

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11], Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL ND E5 Ashley, ND [Establish]

Ashley Municipal Airport, ND

(Lat. 46°01'23" N, long. 99°21'09" W)

That airspace extending upward from 700 feet above the surface within a 7.2-mile radius of Ashley Municipal Airport.

* * * * *

Issued in Fort Worth, Texas, on December 31, 2024.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–31637 Filed 1–3–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 241217–0329]

RIN 0694–AJ99

Revisions to the Entity List

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding 13 entities under 13 entries to the Entity List. These entities are listed on the Entity List under the destinations of Burma (1), China, People's Republic of (China) (11), and Pakistan (1). These entities have been determined by the U.S. Government to be acting contrary to the national security and/or foreign policy interests of the United States. This rule also amends the EAR by making certain editorial corrections and clarifications.

BIS is making the corrections and clarifications in order to minimize confusion and not impede the free flow of commerce.

DATES: This rule is effective January 6, 2025.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

The Entity List (supplement no. 4 to part 744 of the EAR (15 CFR parts 730–774)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States, pursuant to § 744.11(b) of the EAR. The EAR impose additional license requirements on and limit the availability of most license exceptions for exports, reexports, and transfers (in-country) when a listed entity is a party to the transaction. The license review policy for each listed entity is identified in the “License Review Policy” column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document that added the entity to the Entity List. BIS places entities on the Entity List pursuant to parts 744 (Control Policy: End-User and End-Use Based) and 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

Additions to the Entity List

The ERC determined to add Telecom International Myanmar Company Limited, under the destination of Burma, to the Entity List. This addition is based on actions and activities that are contrary to the national security and foreign policy interests of the United States under § 744.11 of the EAR. Specifically, this entity is being added for providing surveillance services and

financial support to Burma's military regime, enabling the regime to carry out human rights abuses through the tracking and identification of target individuals and groups. A license is required for the export, reexport and transfer (in-country) of all items subject to the EAR to this entity and license applications will be reviewed under a presumption of denial.

The ERC has determined to add Chengdu RML Technology Co., Ltd.; Chengdu Yaguang Electronics Co., Ltd.; Hefei Starwave Communication Technology Co., Ltd.; and Yaguang Technology Group Co., Ltd., all under the destination of China, to the Entity List. These entities are added for acquiring and attempting to acquire U.S.-origin items in support of China's military modernization. Specifically, Chengdu RML Technology Co., Ltd. has supplied the People's Liberation Army (PLA) with precision-guided missiles and satellite communication systems. Chengdu Yaguang Electronics Co., Ltd. and its parent company, Yaguang Technology Group Co., Ltd., have supplied the PLA and multiple Chinese parties on the Entity List with dual-use electronic components. Lastly, Hefei Starwave Communication Technology Co., Ltd. has supplied radio frequency/microwave products explicitly for military equipment application to the PLA and Chinese parties on the Entity List. These activities are contrary to the national security and foreign policy interests of the United States under § 744.11 of the EAR. These entities are added with a license requirement for the export, reexport and transfer (in-country) of all items subject to the EAR and a license review policy of a presumption of denial.

The ERC determined to add the following seven entities, all under the destination of China, to the Entity List: Chinese Academy of Sciences Changchun Institute of Optics, Fine Mechanics, and Physics; Ji Hua Laboratory; Nanjing Simite Optical Instruments Co., Ltd.; Peng Cheng Laboratory; Shanghai Institute of Optics and Fine Mechanics; Suzhou Ultrano Precision Optoelectronics Technology Co., Ltd.; and Wuhu Kewei Zhaofu Electronics Co., Ltd. These entities are being added for acquiring and attempting to acquire U.S.-origin items in support of China's military modernization. In addition, these entities have demonstrable ties to activities of concern, including hypersonic weapons development, design and modeling of vehicles in hypersonic flight, using proprietary software to model weapons design and damage; and otherwise supporting

China's military-civil fusion efforts. These activities are contrary to the national security and foreign policy interests of the United States under § 744.11 of the EAR. These entities are added with a license requirement for the export, reexport, and transfer (in-country) of all items subject to the EAR and a license review policy of presumption of denial.

Finally, the ERC determined to add Emerging Future Solutions Private Limited, under the destination of Pakistan, to the Entity List. This addition is made as a result of the entity's contributions to Pakistan's ballistic missile program. This activity is contrary to U.S. national security and foreign policy interests under § 744.11 of the EAR. This entity is added with a license requirement for the export, reexport and transfer (in-country) of all items subject to the EAR and a license application review policy of a presumption of denial.

For the reasons described above, this final rule adds the following 13 entities under 13 entries to the Entity List and includes, where appropriate, aliases:

Burma

- Telecom International Myanmar Company Limited

China

- Chengdu RML Technology Co., Ltd.,
- Chengdu Yaguang Electronics Co., Ltd.,
- Chinese Academy of Sciences Changchun Institute of Optics, Fine Mechanics, and Physics,
- Hefei Starwave Communication Technology Co., Ltd.,
- Ji Hua Laboratory,
- Nanjing Simite Optical Instruments Co., Ltd.,
- Peng Cheng Laboratory,
- Shanghai Institute of Optics and Fine Mechanics,
- Suzhou Ultrananano Precision Optoelectronics Technology Co., Ltd.,
- Wuhu Kewei Zhaofu Electronics Co., Ltd., and
- Yaguang Technology Group Co., Ltd.

Pakistan

- Emerging Future Solutions Private Limited.

Corrections to the Entity List

This final rule also corrects one spelling error and two punctuation errors in the addresses listed for the entry of Shenzhen Guowei Sensing Technology Co., Ltd. This entity was originally added to the Entity List on December 2, 2024, in a final rule

published on December 5, 2024 (89 FR 96830).

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on January 6, 2025, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) before February 5, 2025. Any such items not actually exported, reexported, or transferred (in-country) before midnight, on February 5, 2025, require a license in accordance with this final rule.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. In particular, section 1753 of ECRA (50 U.S.C. 4812) authorizes the regulation of exports, reexports, and transfers (in-country) of items subject to U.S. jurisdiction. Further, section 1754(a)(1)–(16) of ECRA (50 U.S.C. 4813(a)(1)–(16)) authorizes, *inter alia*, establishing and maintaining a list of foreign persons and end uses that are determined to be a threat to the national security and foreign policy of the United States pursuant to the policy set forth in section 1752(2)(A), and restricting exports, reexports, and in-country transfers of any controlled items to any foreign person or end-use so listed; apprising the public of changes in policy, regulations, and procedures; and any other action necessary to carry out ECRA that is not otherwise prohibited by law. Pursuant to section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection

of information, subject to the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves an information collection approved by OMB under control number 0694–0088, Simplified Network Application Processing System. BIS does not anticipate a change to the burden hours associated with this collection as a result of this rule. Information regarding the collection, including all supporting materials, can be accessed at: <https://www.reginfo.gov/public/do/PRAMain>.

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While section 1762 of ECRA provides sufficient authority for such an exemption, this action is also independently exempt from these APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)).

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—CONTROL POLICY: END-USER AND END-USE BASED

■ 1. The authority citation for part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p.

783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 18, 2024, 89 FR 77011 (September 20, 2024); Notice of November 7, 2024, 89 FR 88867 (November 8, 2024).

■ 2. Supplement no. 4 to part 744 is amended:

■ a. Under BURMA, by adding, in alphabetical order, an entry for “Telecom International Myanmar Company Limited;”

■ b. Under CHINA, PEOPLE’S REPUBLIC OF, by:

■ i. Adding, in alphabetical order, entries for “Chengdu RML Technology

Co., Ltd.,” “Chengdu Yaguang Electronics Co., Ltd.,” “Chinese Academy of Sciences Changchun Institute of Optics, Fine Mechanics, and Physics;” “Hefei Starwave Communication Technology Co.,” “Ji Hua Laboratory;” “Nanjing Simite Optical Instruments Co., Ltd.,” “Peng Cheng Laboratory;” and “Shanghai Institute of Optics and Fine Mechanics;”

■ ii. Revising the entry for “Shenzhen Guowei Sensing Technology Co., Ltd.,” and

■ iii. Adding in alphabetical order, entries for “Suzhou Ultrnano Precision

Optoelectronics Technology Co., Ltd.,” “Wuhu Kewei Zhaofu Electronics Co., Ltd.,” and “Yaguang Technology Group Co., Ltd.,” and

■ c. Under PAKISTAN, by adding, in alphabetical order, an entry for “Emerging Future Solutions Private Limited.”

The additions and revision read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
BURMA	Telecom International Myanmar Company Limited, a.k.a., the following two aliases: —Mytel; and —MyTel. 61–63 Zoological Garden Road, Yangon, Burma.	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.
CHINA, PEOPLE’S REPUBLIC OF.	Chengdu RML Technology Co., Ltd., a.k.a., the following two aliases: —Chengdu Thunderbolt Micro Power Technology Co., Ltd.; and —RML Technology. No. 19, Section 4, Huaifu Avenue, Chengdu, China; and Shiyang Industrial Park, No. 288, Yixin Avenue, Chengdu, China; and the First Floor, Jinhe Hotel, 18 Jinhe Road, Chengdu, 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.
	Chengdu Yaguang Electronics Co., Ltd., a.k.a., the following three aliases: —Chengdu Yaguang; —Chengdu OPTO Electronics Co., Ltd.; and —970 Factory. No. 66, Donghong Road, Chengdu, China; and No. 36, Beisen Road, Chengdu, 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.
	Chinese Academy of Sciences Changchun Institute of Optics, Fine Mechanics, and Physics, a.k.a., the following three aliases: —Changchun Institute of Optics, Fine Mechanics, and Physics, CAS; —CAS Institute of Optics, Fine Mechanics, and Physics; and —CIOMP. 3888 E Nanhu Road, Changchun, 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.
	Hefei Starwave Communication Technology Co., Ltd., a.k.a., the following three aliases: —Starwave Comm Tech Corp; —Star Wave Communication; and —Hefei Xingbo Communication Technology Co., Ltd. No. 11, Mechanical and Electrical Industrial Park, No. 767, Yulan Avenue, Hefei, 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.
	Ji Hua Laboratory, a.k.a., the following four aliases: —Guangdong Provincial Laboratory of Advanced Manufacturing Science and Technology; —Guangdong Provincial Lab of Chemicals and Fine Chemicals; —Ji Hua Lab; and —Yan Chang Ji Hua Lab.	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.

Country	Entity	License requirement	License review policy	Federal Register citation
	No. 28, Huan Dao Nan Road, Guangdong Province, Foshan, 528000, China; <i>and</i> No.28 Huandao South Road, Guicheng Street, Nanhai District, Foshan City, Guangdong Province, China; <i>and</i> No. 27/28 Island Ring South Road, Guicheng St., Nanhai Dist., Foshan, Guangdong, China; <i>and</i> No. 1 Xueyuan Road, Tuojiang Street, Jinping District, Shantou China; <i>and</i> No. 88 Keling Road, Science and Technology City, Suzhou High Tech, Foshan, China; <i>and</i> 13 Chengye Road, Shunde District, Foshan, China; <i>and</i> The Core Area of Sanlongwan High End Innovation Center, Foshan, China; <i>and</i> 13 Nanping West Road, Foshan, China.	*	*	*
	Nanjing Simite Optical Instruments Co., Ltd., a.k.a., the following two aliases: —SMT Optical Instruments; <i>and</i> —Nanjing Schmidt Optical Instruments Co., Ltd. Third Industrial Concentration Zone, Dongping Town, Lishui District, Nanjing, Jiangsu, 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.
	Peng Cheng Laboratory, a.k.a., the following five aliases: —Pengcheng Laboratory; —Peng Cheng Lab; —Pengcheng Lab; —Shenzhen Provincial Laboratory of Cyberspace Science and Technology; <i>and</i> —PCL	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.
	No. 2 Xingke First Street, Nanshan District, Shenzhen, Guangdong, China; <i>and</i> Building 8, Phase 1, Vanke Cloud City, Liuxiandong, Xili Street, Nanshan District, Shenzhen, China; <i>and</i> Wan Ke Yun Cheng, Yi Qi 8 Dong, Shenzhen, China. Zhigu 2nd Street, Songbei District, Harbin, Heilongjiang, 15000, China.	*	*	*
	Shanghai Institute of Optics and Fine Mechanics, a.k.a., the following seven aliases: —SIOM; —CAS SIOM; —Hangzhou Spectrometer Laser PH; —Lab of Information Optics; —Shanghai Institute of Optics; —Shanghai Institute of Optics & Fine Mechanics; <i>and</i> —SIOM Chinese Academy of Sciences.	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.
	No. 899, Huiwang East Road, Jiading District, Shanghai, China; <i>and</i> No. 390, Qinghe Road, Jiading District, Shanghai, 201801, China; <i>and</i> 295 Tacheng Road, Jiading, Shanghai, China; <i>and</i> 52 Sanlihe Road, Shanghai, China; <i>and</i> 768 Zhaojiabang Road, Shanghai, China; <i>and</i> 9900 North Shengxin Road, Shanghai, China; <i>and</i> 200 Zhaoxian Rd, Jiading District, Shanghai, China; <i>and</i> No. 4775, Shuangzhu Road, Shanghai, China; <i>and</i> Rm. 904–905, Kuen Yang International Business Plaza, Shanghai, China.	*	*	*
	Shenzhen Guowei Sensing Technology Co., Ltd., a.k.a., the following one alias: —SMIT Sense. Room 22B, Guoshi Building, No. 1801 Shahe West Road, High-tech Zone Community, Yuehai Street, Nanshan District, Shenzhen, China; <i>and</i> Floor 23, Building 3, Chongwen Park, Nanshan Intelligence Valley, No. 3370 Liuxian Avenue, Shenzhen, China; <i>and</i> Floor 23, Building 3, Chongwen Park, Nanshan Zhiyuan, No. 3370 Liuxian Avenue, Shenzhen, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	89 FR 96837, 12/5/2024. 90 FR [INSERT FR PAGE NUMBER AND 1/6/25.
	Suzhou Ultrano Precision Optoelectronics Technology Co., Ltd., a.k.a., the following two aliases: —Suzhou Chaona Precision Optoelectronics Technology Co., Ltd.; <i>and</i> —Suzhou Ultrano.	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.

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.
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 manufacturers 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