

registry would be affected by this proposed AD, that it would take approximately 30 work hours per engine to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$75,000 per engine. Based on these figures, the cost impact for incorporation of engine modifications required by the proposed AD on U.S. operators is estimated to be \$7,680,000.

In addition to the above engine modifications, further aircraft modifications specified by BAe SB No. 71-68-01581A, and BAe SB No. 26-40-01601A, Revision 1, are required prior to installation of modified engines onto BAe 146 aircraft. The FAA estimates that 20 aircraft of U.S. registry would be affected by this proposed AD, that it would take approximately 33 work hours per aircraft to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$2,400 per aircraft. Based on these figures, the cost impact for incorporation of aircraft modifications required by the proposed AD on U.S. operators is estimated to be \$87,600.

Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$7,767,600.

The regulations proposed herein would not have substantial direct effects 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this 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) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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 adding the following new airworthiness directive:

**AlliedSignal Inc.:** Docket No. 98-ANE-42-AD.

**Applicability:** AlliedSignal Inc. (formerly Textron Lycoming) ALF502R-5 and ALF502R-3A model turbofan engines, installed on but not limited to British Aerospace (BAe) 146100A, -200A and -300A series aircraft.

**Note 1:** This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent uncommanded reduction of engine thrust and loss of thrust control in icing conditions, accomplish the following:

(a) At the next engine shop visit, but not later than December 31, 2002, install an improved fan core inlet anti-ice system in accordance with Accomplishment Instructions, Paragraphs 2.B. through 2.I.(1-4), of AlliedSignal Inc. Service Bulletin (SB) No. ALF/LF 72-1020, Revision 2, dated September 30, 1998. In order to install engines with the required modifications onto BAe 146-100A, -200A and -300A series aircraft, accomplish BAe Regional Aircraft SB No. 2640-01601A, dated March 25, 1998, and BAe Regional Aircraft SB No. 71-68-01581A, Revision 1, dated March 25, 1998.

(b) For the purpose of this AD, an engine shop visit is defined as maintenance that includes separation of either the fan module or the combustor turbine module from the remainder of the engine.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine

Certification Office. Operators shall submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Certification Office.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on December 7, 1998.

**David A. Downey,**

*Assistant Manager, Engine and Propeller*

*Directorate, Aircraft Certification Service*

[FR Doc. 98-33027 Filed 12-11-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 312

[Docket No. 98N-0979]

#### Investigational New Drug Applications; Clinical Holds; Companion Document to Direct Final Rule

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations governing investigational new drug applications (IND's) for human drug and biological products. This proposed action would amend the IND clinical hold requirements to state that the agency will respond in writing to a sponsor's request that a clinical hold be removed from an investigation within 30-calendar days of the agency's receipt of the request and the sponsor's complete response to the issue(s) that led to the clinical hold. This proposed action is being taken in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). This proposed rule is a companion document to a direct final rule published elsewhere in this issue of the **Federal Register**. If FDA receives any significant adverse comment, the direct final rule will be withdrawn, and the comments will be considered in the development of a final rule using usual notice-and-comment rulemaking based on this proposed rule.

**DATES:** Comments must be received on or before March 1, 1999.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5417, or  
Rebecca A. Devine, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On November 21, 1997, President Clinton signed into law the Modernization Act (Pub. L. 105-115). Section 117 of the Modernization Act amends the Federal Food, Drug, and Cosmetic Act (the act) by codifying in section 505(i) (21 U.S.C. 355(i)) several of the procedures and requirements governing the use of investigational new drugs that are already set forth in FDA regulations (parts 50 and 312 (21 CFR parts 50 and 312)).

Section 505(i)(2) of the act, as amended by the Modernization Act, provides that if a sponsor of an IND that has been placed on clinical hold requests in writing that the clinical hold be removed and submits a complete response to the issue(s) identified in the clinical hold order, FDA is required to respond in writing to the sponsor within 30-calendar days of receipt of the complete response. This proposed rule would amend § 312.42(e) to reflect this new statutory requirement and to clarify when a sponsor may resume an investigation after FDA issues a clinical hold order.

**II. Additional Information**

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. The companion proposed rule and the direct final rule are identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule.

The amendments in this proposed rule are a direct result of the new provisions in section 505(i)(2) of the act. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this companion proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on April 28, 1999. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to respond to comments received regarding the rule and, if appropriate, the rule will be finalized under this companion proposed rule using usual notice-and-comment procedures.

For additional information, see the corresponding direct final rule published elsewhere in this issue of the **Federal Register**. All persons who wish to comment should review the detailed rationale for these amendments set out in the preamble discussion of the direct final rule. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change.

**III. Environmental Impact**

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IV. Analysis of Impact**

FDA has examined the impacts of this companion proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having

an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact on small entities. The agency has considered the effect that this rule will have on small entities, including small businesses, and certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Reform Act requires an agency to prepare a budgetary impact statement before issuing any rule likely to result in a Federal mandate that may result in expenditures by State, local, and tribal governments or the private sector of \$100 million (adjusted annually for inflation) in any 1 year. This proposed rule will not result in an expenditure of \$100 million or more on any governmental entity or the private sector, so no budgetary impact statement is required.

**V. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**VI. Request for Comments**

Interested persons may, on or before March 1, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 312**

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 312 be amended to read as follows:

**PART 312—INVESTIGATIONAL NEW DRUG APPLICATION**

1. The authority citation for 21 CFR part 312 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

2. Section 312.42 is amended by revising paragraph (e) to read as follows:

**§ 312.42 Clinical holds and requests for modification.**

\* \* \* \* \*

(e) *Resumption of clinical investigations.* An investigation may only resume after FDA (usually the Division Director, or the Director's designee, with responsibility for review of the IND) has notified the sponsor that the investigation may proceed. Resumption of the affected investigation(s) will be authorized when the sponsor corrects the deficiency(ies) previously cited or otherwise satisfies the agency that the investigation(s) can proceed. FDA may notify a sponsor of its determination regarding the clinical hold by telephone or other means of rapid communication. If a sponsor of an IND that has been placed on clinical hold requests in writing that the clinical hold be removed and submits a complete response to the issue(s) identified in the clinical hold order, FDA shall respond in writing to the sponsor within 30-calendar days of receipt of the request and the complete response. FDA's response will either remove or maintain the clinical hold, and will state the reasons for such determination. Notwithstanding the 30-calendar day response time, a sponsor may not proceed with a clinical trial on which a clinical hold has been imposed until the sponsor has been notified by FDA that the hold has been lifted.

\* \* \* \* \*  
Dated: December 4, 1998.

**William B. Schultz,**  
*Deputy Commissioner for Policy.*  
[FR Doc. 98-33030 Filed 12-11-98; 8:45 am]  
BILLING CODE 4160-01-F

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[FRL-6200-4]

**National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of intent to delete the Whittaker Superfund Site from the National Priorities List; request for comments.

**SUMMARY:** The United States Environmental Protection Agency (U.S. EPA) Region V announces its intent to delete the Whittaker Site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which U.S. EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended. This action is being taken by U.S. EPA, because it has been determined that all Fund-financed responses under CERCLA have been implemented and U.S. EPA, in consultation with the State of Minnesota, has determined that no further response is appropriate. Moreover, U.S. EPA and the State have determined that remedial activities conducted at the Site to date have been protective of public health, welfare, and the environment.

**DATES:** Comments concerning the proposed deletion of the Site from the NPL may be submitted on or before January 13, 1999.

**ADDRESSES:** Comments may be mailed to Gladys Beard, Associate Remedial Project Manager, Superfund Division, U.S. EPA, Region V, 77 W. Jackson Blvd. (SR-6J), Chicago, IL 60604.

Comprehensive information on the site is available at U.S. EPA's Region V office and at the local information repository located at: Minnesota Pollution Control Agency, 520 Lafayette Rd. North, St. Paul, Minnesota 55155-4194. Requests for comprehensive copies of documents should be directed formally to the Region V Docket Office. The address and phone number for the Regional Docket Officer is Jan Pfundheller (H-7J), U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353-5821.

**FOR FURTHER INFORMATION CONTACT:** Gladys Beard, Associate Remedial

Project Manager, Superfund Division (SR-6J), U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886-7253 or Don de Blasio (P-19J), Office of Public Affairs, U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886-4360.

**SUPPLEMENTARY INFORMATION:**

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- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis for Intended Site Deletion

**I. Introduction**

The U.S. Environmental Protection Agency (U.S. EPA) Region V announces its intent to delete the Whittaker Site from the National Priorities List (NPL), which constitutes Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), and requests comments on the proposed deletion. The EPA identifies sites that appear to present a significant risk to public health, welfare, the environment, and maintains the NPL as the list of those sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund Response Trust Fund (Fund). Pursuant to § 300.425(e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions if the conditions at the site warrant such action.

The U.S. EPA will accept comments on this proposal for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that U.S. EPA is using for this action. Section IV discusses the history of this site and explains how the site meets the deletion criteria.

Deletion of sites from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Furthermore, deletion from the NPL does not in any way alter U.S. EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist in Agency management.

**II. NPL Deletion Criteria**

The NCP establishes the criteria the Agency uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making this determination, U.S. EPA will consider, in consultation with the State, whether any of the following criteria have been met: