

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); 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.

We prepared a summary of the costs to comply with this proposal and placed it in the AD Docket. You may get a copy of this summary at the address listed under **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Under the authority delegated to me by the Administrator, the Federal Aviation Administration 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. Section 39.13 is amended by removing Amendment 39–13183 (68 FR 33621, June 5, 2003) and by adding the following new airworthiness directive:

International Aero Engines AG (IAE): Docket No. 2003–NE–21–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by March 20, 2006.

Affected ADs

(b) This AD supersedes AD 2003–11–23, Amendment 39–13183.

Applicability

(c) This AD applies to International Aero Engines AG (IAE) V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 turbofan engines with engine serial numbers V10600 through V11365 and bearings P/N 2A1165 installed. These engines are installed on, but not limited to, Airbus Industrie A319, A320, and A321 series airplanes.

Unsafe Condition

(d) This AD results from reports of No. 3 bearing failures that caused in-flight shutdown (IFSD) and smoke in the cockpit and cabin. We are issuing this AD to prevent failure of the No. 3 bearing, which could result in an IFSD and smoke in the cockpit and cabin.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

Inspection of the Master Magnetic Chip Detector (MCD) or the No. 1, 2, 3 Bearing Chamber MCD

(f) For engines listed in Appendix 1, Tables 1 and 2 of IAE service bulletin (SB) V–2500–ENG–72–0452, Revision 3, dated March 4, 2005, and that have a No. 3 bearing, part number (P/N) 2A1165, installed at new production build, do the following:

(1) Within 125 hours time-in-service (TIS) after the effective date of this AD, inspect the master MCD or the No. 1, 2, 3 bearing chamber MCD.

(2) Thereafter, within 125 hours time-since-last inspection, inspect the master MCD or the No. 1, 2, 3 bearing chamber MCD.

(3) If you find bearing material on the master MCD or No. 1, 2, 3 bearing chamber MCD, replace the engine before further flight.

Replacement of No. 3 Bearing

(g) For engines listed in Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005, that have a serial number (SN) from V10600 through V11365 inclusive, and that have a No. 3 bearing, part number (P/N) 2A1165, installed at new production, replace the No. 3 bearing at the next shop visit for any reason.

(h) After the effective date of this AD, do not install any No. 3 bearing, P/N 2A1165, removed in paragraph (g) of this AD, into any engine.

Replacement or Rework of High Pressure Compressor (HPC) Stubshaft

(i) For engines listed in Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005, that have a SN from V10600 through V11365 inclusive, at the next shop visit for any reason, replace the HPC stubshaft that has a low-energy plasma coating with an HPC stubshaft that has a high-energy plasma coating.

Terminating Action

(j) Performing the requirements specified in paragraphs (g) and (i) of this AD is terminating action to the repetitive MCD inspections specified in paragraph (f)(1) through (f)(3) of this AD.

Alternative Methods of Compliance (AMOCs)

(k) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(l) For lists identifying engines within the engine SN range of V10600 to V11365 inclusive, known to have had P/N 2A1165 installed, you must use Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0452, Revision 3, dated March 4, 2005, and IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005.

Related Information

(m) The following service bulletins contain additional information and procedures:

(1) You can find information on inspecting the master MCD and the No. 1, 2, 3 bearing chamber MCD in section 79–00–00–601 of the Aircraft Maintenance Manual.

(2) Additional information on inspection procedures is included in IAE SB V–2500–ENG–72–0452, Revision 3, dated March 4, 2005.

(3) You can find information on replacing the No. 3 bearing, and replacing or recoating the HPC stubshaft in IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005.

Issued in Burlington, Massachusetts, on January 9, 2006.

Peter A. White,

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

[FR Doc. E6–379 Filed 1–13–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. 2001N–0322 (formerly 01N–0322)]

Institutional Review Boards: Requiring Sponsors and Investigators to Inform Institutional Review Boards of Any Prior Institutional Review Board Reviews; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of an advance notice of proposed rulemaking (ANPRM) entitled "Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews" that published in the **Federal Register** of March 6, 2002 (67 FR 10115).

DATES: The ANPRM is withdrawn February 16, 2006.

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C24, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION: In 1998, the Department of Health and Human Services, Office of the Inspector General (OIG) issued several reports on institutional review boards (IRBs). The OIG sought to identify the challenges facing IRBs and to make recommendations on improving Federal

oversight of IRBs. One recommendation was that sponsors and clinical investigators be required to notify IRBs of any prior review (see OIG, Department of Health and Human Services, "Institutional Review Boards: A Time for Reform," p. 14, June 1998; <http://oig.hhs.gov/oei/reports/oei-01-97-00193.pdf>). The OIG report stated that the OIG had:

* * * heard of a few situations where sponsors and/or research investigators who were unhappy with one IRB's reviews switched to another without the new IRB being aware of the other's prior involvement. This kind of IRB shopping deprives the new IRB of information that it should have and that can be important in protecting human subjects. The ground rules should be changed so that sponsors and investigators have the clear obligation to inform an IRB of any prior reviews (footnote omitted). The obligation should be applied to all those conducting research funded by HHS or carried out on FDA-regulated products. It will have particular importance for those sponsors and investigators working with independent IRBs.

Id. After reviewing the OIG's recommendation, FDA published an ANPRM on March 6, 2002 (67 FR 10115) (see <http://www.fda.gov/OHRMS/DOCKETS/98fr/030602a.pdf>) announcing it was considering whether to amend its IRB regulations to require sponsors and investigators to inform IRBs about any prior IRB review decisions. We invited public comments on: (1) The frequency of IRB shopping and under what circumstances IRB shopping has occurred; (2) what information about prior IRB review should be disclosed, where should it be disclosed, and who should disclose it; and (3) what methods, other than disclosure of prior IRB reviews, might prove to be valuable for dealing with IRB shopping.

In response to this ANPRM, FDA received 55 comments. The majority of the comments reported they had little or no first hand knowledge of instances of IRB shopping, and did not believe IRB shopping presented a significant problem. Many comments expressed concern about the logistics of maintaining a system that would enable the exchange of information among IRBs, especially when studies involved multiple study sites. There was concern that maintaining such a system would substantially increase the IRBs' workload and not provide any additional human subject protection. There was also concern that waiting for information from other IRBs prior to the review of research proposals within a particular institution might contribute to delays in the review of these proposals.

The Office for Human Research Protections (OHRP) also informed FDA that it considered the OIG's recommendation to require sponsors and investigators to notify IRBs of any prior IRB review of a research plan. OHRP concluded that it had no reason to believe that IRB shopping was occurring with any regularity in the review of HHS conducted or supported human subjects research.

Based on these reasons, FDA concluded that IRB shopping either does not occur or does not present a problem to an extent that would warrant rulemaking at this time.

In a letter dated February 26, 2005, FDA advised the OIG of these findings and conclusions. FDA is now withdrawing this ANPRM. A withdrawal does not prevent the agency from taking action in the future. Should FDA decide to undertake rulemaking sometime in the future, the agency will provide new opportunities for comment.

Dated: January 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-357 Filed 1-13-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 210

[Docket No. 2005N-0285]

Current Good Manufacturing Practice Regulation and Investigational New Drugs; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, which is intended to amend our current good manufacturing practice (CGMP) regulations for human drugs, including biological products, to exempt most investigational "Phase 1" drugs from complying with the regulatory requirements. We will instead exercise oversight of production of these drugs under the agency's general statutory CGMP authority and investigational new drug application (IND) authority. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for

industry entitled "INDs—Approaches to Complying With CGMP During Phase 1" to provide further guidance on the subject.

DATES: Submit written or electronic comments by April 3, 2006.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/comments>.

FOR FURTHER INFORMATION CONTACT: Monica Caphart, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-9047; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-435-5681.

SUPPLEMENTARY INFORMATION:

I. Background

As described more fully in the related direct final rule, a Phase 1 clinical trial includes the initial introduction of an investigational new drug into humans. Such studies are aimed at establishing basic safety and are designed to determine the metabolism and pharmacologic actions of the drug in humans. The total number of subjects in a Phase 1 study is limited—generally no more than 80 subjects. This is in contrast to Phase 2 and Phase 3 trials, which may involve substantially greater numbers of subjects, exposing more subjects to the drug product, and which aim to test the effectiveness of the drug product.

For several reasons, we believe that production of human drug products, including biological drug products, intended for use in Phase 1 clinical trials should be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211 (21 CFR parts 210 and 211). First, even if exempted from the requirements of our CGMP regulations in parts 210 and 211, investigational drugs remain subject to the statutory provisions that deem a drug adulterated for failure to comply with CGMPs (21 U.S.C. 351(a)(2)(B)).

Second, we oversee drugs for use in Phase 1 trials through our existing IND authority. Every IND must contain, among other things, a section on chemistry, manufacturing, and control information that describes the composition, manufacture, and control of the investigational drug product (21 CFR 312.23(a)(7)). This information should suffice to enable us to