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 a high pressure fuel leak, which could result in an engine nacelle fire and damage to the aircraft, accomplish the following:

(a) For R-R Viper Mk. 521, and 522 series engines, perform a one-time inspection of the barometric flow control unit (BFCU) augmentor and bypass valve joint washer for joint washer integrity, and replace, if necessary, with serviceable parts, in accordance with R-R Alert Service Bulletins (ASBs) Nos. 73–A120 and 73–A121, as applicable, dated November 1997, as follows:

(1) For engines with less than 200 hours time in service (TIS) since new, overhaul, or repair of the BFCU, inspect within 2 months, or 100 hours TIS after the effective date of this AD, whichever occurs first.

(2) For engines with 200 or more hours TIS since new, overhaul, or repair of the BFCU, inspect at the next engine removal after the effective date of this AD.

(b) For R-R Viper Mk. 526 series engines, perform a one-time inspection of the barometric flow control unit (BFCU) augmentor and bypass valve joint washer for joint washer integrity, and replace, if necessary, with serviceable parts, in accordance with R-R ASBs Nos. 73–A68 and 73–A69, as applicable, dated November 1997, as follows:

(1) For engines with less than 200 hours time in service (TIS) since new, overhaul, or repair of the BFCU, inspect within 2 months, or 100 hours TIS after the effective date of this AD, whichever occurs first.

(2) For engines with 200 or more hours TIS since new, overhaul, or repair of the BFCU, inspect at the next engine removal after the effective date of this AD.

(c) For R-R Viper Mk. 601 series engines, perform a one-time inspection of the BFCU augmentor and bypass valve joint washer for joint washer integrity, and replace, if necessary, with serviceable parts, in accordance with R-R ASBs Nos. 73–A35 and 73–A36, as applicable, dated November 1997, as follows:

(1) For engines with less than 200 hours TIS since new, overhaul, or repair of the BFCU, inspect within 2 months, or 100 hours TIS after the effective date of this AD, whichever occurs first.

(2) For engines with 200 or more hours TIS since new, overhaul, or repair of the BFCU, inspect at the next engine removal after the effective date of this AD.

(d) 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 requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine 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.

(e) 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.

(f) The actions required by this AD shall be done in accordance with the following R-R ASBs:

Document No.	Pages	Date
73–A35 ..... Total Pages: 6.	1–6	Nov. 1997.
73–A36 ..... Total Pages: 6.	1–6	Nov. 1997.
73–A68 ..... Total Pages: 6.	1–6	Nov. 1997.
73–A69 ..... Total Pages: 6.	1–6	Nov. 1997.
73–A120 ..... Total Pages: 6.	1–6	Nov. 1997.
73–A121 ..... Total Pages: 6.	1–6	Nov. 1997.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Rolls-Royce Limited, Bristol Engines Division, Technical Publications Department CLS–4, P.O. Box 3, Filton, Bristol, BS34 7QE England; telephone 117–979–1234, fax 117–979–7575. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(g) This amendment becomes effective on February 12, 1999.

Issued in Burlington, Massachusetts, on November 30, 1998.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 98–32800 Filed 12–11–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 93–AWA–5]

Establishment of the Cincinnati/ Northern Kentucky International Airport Class B Airspace Area, and Revocation of the Cincinnati/Northern Kentucky International Class C Airspace Area; KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; delay of effective date.

SUMMARY: This action delays the effective date for the establishment of the Cincinnati/Northern Kentucky International Airport Class B airspace area, and revocation of the Cincinnati/ Northern Kentucky International Airport Class C airspace area, until further notice. The FAA is taking this action to conduct an administrative review of the Cincinnati terminal airspace area.

DATES: The effective date of 0910 UTC, December 31, 1998, is delayed until further notice.

FOR FURTHER INFORMATION CONTACT: Ms. Sheri Edgett Baron, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Airspace Docket No. 93–AWA–5, published in the **Federal Register** on November 30, 1998 (63 FR 65972), established the Cincinnati/Northern Kentucky International Airport Class B airspace area, and revoked the Cincinnati/Northern Kentucky International Airport Class C airspace area, and was orginally scheduled to be implemented on December 31, 1998. However, to allow additional time for an administrative review of the Cincinnati terminal airspace area, the FAA is delaying the effective date of the establishment of the Cincinnati/ Northern Kentucky International Airport Class B airspace area, and revocation of the Cincinnati/Northern Kentucky International Class C airspace area, KY, Final Rule until further notice.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation (1) is not a significant regulatory action under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (air).

Delay of Effective Date

The effective date of the final rule, Airspace Docket 93–AWA–5, as published in the **Federal Register** on November 30, 1998 (63 FR 65972), is hereby delayed until further notice.

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

Issued in Washington, DC, on December 7, 1998.

John S. Walker,

Program Director for Air Traffic Airspace Management.

[FR Doc. 98–33094 Filed 12–11–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 98N–0979]

Investigational New Drug Applications; Clinical Holds

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing investigational new drug applications (IND's) for human drug and biological products. This action amends 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. FDA is taking this action in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedure for notice-and-comment rulemaking to provide a procedural framework to finalize the rule in the event the agency receives significant adverse comments and withdraws this direct final rule.

DATES: This regulation is effective April 28, 1999. Submit written comments on or before March 1, 1999. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before March 29, 1999, confirming the effective date of the direct final rule. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule before March 29, 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, 301–594–5400, 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. Discussion

A. Introduction

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's 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 direct final rule amends § 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.

In the **Federal Register** of May 14, 1998 (63 FR 26809), FDA announced the availability of a guidance document entitled ''Submitting and Reviewing Complete Responses to Clinical Holds.'' This guidance to industry describes how applicants should submit responses to clinical holds so that they may be identified as complete responses.

B. Background

The procedures and requirements governing the use of investigational new drugs, including the submission and review of IND's, are set forth in part 312. An investigational new drug is a new drug or biological drug that is used in a clinical investigation. A clinical investigation is an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. An investigational new drug that meets the requirements of part 312 is exempt from the premarket approval requirements that are otherwise applicable, and may be shipped lawfully for the purpose of conducting clinical investigations of the drug.

Part 312 applies to all clinical investigations of products that are subject to section 505 of the act, or to the licensing provisions of section 351 of the Public Health Service Act (42 U.S.C. 262), with one principal exemption—certain clinical investigations of drugs that have received premarket approval and are lawfully marketed.

The person who takes responsibility for and initiates a clinical investigation of an investigational new drug is the IND sponsor. The sponsor may be an individual, a pharmaceutical company, a government agency, an academic institution, or other entity. The individual who actually conducts a clinical investigation and administers the investigational drug to patients is the investigator (the investigator may also be the sponsor). Responsibilities of a sponsor include: (1) Notifying FDA of any serious and unexpected adverse experience associated with the use of the drug; (2) selecting qualified investigators and overseeing the conduct of those investigators; (3) ensuring that the investigations are performed in accordance with the investigational plan and protocols contained in the IND; (4) providing investigators with an investigator's brochure; and (5) submitting an annual report to FDA.

A sponsor may not begin clinical testing with an investigational new drug until an IND is submitted to FDA and is in effect for that drug. The IND content and format requirements are set forth in § 312.23. An IND automatically becomes effective 30-calendar days after FDA receives the initial IND submission (or earlier upon FDA's notification), unless FDA informs the sponsor that the investigation may not proceed (i.e., a clinical hold is issued).

A clinical hold is an order that FDA issues to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. Section 505(i) of the act, as amended by the Modernization Act, verifies FDA's authority to issue a clinical hold and