

### Signing Authority

This document of the Department of Energy was signed on October 3, 2022, by Francisco Alejandro Moreno, Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 4, 2022.

**Treena V. Garrett,**

*Federal Register Liaison Officer, U.S. Department of Energy.*

[FR Doc. 2022-21890 Filed 10-6-22; 8:45 am]

**BILLING CODE 6450-01-P**

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2019-0766; Project Identifier 2019-NE-23-AD]

RIN 2120-AA64

#### Airworthiness Directives; General Electric Company Turbofan Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Supplemental notice of proposed rulemaking (SNPRM).

**SUMMARY:** The FAA is revising a notice of proposed rulemaking (NPRM) that applied to all General Electric Company (GE) CF34-8C1, CF34-8C5, CF34-8C5A1, CF34-8C5B1, CF34-8C5A2, CF34-8C5A3, CF34-8E2, CF34-8E2A1, CF34-8E5, CF34-8E5A1, CF34-8E5A2, CF34-8E6, and CF34-8E6A1 model turbofan engines. This action revises the NPRM by updating the service information references and removing the initial and repetitive fluorescent penetrant inspections (FPIs) of the combustion chamber assembly. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions change the required actions as proposed in the NPRM, the agency is requesting comments on this SNPRM.

**DATES:** The FAA must receive comments on this SNPRM by November 21, 2022.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*AD Docket:* You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA-2019-0766; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, this SNPRM, any comments received, and other information. The street address for Docket Operations is listed above.

*Material Incorporated by Reference:*

- For GE service information identified in this SNPRM, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552-3272; email: *aviation.fleetsupport@ge.com*; website: *ge.com*.

- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222-5110.

**FOR FURTHER INFORMATION CONTACT:** Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238-7132; email: *Scott.M.Stevenson@faa.gov*.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2019-0766; Project Identifier 2019-NE-23-AD" at the beginning of your comments.

The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may again revise this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

**Confidential Business Information**

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this SNPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this SNPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this SNPRM. Submissions containing CBI should be sent to Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

**Background**

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to all GE CF34-8C1, CF34-8C5, CF34-8C5A1, CF34-8C5B1, CF34-8C5A2, CF34-8C5A3, CF34-8E2, CF34-8E2A1, CF34-8E5, CF34-8E5A1, CF34-8E5A2, CF34-8E6, and CF34-8E6A1 (CF34-8C and GE CF34-8E) model turbofan engines, including engine models marked on engine data plate as CF34-8C5/B, CF34-8C5/M, CF34-8C5A1/B, CF34-8C5A1/M, CF34-8C5B1/B, CF34-8C5A2/B, and CF34-8C5A2/M. The NPRM published in the **Federal Register** on December 3, 2019 (84 FR 66082). The NPRM was prompted by a predicted reduction in the cyclic life of the combustion chamber assembly aft flange. As a result, the manufacturer added a scheduled maintenance check. In the NPRM, the FAA proposed to require revisions to the airworthiness limitations section (ALS) of the manufacturer's instructions for continued airworthiness and the air carrier's approved continued airworthiness maintenance program to

incorporate initial and repetitive FPIs of the combustion chamber assembly.

#### Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, the manufacturer incorporated the temporary revisions (TRs) into the GE CF34-8C and GE CF34-8E engine manuals (EMs). Based on the revised service information, the FAA has revised the proposal by removing paragraph (g)(2) from the NPRM, which proposed to require initial and repetitive FPIs of the combustion chamber assembly installed on GE CF34-8C and GE CF34-8E model turbofan engines.

#### Comments

The following discussion presents the comments received on the NPRM and the FAA's response.

#### Request To Change References From TRs to EMs

Horizon Air and Japan Airlines (JAL) requested that the FAA revise the references GE CF34-8E EM TR 05-0085, dated February 21, 2019, and GE CF34-8E TR 05-0086, dated February 13, 2019, because the TRs have since been incorporated into the GE CF34-8C and GE CF34-8E EMs, as applicable.

In response to these comments, the FAA has revised this proposed AD by replacing GE CF34-8E EM TR 05-0085, dated February 21, 2019; GE CF34-8C TR 05-0141, dated February 21, 2019; GE CF34-8C TR 05-0143, dated February 13, 2019; GE CF34-8E TR 05-0086, dated February 13, 2019; and GE CF34-8C TR 05-0142, dated February 13, 2019, with the applicable tasks in the GE CF34-8C or GE CF34-8E EM.

#### Request To Add FPI Procedure for the Disassembled (Off-Wing) Engine

JAL requested that the FAA add the FPI procedure to paragraph (g)(2)(i) of this proposed AD, as specified in TASK 72-41-01-200-801, of GE CF34-8E EM GEK112031 for the disassembled (off-wing) engine. JAL reasoned that TASK 05-21-03-200-801 from ESM 05-21-03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34-8E EM GEK112031, which incorporated GE CF34-8E TR 05-0086, dated February 13, 2019, refers to TASK 72-41-01-200-801, on-wing inspections.

The FAA disagrees with the request to add disassembled or off-wing FPI procedures to this proposed AD. Since TASK 72-41-01-200-801 and TASK 72-41-01-200-801 are not referenced in GE CF34-8E EM GEK112031, the FAA interprets JAL's comment as a request to add TASK 72-00-41-200-806, as referenced in GE CF34-8E EM GEK112031. Additionally, the FAA has determined that the FPIs proposed in the NPRM are not required to address the unsafe condition. Therefore, the FAA has removed the proposed FPI of the combustion chamber assembly, paragraph (g)(2), as proposed in the NPRM, from this proposed SNPRM.

#### Support for the AD

The Air Line Pilots Association, International expressed support for the AD as written.

#### FAA's Determination

The FAA is proposing this AD after determining the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above revise the scope of the NPRM. As a result, it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

#### Related Service Information Under 1 CFR Part 51

The FAA reviewed the following tasks:

- TASK 05-11-05-200-801, dated March 4, 2021, from ESM 05-11-05 Static Structures—Life Limits, of GE CF34-8C EM GEK105091, Rev 51, dated April 1, 2022;
- TASK 05-11-05-200-801, dated March 4, 2021, from ESM 05-11-05 Static Structures—Life Limits, of GE CF34-8E EM GEK112031, Rev 43, dated April 1, 2022; and
- TASK 05-11-25-200-801, dated November 3, 2020, from ESM 05-11-25 Static Structures—BJ Life Limits, of GE CF34-8C EM GEK105091, Rev 51, dated April 1, 2022.

These tasks, differentiated by GE CF34-8 turbofan engine model, identify the combustion chamber assembly part number, life limit cycles, and revised inspections.

The FAA also reviewed the following tasks:

- TASK 05-21-03-200-801, dated April 1, 2019, from ESM 05-21-03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34-8C EM GEK105091, Rev 51, dated April 1, 2022; and
- TASK 05-21-03-200-801, dated April 1, 2019, from ESM 05-21-03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34-8E EM GEK112031, Rev 43, dated April 1, 2022.

These tasks, differentiated by GE CF34-8 turbofan engine model, describe revised inspection threshold limits and re-inspection interval limits for the combustion chamber assembly.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in ADDRESSES.

#### Proposed AD Requirements in This SNPRM

This proposed AD would require revisions to the ALS of the existing EM and the operator's existing approved maintenance or inspection program, as applicable, to incorporate initial and repetitive FPIs of the combustion chamber assembly, except as discussed under "Differences Between this proposed SNPRM and the Service Information."

#### Differences Between This SNPRM and the Service Information

TASK 05-21-03-200-801 of the GE CF34-8E EM GEK112031 and GE CF34-8C EM GEK105091, both dated April 1, 2022, specify to perform the inspection from the issuance date of the TR. This SNPRM would require performing the inspection after the effective date of this AD.

#### Costs of Compliance

The FAA estimates that this proposed AD affects 1,633 GE CF34-8C turbofan engine models and 857 GE CF34-8E turbofan engine models installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

#### ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise the ALS of the EM and operator's existing approved maintenance or inspection program (GE CF34-8C and CF34-8E).	1 work-hour × \$85 per hour = \$85 ..	\$0	\$85	\$211,650

### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs" describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

### Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

#### PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

**General Electric Company:** Docket No. FAA-2019-0766; Project Identifier 2019-NE-23-AD.

##### (a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 21, 2022.

##### (b) Affected ADs

None.

##### (c) Applicability

This AD applies to General Electric Company (GE) CF34-8C1, CF34-8C5, CF34-8C5A1, CF34-8C5B1, CF34-8C5A2, CF34-8C5A3, CF34-8E2, CF34-8E2A1, CF34-8E5, CF34-8E5A1, CF34-8E5A2, CF34-8E6, and CF34-8E6A1 model turbofan engines, including engine models marked on engine data plate as CF34-8C5/B, CF34-8C5/M, CF34-8C5A1/B, CF34-8C5A1/M, CF34-8C5B1/B, CF34-8C5A2/B, and CF34-8C5A2/M.

##### (d) Subject

Joint Aircraft System Component (JASC) Code 7240, Turbine Engine Combustion Section.

##### (e) Unsafe Condition

This AD was prompted by a predicted reduction in the cyclic life of the combustion chamber assembly aft flange. The FAA is issuing this AD to prevent failure of the combustion chamber assembly. The unsafe condition, if not addressed, could result in combustion chamber assemblies failing before reaching their published life limit, uncontained release of the combustion chamber assembly, damage to the engine, and damage to the airplane.

##### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

##### (g) Required Actions

Within 90 days after the effective date of this AD, revise the airworthiness limitations section (ALS) of the existing engine manual (EM) and the operator's existing approved maintenance or inspection program, as applicable, to incorporate the following requirements for fluorescent penetrant inspections of the combustion chamber assembly aft flange.

(1) For combustion chamber assemblies with part numbers (P/Ns) 4145T11G08, 4145T11G09, 4180T27G01, or 4180T27G03 installed on GE CF34-8E model turbofan engines:

- (i) Replace Table 801, Static Structures—Life Limits (Table 801), with the revised Table 801 in TASK 05-11-05-200-801, dated March 4, 2021, from ESM 05-11-05 Static Structures—Life Limits (TASK 05-11-05-200-801), of GE CF34-8E EM GEK112031, Rev 43, dated April 1, 2022 (GE CF34-8E EM GEK112031), and
- (ii) Add TASK 05-21-03-200-801, dated April 1, 2019, including the note, from ESM

05-21-03 Airworthiness Limitations—Mandatory Inspection 001 (TASK 05-21-03-200-801), of GE CF34-8E EM GEK112031. Where TASK 05-21-03-200-801 of GE CF34-8E EM GEK112031 specifies to perform the inspection within 2,200 cycles from the issuance date of the temporary revision (TR), this AD requires performing the inspection within 2,200 cycles from the effective date of this AD.

(2) For combustion chamber assemblies with P/Ns 4126T87G04, 4126T87G05, 4126T87G07, 4126T87G08, 4180T27G04, 4923T82G01, or 4923T82G02 installed on GE CF34-8C1 model turbofan engines, or with P/Ns 4145T11G08, 4145T11G10, 4180T27G02, 4180T27G04, or 4923T82G02 installed on GE CF34-8C5, CF34-8C5/M, CF34-8C5A1, CF34-8C5A1/M, CF34-8C5A2, CF34-8C5A2/M, CF34-8C5A3, or CF34-8C5B1 model turbofan engines:

(i) Replace Table 801 (For -8C1) and Table 802 (For -8C5) Static Structures—Life Limits (Table 801 and Table 802), with the revised Table 801 in TASK 05-11-05-200-801 and Table 802 in TASK 05-11-25-200-801, dated November 3, 2020, from ESM 05-11-25 Static Structures—BJ Life Limits (TASK 05-11-25-200-801), of GE CF34-8C EM GEK105091, Rev 51, dated April 1, 2022 (GE CF34-8C EM GEK105091); and

(ii) Add TASK 05-21-03-200-801, dated April 1, 2019, including the note, from ESM 05-21-03 Airworthiness Limitations—Mandatory Inspection 001 (TASK 05-21-03-200-801), of GE CF34-8C EM GEK105091. Where TASK 05-21-03-200-801 of GE CF34-8C EM GEK105091 specifies to perform the inspection within 2,200 cycles from the issuance date of the TR, this AD requires performing the inspection within 2,200 cycles from the effective date of this AD.

(3) For combustion chamber assemblies with P/Ns 4145T11G08, 4145T11G10, 4180T27G02, 4180T27G04, or 4923T82G02 installed on GE CF34-8C5B1/B, CF34-8C5/B, CF34-8C5A1/B, or CF34-8C5A2/B model turbofan engines:

(i) Replace Table 801 (For/B -8C5) Static Structures—Life Limits with the revised Table 801 in TASK 05-11-25-200-801, of GE CF34-8C EM GEK105091; and

(ii) Add TASK 05-21-03-200-801, including the note, of GE CF34-8C EM GEK105091. Where TASK 05-21-03-200-801 of GE CF34-8C EM GEK105091 specifies to perform the inspection within 2,200 cycles from the issuance date of the TR, this AD requires performing the inspection within 2,200 cycles from the effective date of this AD.

(4) After performing the actions required by paragraphs (g)(1) through (3) of this AD, except as provided in paragraph (i) of this AD, no alternative life limits may be approved.

##### (h) Credit for Previous Actions

You may take credit for revising the ALS of the existing EM and the operator's existing approved maintenance or inspection program, as applicable, required by paragraphs (g)(1) through (3) of this AD if the actions were completed before the effective date of this AD using GE CF34-8E EM TR

05–0085, dated February 21, 2019; GE CF34–8C TR 05–0141, dated February 21, 2019; GE CF34–8C TR 05–0143, dated February 13, 2019; GE CF34–8E TR 05–0086, dated February 13, 2019; or GE CF34–8C TR 05–0142, dated February 13, 2019.

**(i) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD and email it to: [ANE-AD-AMOC@faa.gov](mailto:ANE-AD-AMOC@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

**(j) Related Information**

For more information about this AD, contact Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; email: [Scott.M.Stevenson@faa.gov](mailto:Scott.M.Stevenson@faa.gov).

**(k) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) TASK 05–11–05–200–801, dated March 4, 2021, from ESM 05–11–05 Static Structures—Life Limits, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022.

(ii) TASK 05–11–05–200–801, dated March 4, 2021, from ESM 05–11–05 Static Structures—Life Limits, of GE CF34–8E EM GEK112031, Rev 43, dated April 1, 2022.

(iii) TASK 05–11–25–200–801, dated November 3, 2020, from ESM 05–11–25 Static Structures—BJ Life Limits, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022.

(iv) TASK 05–21–03–200–801, dated April 1, 2019, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022.

(v) TASK 05–21–03–200–801, dated April 1, 2019, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34–8E EM GEK112031, Rev 43, dated April 1, 2022.

(3) For GE service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: [aviation.fleetsupport@ge.com](mailto:aviation.fleetsupport@ge.com); website: [ge.com](http://ge.com).

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

Issued on October 3, 2022.

**Christina Underwood,**

*Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2022–21860 Filed 10–6–22; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 1**

[Docket No. FDA–2021–N–1348]

**RIN 0910–AI59**

**Administrative Destruction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is proposing a regulation to implement its new authority to destroy a device valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (FD&C Act), by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction. Once finalized, this regulation will allow FDA to better protect the public health by preventing re-importation and deterring future shipments of refused devices subject to administrative destruction.

We also discuss in this Notice of Proposed Rulemaking our intent to change FDA’s procedures for administrative destruction of drugs and, if this proposed rule is finalized, these procedures will also include devices subject to administrative destruction. We described our current procedures in the proposed and final rules entitled “Administrative Destruction of Certain Drugs Refused Admission to the United States.”

**DATES:** Either electronic or written comments on the proposed rule must be submitted by December 6, 2022.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://>

[www.regulations.gov](http://www.regulations.gov) electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 7, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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–N–1348 for “Administrative Destruction.” 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.