Country	Entity	License requirement	License review policy	Federal Register citation
	Room 2005, Building 6, No. 77 Heshun Road, Suzhou Industrial Park, Suzhou, Jiangsu, 215000, China; *and* Room 301 Building 3, No. 99 Jinyahu Avenue, Suzhou Industrial Park, Jiangsu Pilot Free Trade Zone, China.			
	* *	* *	*	*
	Wuhu Kewei Zhaofu Electronics Co., Ltd., West side of North Jiuhua Road, Economic and Technological Development Zone, Wuhu, Anhui, China; *and* No.10 Ruifu Road, Longshan Avenue, Wuhu Economic and Technological Development Zone, Wuhu, Anhui, 241000, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER AND 1/6/25.
	* *	* *	*	*
	Yaguang Technology Group Co., Ltd., a.k.a., the following one alias: —Sunbird Yachting Co., Ltd. Yacht Industrial Park, Yuanjiang, China; *and* No. 18, Shijihu Road, Yuanjiang City, Yiyang City, China; *and* Yaguang Science and Technology Park, No. 1820 Yuelu West Avenue, Changsha, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER AND 1/6/25.
	* *	* *	*	*
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PAKISTAN	* *	* *	*	*
	Emerging Future Solutions Private Limited, a.k.a., the following four aliases: —Emerging Future Solutions; —Emerging Future Solutions (Pvt) Ltd Pakistan; —Emerging Future Solutions Pvt Ltd.; *and* —Emerging Future Solutions Limited. Office No. 46–A, Street No. 5, Chaklala Scheme-III, Rawalpindi, 46000, Pakistan.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	90 FR [INSERT FR PAGE NUMBER AND 1/6/25.
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Matthew S. Borman,

Principal Deputy Assistant Secretary for Strategic Trade and Technology Security.

[FR Doc. 2024–31468 Filed 1–3–25; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. FDA–2024–D–5374]

Considerations for Complying With 21 CFR 211.110; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of draft guidance.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Considerations for Complying With 21 CFR 211.110.'' This guidance, when finalized, will describe considerations for complying with the requirements for ensuring batch uniformity and drug product integrity. In addition, this guidance discusses related quality considerations for drug products that are manufactured using advanced manufacturing. FDA is committed to supporting and enabling pharmaceutical innovation and modernization as part of the Agency's mission to protect and promote the public health. FDA encourages industry representatives and manufactures who are interested in using innovative control strategies to contact the Agency.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2025 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–2024–D–5374 for ''Considerations for Complying With 21 CFR 211.110.'' 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 this 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; the 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 Policy and Regulations Staff, HFV–6, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, 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: Brittany Avaritt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6649, Silver Spring, MD 20993–0002, 240–402–5982; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bld. 71, Rm. 7301, Silver Spring, MD 20993–002, 240–402–7911; or Kevin Rice, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–402–0680.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Considerations for Complying with 21 CFR 211.110.'' This guidance, when finalized, will describe considerations for complying with the requirements in § 211.110 (21 CFR 211.110) to ensure batch uniformity and drug product integrity. In addition, this guidance discusses related quality considerations for drug products that are manufactured using advanced manufacturing. It also discusses how manufacturers can incorporate process models into commercial manufacturing control strategies. This guidance applies to the manufacture of human drug products, including biological products, and animal drug products. This guidance does not apply to the manufacture of active ingredients.

To ensure batch uniformity and drug product integrity, the current good manufacturing practice (CGMP) regulations [1] require, among other things, that manufacturing processes are designed and controlled to ensure that in-process materials consistently and reliably meet predetermined quality requirements.[2] This guidance explains the requirements for drug product manufacturing in § 211.110. This guidance also describes considerations for the use of advanced manufacturing (*e.g.,* 3D printing, continuous manufacturing) and the use of process models as a part of commercial manufacturing control strategies. FDA supports the adoption of advanced manufacturing as a foundation for improving the overall quality and availability of drug products for patients.

All manufacturers, regardless of whether they are using advanced manufacturing, should apply a scientific- and risk-based approach to controlling processes and ensuring drug product quality. This approach should be based on robust product and process understanding. Advanced manufacturing (such as continuous manufacturing) generally lends itself to more extensive understanding and control of the manufacturing process; thus, it is generally suitable for implementing process models as part of the control strategy. FDA is aware of industry's interest in using in-process control strategies that rely solely on process models to satisfy the requirements of § 211.110. However, control strategies that rely solely on current process models would be insufficient to satisfy the requirements of § 211.110.

FDA is committed to supporting and enabling pharmaceutical innovation and modernization as part of the Agency's mission to protect and promote the public health. This guidance provides information on how process models can be paired with in-process material testing or process monitoring to meet current regulatory requirements. As the science supporting innovative in-process control tools and methods continues to develop, FDA anticipates that these scientific advancements can be leveraged to pursue in-process control strategies that increasingly rely on process models. FDA encourages industry representatives and manufacturers to discuss their proposed innovative control strategies with the Agency to help inform future policy development.

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 ''Considerations for Complying With

[1] See 21 CFR parts 210 and 211. Positron emission tomography drug products are subject to CGMP regulations at 21 CFR part 212 and are not covered by this guidance.

[2] See § 211.110.

21 CFR 211.110.'' 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.[3]

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in parts 210 and 211 relating to CGMP have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of 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, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 23, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31356 Filed 1–3–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–1099]

Security Zone; Potomac River and Anacostia River, and Adjacent Waters, Washington, DC

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a security zone along the Potomac River, Anacostia River, and adjacent waters at Washington, DC, for the State Funeral for former President James Carter. This action is necessary to protect government officials, mitigate potential terrorist acts and incidents, and enhance public and maritime safety and security immediately before, during, and after this activity. During the enforcement period, entry into or remaining within the zone is prohibited unless authorized by the Captain of the Port or their designated representative.

DATES: The regulations in 33 CFR 165.508 will be enforced from 8 a.m., January 7, 2025, through 4 p.m., January 9, 2025, for the security zone location identified in 33 CFR 16.508(a)(6).

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate Newkirk, U.S. Coast Guard Sector Maryland-National Capital Region, Waterways Management Division; telephone 410–576–2596, email *Kate.M.Newkirk@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce regulations in 33 CFR 165.508 for the locations identified in paragraph (a)(6) from 8 a.m., January 7, 2025, through 4 p.m., January 9, 2025. This action is being taken to protect government officials, mitigate potential terrorist acts and incidents, and enhance public and maritime safety and security immediately before, during, and after this event. Our regulations for the Security Zone; Potomac River and Anacostia River, and adjacent waters at Washington, DC. The regulation at 33 CFR 165.508(a)(6) specifies the location for this security zone as an area that includes all navigable waters described in paragraphs (a)(1) through (3), which includes Zones 1, 2, and 3.

- Security Zone 1, paragraph (a)(1); all navigable waters of the Potomac River, from shoreline to shoreline, bounded to the north by the Francis Scott Key (US–29) Bridge, at mile 113, and bounded to the south by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport at 38°51′21.3″ N, 077°02′00.0″ W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, including the waters of the Boundary Channel, Pentagon Lagoon, Georgetown Channel Tidal Basin, and Roaches Run.
- Security Zone 2, paragraph (a)(2); all navigable waters of the Anacostia River, from shoreline to shoreline, bounded to the north by the John Philip Sousa (Pennsylvania Avenue) Bridge, at mile 2.9, and bounded to the south by a line drawn from the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at position 38°50′52.4″ N, 077°01′10.9″ W, including the waters of the Washington Channel.
- Security Zone 3 paragraph (a)(3); all navigable waters of the Potomac River, from shoreline to shoreline, bounded to the north by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport, at 38°51′21.3″ N, 077°02′00.0″ W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, thence southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at position 38°50′52.4″ N, 077°01′10.9″ W, and bounded to the south by the Woodrow Wilson Memorial (I–95/I–495) Bridge, at mile 103.8.

During the enforcement period, as specified in § 165.508(b), entry into or remaining in these zones is prohibited unless authorized by the Coast Guard Captain of the Port Maryland-National Capital Region. Public vessels and vessels already at berth at the time of the security zone is implemented do not have to depart the security zone. All vessels underway within the security zone at the time the security zone is implemented are to depart the zone. To seek permission to transit the zone, the Captain of the Port Maryland-National Capital Region can be contacted at telephone number (410) 576–2525 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Coast Guard vessels enforcing this zone can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard may be assisted by other Federal, state, or local law enforcement agencies in enforcing this regulation. If the Captain of the Port or his designated on-scene patrol personnel determines the security zone need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to suspend enforcement and grant general permission to enter the security zone.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification to this enforcement period via the Local Notice to Mariners, and marine information broadcasts.

[3] The Office of the Federal Register has published this document under the category ''Rules and Regulations'' pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the content or intent of the document. See 1 CFR 5.1(c).