02 applicable to General Electric Company CF34–8C1 turbofan engines that was published in the **Federal Register** on December 11, 2002 (67 FR 76111). A typographical error was made in the AD number in line three of the Summary. This document corrects that number. In all other respects, the original document remains the same.

EFFECTIVE DATE: December 26, 2002.

FOR FURTHER INFORMATION CONTACT: Keith Mead, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7744; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A final rule correction AD, FR Doc. 02–31173 applicable to General Electric Company CF34–8C1 turbofan engines was published in the **Federal Register** on December 11, 2002 (67 FR 76111). The following correction is needed:

On page 76111, in the third column, in the third line of the Summary, remove the AD number ''(AD) 2002–23–09'' and add in its place ''(AD) 2002–23-02''.

Issued in Burlington, MA, on December 12, 2002.

Francis A. Favara,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 02–31999 Filed 12–18–02; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Parts 1260 and 1274

Implementation of Executive Order 13202, as Amended by E.O. 13208, in the NASA Grant and Cooperative Agreement Handbook

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This is a final rule that revises Sections A, Grants and Cooperative Agreements, and D, Cooperative Agreements with Commercial Firms, of the NASA Grant and Cooperative Agreement Handbook to require that NASA grants and cooperative agreements follow the requirements of Executive Order 13202, ''Preservation of Open Competition and Government Neutrality Towards Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects''.

EFFECTIVE DATE: December 19, 2002.

FOR FURTHER INFORMATION CONTACT: Celeste Dalton, NASA Headquarters, Office of Procurement, Contract Management Division (Code HK), Washington, DC 20546–0001, (202) 358–1645, e-mail: *celeste.dalton@hq.nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Executive Order 13202 was signed on February 17, 2001, and amended on April 6, 2001 (E.O. 13208). The order provides that agencies may not require or prohibit offerors, contractors, or subcontractors from entering into or adhering to agreements with one or more labor organizations. It also permits agency heads to exempt a project from the requirements of the E.O. under special circumstances, but the exemption may not be related to a possible or an actual labor dispute. The amended E.O. also allows for exemption of a project governed by a project labor agreement in place as of February 17, 2001, which had a construction contract awarded as of February 17, 2001.

The E.O. applies to any construction project using Federal funds regardless of whether the award is expected to result in a contract, grant, or cooperative agreement. The Federal Acquisition Regulation (FAR) has already been revised to implement the E.O. relative to contracts. NASA is revising its Grant and Cooperative Agreement Handbook to implement the E.O. using language substantially the same as found in FAR section 36.202(d)), to ensure that E.O. 13202 requirements are consistently followed when funding construction projects under grants and cooperative agreements.

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This final rule is not a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small business entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because most NASA construction projects are accomplished by contracts subject to the FAR and very few through grants or cooperative agreements.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this final rule does not impose any recordkeeping or information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 14 CFR Parts 1260 and 1274

Grant Programs—Science and Technology.

Tom Luedtke,

Assistant Administrator for Procurement.

Accordingly, 14 CFR Parts 1260 and 1274 are amended as follows:

PART 1260—GRANTS AND COOPERATIVE AGREEMENTS

1. The authority citation for 14 CFR part 1260 continues to read as follows:

Authority: 42 U.S.C. 2374(c)(1), Pub. L. 97–258, 96 Stat. 1003 (31 U.S.C. 6301 *et seq.*) and OMB Circular A–110.

2. Amend section 1260.10 by adding paragraph (d) to read as follows:

§ 1260.10 Proposals.

* * * * *

(d)(1) In accordance with E.O. 13202 of February 17, 2001, ''Preservation of Open Competition and Government Neutrality Towards Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects'', as amended on April 6, 2001, the Government, or any construction manager acting on behalf of the Government, shall not—

(i) Require or prohibit recipients, potential recipients or subrecipients to enter into or adhere to agreements with one or more labor organizations (as defined in 42 U.S.C. 2000e(d)) on the same or other related construction projects; or

(ii) Otherwise discriminate against recipients, potential recipients or subrecipients for becoming, refusing to become, or remaining signatories or otherwise adhering to agreements with one or more organizations, on the same or other related construction projects.

(2) Nothing in this section prohibits the recipient, potential recipients or subrecipients from voluntarily entering into project labor agreements.

(3) The Assistant Administrator for Procurement may exempt a construction project from this policy if, as of February 17, 2001—

(i) The agency or a construction manager acting on behalf of the Government had issued or was party to bid specifications, project agreements, agreements with one or more labor organizations, or other controlling documents with respect to that particular project, which contained any of the requirements or prohibitions in paragraph (d)(1)of this section; and

(ii) One or more construction contracts (includes any contract awarded by the recipient) subject to such requirements or prohibitions had been awarded.

(4) The Assistant Administrator for Procurement may exempt a particular project, contract, or subcontract from this policy upon a finding that special circumstances require an exemption in order to avert an imminent threat to public health or safety, or to serve the national security. A finding of ''special circumstances'' may not be based on the possibility or presence of a labor dispute concerning the use of contractors or subcontractors who are nonsignatories to, or otherwise do not adhere to, agreements with one or more labor organizations, or concerning employees on the project who are not members of, or affiliated with, a labor organization.

PART 1274—COOPERATIVE AGREEMENTS WITH COMMERCIAL FIRMS

3. The authority citation for part 1274 continues to read as follows:

Authority: 31 U.S.C. 6301 to 6308; 42 U.S.C. 2451 *et seq.*

4. 1274.215 is added to read as follows:

§ 1274.215 Federal and federally funded construction projects.

(a) In accordance with E.O. 13202 of February 17, 2001, ''Preservation of Open Competition and Government Neutrality Towards Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects'', as amended on April 6, 2001, the Government, or any construction manager acting on behalf of the Government, shall not—

(1) Require or prohibit recipients, potential recipients or subrecipients to enter into or adhere to agreements with one or more labor organizations (as defined in 42 U.S.C. 2000e(d)) on the same or other related construction projects; or

(2) Otherwise discriminate against recipients, potential recipients or subrecipients for becoming, refusing to become, or remaining signatories or otherwise adhering to agreements with one or more organizations, on the same or other related construction projects.

(b) Nothing in this section prohibits the recipient, potential recipients or subrecipients from voluntarily entering into project labor agreements.

(c) The Assistant Administrator for Procurement may exempt a construction project from this policy if, as of February 17, 2001—

(1) The agency or a construction manager acting on behalf of the Government had issued or was party to bid specifications, project agreements, agreements with one or more labor organizations, or other controlling documents with respect to that particular project, which contained any of the requirements or prohibitions in paragraph (d)(1) of this section; and

(2) One or more construction contracts (includes any contract awarded by the recipient) subject to such requirements or prohibitions had been awarded.

(d) The Assistant Administrator for Procurement may exempt a particular project, contract, or subcontract from this policy upon a finding that special circumstances require an exemption in order to avert an imminent threat to public health or safety, or to serve the national security. A finding of ''special circumstances'' may not be based on the possibility or presence of a labor dispute concerning the use of contractors or subcontractors who are nonsignatories to, or otherwise do not adhere to, agreements with one or more labor organizations, or concerning employees on the project who are not members of, or affiliated with, a labor organization.

[FR Doc. 02–31682 Filed 12–18–02; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. 98N–0778]

RIN 0910–AC47

Bioavailability and Bioequivalence Requirements; Abbreviated Applications; Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on bioavailability and bioequivalence and on the content and format of an abbreviated application to reflect current FDA policy and to correct certain typographical and inadvertent errors. This action is intended to improve the accuracy and clarity of the regulations.

DATES: This rule is effective February 18, 2003.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulations require persons submitting a new drug application (NDA) to provide bioavailability information (21 CFR 314.50(c)(2)(vi) and (d)(3)), and persons submitting an abbreviated new drug application (ANDA) to provide information pertaining to bioavailability and bioequivalence (§ 314.94(a)(7) (21 CFR 314.94(a)(7)).

FDA regulations in part 320 (21 CFR part 320) establish definitions and requirements for bioavailability and bioequivalence studies. FDA finalized the bioavailability and bioequivalence regulations on January 7, 1977 (42 FR 1624), and amended these regulations on April 28, 1992 (57 FR 17950). The 1992 amendments were designed to reflect statutory changes resulting from the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417).

In the **Federal Register** of November 19, 1998 (63 FR 64222), FDA proposed to revise its regulations on bioavailability and bioequivalence and the content and format of an ANDA to reflect current FDA policy and to correct certain typographical and inadvertent errors (the proposed rule). The publication of this final rule completes this rulemaking.

II. Description of the Final Rule

FDA is finalizing the proposed rule with the following revisions made in response to comments received on the proposal.

As proposed, the final rule changes the term ''enteric coated'' to ''delayed release'' and the term ''controlled release'' to ''extended release'' in § 320.22(c). To conform to this change, the final rule also amends §§ 320.1, 320.22(d)(2)(iv), 320.25(f), 320.27(a)(3)(iv), 320.27(b)(2), 320.28, and 320.31 by changing ''controlled release'' to ''extended release.'' To conform to the new terminology, the final rule also amends § 320.25(f) by changing ''noncontrolled release'' to ''nonextended release.''

The following new first sentence has been added to redesignated § 320.25(a)(2): ''An in vivo bioavailability study is generally done in a normal adult population under standardized conditions.'' This sentence is a necessary lead-in for the existing text that refers to situations in which