Continent Airport, Wichita, Kansas, 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from Wichita ACO.

(f) Questions or technical information related to the service information specified in this AD should be directed to the Cessna Aircraft Company, P. O. Box 7706, Wichita, Kansas 67277, telephone: (316) 941–7550, facsimile: (316) 942–9008. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on October 15, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–28300 Filed 10–21–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–CE–10–AD]

RIN 2120–AA64

Airworthiness Directives; de Havilland Inc. Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to all de Havilland Inc. Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes. The proposed AD would require amending the Limitations Section of the airplane flight manual (AFM) to prohibit the positioning of the power levers aft of the flight idle stop while the airplane is in flight. This AFM amendment would include a statement of consequences if the limitation is not followed. The proposed AD is a result of numerous incidents and five documented accidents involving airplanes equipped with turboprop engines where the propeller beta was improperly utilized during flight. None of the incidents or accidents involved de Havilland Inc. Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes. The actions specified by the proposed AD are intended to prevent loss of airplane control or engine overspeed with consequent loss of engine power caused by the power levers being positioned aft of the flight idle stop while the airplane is in flight.

DATES: Comments must be received on or before December 22, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–CE–10–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

FOR FURTHER INFORMATION CONTACT: Peter LeVoci, Flight Test Pilot, New York Aircraft Certification Office, FAA, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone: (516) 256–7536; facsimile: (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–CE–10–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–CE–10–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has received reports of 14 occurrences in recent years of incidents or accidents on airplanes equipped with turboprop engines related to intentional or inadvertent operation of the propellers in the beta range during flight. Beta is the range of propeller operation intended for use during taxi, ground idle, or reverse operations as controlled by the power lever settings aft of the flight idle stop. None of the incidents or accidents involved de Havilland Inc. Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes.

Of the 14 documented in-flight beta occurrences, five were classified as accidents. In-flight beta operation results that preceded the accidents can be classified in one of two categories: (1) Permanent engine damage and total loss of thrust on all engines when the propellers that were operating in the beta range drove their respective engines to overspeed; and (2) loss of airplane control because at least one propeller operated in the beta range during flight.

The most recent accident occurred when both engines of a Saab Model 340B permanently lost power after eight seconds of beta range propeller operation. The propellers consequently drove the engines into overspeed, which resulted in internal engine failure.

Communication between the FAA and the public during a meeting held on June 11–12, 1996, in Seattle, Washington, revealed a lack of consistency of the information on in-flight beta operation contained in the airplane flight manual (AFM) for airplanes not certificated for in-flight operation with the power levers aft of the flight idle stop. Airplanes that are certificated for this type of operation are not affected by the above-referenced conditions.

The FAA's Determination

After examining the circumstances and reviewing all available information related to the incidents and accidents referenced above, the FAA has determined that:

All airplanes equipped with turboprop engines (provided the airplane is not certificated for in-flight operation with the power levers aft of the flight idle stop) should have information in the Limitations Section of the AFM that prohibits positioning of power levers aft of the flight idle stop while the airplane is in flight, including

a statement of consequence if the limitation is not followed; and

Because de Havilland Inc. Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes are equipped with turboprop engines, are not certificated for in-flight operation with the power levers aft of the flight idle stop, and do not contain information in the Limitations Section of the AFM that prohibits and explains the consequences of such operation, AD action should be taken. The proposed AD is intended to prevent loss of airplane control or engine overspeed with consequent loss of engine power caused by the power levers being positioned aft of the flight idle stop while the airplane is in flight.

Explanation of Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop on other de Havilland Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes of the same type design, the FAA is proposing AD action. The proposed AD would require amending the Limitations Section of the AFM to prohibit the positioning of the power levers aft of the flight idle stop while the airplane is in flight, including a statement of consequences if the limitation is not followed. This AFM amendment shall consist of the following language:

Positioning of power levers aft of the flight idle stop while the airplane is in flight is prohibited. Such positioning may lead to loss of airplane control or may result in an overspeed condition and consequent loss of engine power.

Compliance Time of the Proposed AD

The FAA has determined that the compliance time of the proposed AD should be specified in calendar time instead of hours time-in-service. While the condition addressed by the proposed AD is unsafe while the airplane is in flight, the condition is not a result of repetitive airplane operation; the potential of the unsafe condition occurring is the same on the first flight as it is for subsequent flights. The proposed compliance time of ''30 days after the effective date of this AD'' would not inadvertently ground airplanes and would assure that all owners/operators of the affected airplanes accomplish the proposed action in a reasonable time period.

Cost Impact

The FAA estimates that 114 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 1 workhour per airplane to incorporate the proposed AFM amendment, and that the average labor rate is approximately $60 an hour. Since an owner/operator who holds at least a private pilot's certificate as authorized by sections 43.7 and 43.9 of the Federal Aviation Regulations (14 CFR 43.7 and 43.9) can accomplish the proposed action, the only cost impact upon the public is the time it would take the affected airplane owners/operators to amend the AFM.

Regulatory Impact

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 action (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) 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 has been placed 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 a new airworthiness directive (AD) to read as follows:

De Havilland Inc: Docket No. 97–CE–10–AD.

Applicability: Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes (all serial numbers), certificated in any category.

Note 1: This AD applies to each airplane 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 airplanes 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 (e) 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 within the next 30 days after the effective date of this AD, unless already accomplished.

To prevent loss of airplane control or engine overspeed with consequent loss of engine power caused by the power levers being positioned aft of the flight idle stop while the airplane is in flight, accomplish the following:

(a) Amend the Limitations Section of the airplane flight manual (AFM) by inserting the following language:

Positioning of power levers aft of the flight idle stop while the airplane is in flight is prohibited. Such positioning may lead to loss of airplane control or may result in an overspeed condition and consequent loss of engine power.

(b) This action may be accomplished by incorporating a copy of this AD into the Limitations Section of the AFM.

(c) Amending the AFM, as required by this AD, may be performed by the owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7), and must be entered into the aircraft records showing compliance with this AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

(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 airplane to a location where the requirements of this AD can be accomplished.

(e) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Systems and Flight Test Branch, FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 1158. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, New York Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York Aircraft Certification Office.

(f) All persons affected by this directive may examine information related to this AD

at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on October 14, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–28276 Filed 10–21–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N–0038]

RIN 0910–AA01

Sunscreen Drug Products for Over-the-Counter Human Use; Amendment to the Tentative Final Monograph; Enforcement Policy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that amends the tentative final monograph (proposed rule) for over-the-counter (OTC) sunscreen drug products. This amendment would establish conditions under which products containing zinc oxide as a sunscreen active ingredient are generally recognized as safe and effective and not misbranded at concentrations of up to 25 percent alone and 2 to 25 percent in combination with any proposed Category I sunscreen active ingredient except avobenzone. OTC marketing of such drug products is being permitted pending establishment under the OTC drug review of a final monograph covering sunscreen drug products. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by January 20, 1999; written comments on the agency's economic impact determination by January 20, 1999. FDA is proposing that any final rule based on this proposal become effective 12 months after its date of publication in the **Federal Register**.

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: Donald Dobbs, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 25, 1978 (43 FR 38206), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC sunscreen drug products. Proposed § 352.10 listed the active ingredients to be generally recognized as safe and effective for use in these products. The Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (the Panel) reviewed zinc oxide as both a sunscreen and skin protectant. The Panel classified zinc oxide at concentrations of 1 to 25 percent as a Category I skin protectant (43 FR 34628 at 34648, August 4, 1978). Although zinc oxide was a labeled ingredient in a marketed sunscreen product, the Panel classified zinc oxide as an inactive ingredient (43 FR 38206 at 38208).

In the **Federal Register** of May 12, 1993 (58 FR 28194), FDA published a notice of proposed rulemaking (tentative final monograph) for OTC sunscreen drug products. The agency discussed a study submitted to the Panel using zinc oxide alone and in combination with phenyl salicylate, another sunscreen ingredient (58 FR 28194 at 28213). The study was designed to measure the ability of zinc oxide (15 to 33.3 percent) to absorb ultraviolet (UV) radiation over a broad range of wavelengths. The agency concluded that the data were not adequate to determine the effectiveness of zinc oxide because the effectiveness data for zinc oxide used alone were limited to one subject. Therefore, the agency classified zinc oxide in Category III (available data are insufficient to determine safety or effectiveness) (58 FR 38213) and requested data to support the effectiveness of zinc oxide as a sunscreen ingredient.

In the proposed rule, the agency also discussed the public health significance of ultraviolet A (UVA) radiation and the characteristics and proposed labeling of OTC sunscreen drug products that claim to provide protection from UVA radiation (58 FR 28194 at 28232 and 28233). Testing procedures for sunscreen drug products with UVA radiation protection claims were discussed in the proposed rule (58 FR 28194 at 28248 to 28250) and at a public meeting on May 12, 1994 (as noted in the **Federal Register** of April 5, 1994 (59 FR 16042)).

In response to the proposed rule, four manufacturers submitted data to support the effectiveness of zinc oxide as an OTC sunscreen active ingredient for both ultraviolet B (UVB) and UVA protection. Copies of the comments received are on public display in the Dockets Management Branch (address above). The four comments requested that the agency reclassify zinc oxide from Category III to Category I status.

II. The Agency's Evaluation of the Comments and Other Data

A. Effectiveness of Zinc Oxide

1. Several comments evaluated the effectiveness of zinc oxide as a sunscreen active ingredient in various formulations utilizing the sun protection factor (SPF) test method in the Panel report (43 FR 38206 at 38265 and 38266). Using the testing procedures in the proposed rule (58 FR 28194 at 28298), the agency recalculated the SPF test results (as stated in the tables in section II.A of this document) after eliminating those results where the homosalate control was out of range.

Two studies evaluated the ability of zinc oxide-containing sunscreen drug products to block sunburning radiation (Ref. 1). In both studies, formulations containing either 4 percent or 25 percent zinc oxide, 2 percent oxybenzone (a proposed Category I sunscreen ingredient (58 FR 28194 at 28295)), and a placebo were tested. The vehicles consisted of commonly utilized oils and emulsifiers and varied only in the concentration of the active ingredients and the amount of purified water. The results of these studies were as follows:

TABLE 1.—SPF TEST DETERMINATIONS FOR FOUR FORMULATIONS

Sunscreen	Anticipated SPF	Test SPF (Study 1)	Test SPF (Study 2)
4% Zinc oxide	SPF 2.5	SPF 3.01	2.79
25% Zinc oxide	SPF 15.0	SPF 16.74	16.14