: December 13, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27341 Filed 12–16–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NIH Electronic Application System for NIH Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide