tier holding company. In what situations might requiring issuance at the holding company level be most beneficial? What range of approaches—other than requiring issuance by the top-tier holding company—may be available to ensure that eligible long-term debt will be available to absorb losses incurred at appropriate legal entities within a given large banking organization's corporate group?

Question 8: The agencies invite comment on whether requirements on governance mechanics should be put in place to ensure that entry into resolution will occur at a time when the eligible long-term debt will be available at the insured depository institution and/or the holding company level to absorb losses? Should such requirements include whether the loss absorbing capacity can absorb losses incurred at appropriate legal entities within a given large banking organization's corporate group? To what extent should such mechanics be aligned with internal recovery planning frameworks to coordinate resolution preparation actions with recovery actions?

Question 9: The agencies invite comment on whether subjecting the operations of the top-tier holding company of large banking organizations to ''clean holding company'' limitations similar to the ones imposed on GSIBs would further enhance the resolvability of a large banking organization. Why or why not?

Question 10: Among the other requirements that must be satisfied under the existing GSIB TLAC rule in order for debt issued by the parent company to qualify as eligible long-term debt (for example, relating to ''plain vanilla'' characteristics, minimum remaining maturity, governing law), which requirements would remain essential in order for long-term debt instruments issued by large banking organizations to properly function as a loss-absorbing resource in resolution? What modifications of such requirements, if any, should the agencies consider in the large banking organization context with respect to loss absorbing debt at insured depository institutions and/or holding companies?

Disclosure

Under the TLAC rule applicable to GSIBs, firms are required to provide the LTD debtholders a description of the financial consequences that could occur if the GSIB entered into a resolution proceeding as well as a summary table of the location of the disclosures (*e.g.,* on the GSIB's website, in public financial reports or public regulatory reports). Where it is necessary to bail-in the LTD, the value of the debtholder's note may be significantly or completely depleted.

Question 11: The agencies invite comment on the appropriate form and content of the disclosure large banking organizations should be required to provide to their long-term debt investors with respect to the potential treatment of such debt in resolution. If LTD requirements are imposed on large banking organizations, what, if any, adaptations should be made relative to the disclosure requirements that apply to GSIBs?

Separability

The agencies are also evaluating whether they should, for some or all large banking organizations, establish separability requirements in the recovery or resolution contexts.

When a large banking organization encounters internal or external stresses or ultimately enters resolution the identification of executable ''separability options,'' such as the sale, transfer, or disposal of significant assets, portfolios, legal entities or business lines on a discrete product line or regional basis could provide alternatives to a wholesale acquisition of a large banking organization's operations by a larger institution such as an existing GSIB.

Question 12: Should the agencies impose any separability requirements for recovery or resolution on all large banking organizations, including GSIBs? To what extent would imposing new separability requirements add net benefits against the backdrop of other existing requirements? In what fashion can or should these requirements be harmonized to promote their effectiveness?

By order of the Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on October 18, 2022.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–23003 Filed 10–21–22; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1302; Project Identifier MCAI–2022–00062–E]

RIN 2120–AA64

Airworthiness Directives; GE Aviation Czech s.r.o. (Type Certificate Previously Held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.) Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all GE Aviation Czech s.r.o. (GEAC) H75–100, H75–200, H80, H80–100, H80–200, H85–100, and H85–200 model turboprop engines. This proposed AD was prompted by the manufacturer revising the airworthiness limitations section (ALS) of the existing engine maintenance manual (EMM) to introduce updated coefficients for the calculation of the cyclic life and safe life for the main shaft. This proposed AD would require revising the ALS of the existing EMM and the operator's existing approved maintenance or inspection program, as applicable, to incorporate the updated coefficients and recalculate the cycles accumulated on critical parts. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by December 8, 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* under Docket No. FAA–2022–1302; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory

continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@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–2022–1302; Project Identifier MCAI–2022–00062–E'' 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 amend 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 NPRM.

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 NPRM 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 NPRM, 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 NPRM. Submissions containing CBI should be sent to Barbara Caufield, 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 European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0008, dated January 19, 2022 (referred to after this as ''the MCAI''), to address an unsafe condition on all GEAC H75–100, H75–200, H80, H80–100, H80–200, H85–100, and H85–200 engines, all build configurations, all serial numbers. The MCAI states that the airworthiness limitations for H series engine models, which are approved by EASA, are currently defined and published in the ALS of the GEAC EMM. These instructions have been identified as mandatory for continued airworthiness. Failure to accomplish these instructions could result in an unsafe condition. Recently, GEAC published the ALS, as defined in the MCAI, introducing updated coefficients for the calculation of the cyclic life and safe life for the main shaft. For the reason described above, the MCAI specifies accomplishment of the actions specified in the ALS.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1302.

Related Service Information

The FAA reviewed the ALS of the GEAC EMM, Part No: 0983402 Rev. 22, dated December 18, 2020. This service information provides updated coefficients for the calculation of the cyclic life and safe life for the main shaft.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the ALS of the existing EMM and the operator's existing approved maintenance or inspection program, as applicable, to incorporate the updated coefficients and recalculate the cycles accumulated on critical parts. An owner/operator (pilot) holding at least a private pilot certificate may revise the ALS of the existing EMM, and the owner/operator must enter compliance with the applicable paragraphs of the AD into the aircraft records in showing compliance with this AD in accordance with 14 CFR 43.9(a) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439. This is an exception to the FAA's standard maintenance regulations.

Differences Between This Proposed AD and the MCAI

The MCAI specifies replacing each component before exceeding the applicable life limit and accomplishing all the applicable maintenance tasks within the thresholds and intervals, as defined in the ALS, from its effective date. The MCAI specifies that in case of finding discrepancies during accomplishment of any task required by paragraph (1) of the MCAI, before the next flight, accomplish the applicable corrective actions in accordance with existing GEAC instructions. The MCAI also specifies to contact GEAC for approved instructions if a detected discrepancy cannot be corrected using existing GEAC instructions. This proposed AD would not require performing corrective actions in accordance with existing GEAC instructions or contacting GEAC for approved instructions. The MCAI specifies revising the aircraft maintenance program within 12 months from its effective date. This proposed AD would require revising the ALS of the existing EMM and the operator's existing approved maintenance or inspection program, as applicable, to incorporate the updated coefficients and recalculate the cycles accumulated on critical parts within 90 days after the effective date of the proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 33 engines installed on aircraft 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 EMM and the operator's existing approved maintenance or inspection program.	1 work-hour × $85 per hour = $85 ..	$0	$85	$2,805

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) Would not affect intrastate aviation in Alaska, and

(3) Would 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:

GE Aviation Czech s.r.o (Type Certificate previously held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.): Docket No. FAA–2022–1302; Project Identifier MCAI–2022–00062–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 8, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to GE Aviation Czech s.r.o. (Type Certificate previously held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.) H75–100, H75–200, H80, H80–100, H80–200, H85–100, and H85–200 model turboprop engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7200, Engine (Turbine/Turboprop).

(e) Unsafe Condition

This AD was prompted by the manufacturer revising the airworthiness limitations section (ALS) of the existing engine maintenance manual (EMM) to introduce updated coefficients for the calculation of the cyclic life and safe life for the main shaft. The FAA is issuing this AD to prevent failure of the engine. The unsafe condition, if not addressed, could result in uncontained release of a critical part, 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

(1) Within 90 days after the effective date of this AD, revise the ALS of the existing EMM to incorporate the information in Table 1 to paragraph (g)(1) of this AD and recalculate the cycles accumulated on critical parts.

TABLE 1 TO PARAGRAPH (g)(1)—EQUIVALENT CYCLIC LIFE (N) AND SAFE LIFE OF CRITICAL PARTS

Description	Drawing No.	Abbreviated flight cycle coefficient	Flight mission coefficient	Equivalent cyclic life limit
		A_V A_P	L	N
Main Shaft	M601–1017.75	0.47	1.05	16,000

(2) After performing the action required by paragraph (g)(1) of this AD, except as provided in paragraph (h) of this AD, no alternative life limits may be approved.

(3) The action required by paragraph (g)(1) of this AD may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in § 39.19. In accordance with § 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 (i)(2) of this AD and email to: *ANE-AD-AMOC@faa.gov.* 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.

(i) Additional Information

(1) Refer to European Union Aviation Safety Agency (EASA) AD 2022–0008, dated January 19, 2022, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1302.

(2) For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

(j) Material Incorporated by Reference

None.

Issued on October 7, 2022.

Christina Underwood,

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

[FR Doc. 2022–22399 Filed 10–21–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 314

[Docket No. FDA–2021–N–0862]

RIN 0910–AH62

Nonprescription Drug Product With an Additional Condition for Nonprescription Use; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule that appeared in the **Federal Register** of June 28, 2022. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published on June 28, 2022 (87 FR 38313). Either electronic or written comments must be submitted by November 25, 2022.

ADDRESSES: You may submit comments as follows. 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 at the end of November 25, 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–0862 for ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use.'' 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.'' 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.

FOR FURTHER INFORMATION CONTACT: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–0151, *Chris.Wheeler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 28, 2022, FDA published a proposed rule entitled ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use.'' The 120-day comment period for the proposed rule is scheduled to close on October 26, 2022. The proposed rule, if finalized, would establish requirements for a nonprescription drug product that has an additional condition for nonprescription use that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner.

The Agency has received separate requests for a 30-day and 90-day