PART 543—INCORPORATION, ORGANIZATION, AND CONVERSION OF FEDERAL MUTUAL ASSOCIATIONS

1. The authority citation for part 543 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 2901 *et seq.*

2. Section 543.8 is amended by revising the heading and paragraph (a) to read as follows:

§ 543.8 Conversion of depository institutions to Federal mutual charter.

(a) With the approval of the OTS, any depository institution, as defined in § 552.13 of this chapter, that is in mutual form, may convert into a Federal mutual savings association, provided that:

(1) The depository institution, upon conversion, will have its deposits insured by the Federal Deposit Insurance Corporation;

(2) The depository institution, in accomplishing the conversion, complies with all applicable state and federal statutes and regulations, and OTS policies, and obtains all necessary regulatory and member approvals; and

(3) The resulting Federal mutual association conforms, within the time prescribed by the OTS, to the requirements of section 5(c) of the Home Owners' Loan Act.

* * * * *

3. Section 543.9 is amended by revising paragraph (a) and the introductory text of paragraph (c) to read as follows:

§ 543.9 Application for conversion to Federal mutual charter.

(a) *Filing.* Any depository institution that proposes to convert to a Federal mutual association as provided in § 543.8 shall, after approval by its board of directors, file in accordance with § 516.1 of this chapter an application on forms obtained from the OTS. The applicant shall submit any financial statements or other information the OTS may require.

* * * * *

(c) *Action on application.* The OTS will consider such application and any information submitted with the application, and may approve the application in accordance with section 5(e) of the Home Owners' Loan Act and § 543.2(g)(1). Converting depository institutions that have been in existence less than three years will be subject to all approval criteria and other requirements applicable to *de novo* Federal associations. Approval of an application and issuance by the OTS of a charter will be subject to:

* * * * *

Dated: August 19, 1997.

By the Office of Thrift Supervision.

Nicolas P. Retsinas,

Director.

[FR Doc. 97–22798 Filed 8–26–97; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–ANE–40; Amendment 39–10112; AD 97–18–02]

RIN 2120–AA64

Airworthiness Directives; Hartzell Propeller Inc. ( )HC–( )(2,3)(X,V)( )–( ) Series and HA–A2V20–1B Series Propellers With Aluminum Blades

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes four existing airworthiness directives (ADs), applicable to Hartzell Propeller Inc. ( )HC–( )(2,3)(X,V)( )–( ) series propellers with aluminum blades, that currently require inspections for cracks in blade shanks and clamps. This amendment requires initial and repetitive dye penetrant and eddy current inspections of the blade and an optical comparator inspection of the blade retention area, and, if necessary, replacement with serviceable parts. In addition, this AD requires initial and repetitive visual and magnetic particle inspection of the blade clamp, dye penetrant inspection of the blade internal bearing bore, and, if necessary, replacement with serviceable parts. Also, for all HC–(1,4,5,8)(2,3)(X,V)( )–( ) steel hub propellers, this AD requires an additional initial and repetitive visual and magnetic particle inspection of the hub and, if necessary, replacement with serviceable parts. This amendment is prompted by reports of cracked blades, blade clamps, and hubs and reports of blade separations. The actions specified by this AD are intended to prevent blade separation due to cracked blades, hubs, or blade clamps, which can result in loss of control of the airplane.

DATES: Effective September 11, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of September 11, 1997.

Comments for inclusion in the Rules Docket must be received on or before October 27, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–ANE–40, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ad-engineprop@faa.dot.gov''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from Hartzell Propeller Inc., One Propeller Place, Piqua, OH 45356–2634, ATTN: Product Support; telephone (937) 778–4200, fax (937) 778–4321. This information may be examined at the FAA, New England Region, Office of the Assistant Chief Counsel, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tomaso DiPaolo, Aerospace Engineer, Chicago Aircraft Certification Office, FAA, Small Airplane Directorate, 2300 East Devon Ave., Des Plaines, IL 60018; telephone (847) 294–7031, fax (847) 294–7834.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration (FAA) issued airworthiness directive (AD) 68–13–02, Amendment 39–614 (33 FR 9252, June 22, 1968), applicable to Hartzell Propeller Inc. Model PHC–A3VF–4/V8433–2R and –4R propellers, to require repetitive inspections for cracks in blade shanks at intervals not to exceed 400 hours Time in Service (TIS). That action was prompted by reports of cracks in blade shanks. That condition, if not corrected, could result in loss of a blade due to blade shank cracks, which could result in loss of aircraft control.

The FAA issued AD 68–19–04, Amendment 39–868 (34 FR 18296, November 15, 1969), applicable to Hartzell Propeller Inc. Model HC–A2XF, HC–12X20, HC–82VF, BHC–A2XF, HC–13X20, HC–82VK, HC–A2XK, HC–D3X20, HC–82VL, HC–A2XL, HC–82X20, HC–83XF, HC–A3XK, HC–82XF, HC–83XK, HC–A3VK, HC–82XG, HC–83X20, HC–82XK, and HC–82KL propellers, with 8433, V8433, 8833, and V8833 blades, to require repetitive inspections for cracks in blade shanks at intervals not to exceed 1,000 hours TIS. That action was prompted by reports of cracks in blade shanks. That condition, if not corrected, could result in loss of a blade due to blade shank cracks,

which could result in loss of aircraft control.

The FAA issued AD 75–17–34, Amendment 39–2337 (40 FR 33433, August 8, 1975), applicable to Hartzell Propeller Inc. Model EHC–A3VF–2B/V7636D propellers installed on Teledyne Continental Motors Model IO–520–E series engines and on the deHavilland Heron D.H. 114 Series aircraft in accordance with STC SA1685WE, to require repetitive inspections for cracks in blade shanks and clamps at intervals not to exceed 1,000 hours TIS. That action was prompted by reports of cracks in blade shanks and clamps. That condition, if not corrected, could result in loss of a blade due to blade shank and clamp cracks, which could result in loss of aircraft control.

The FAA issued AD 77–14–07, Amendment 39–2955 (42 FR 35638, July 11, 1977), applicable to Hartzell Propeller Inc. Model EHC–A3VF–2B/V7636N propellers installed on Teledyne Continental Motors Model IO–520–E series engines and on the deHavilland Heron D.H. 114 Series aircraft in accordance with STC SA1685WE, to require repetitive inspections for cracks in certain blade clamps at intervals not to exceed 32 hours TIS, repetitive inspections for cracks in blade shanks at intervals not to exceed 400 hours TIS, and, as necessary, rework or replace blades at intervals not to exceed 1,200 hours TIS. That action was prompted by reports of cracks in blade shanks and clamps. That condition, if not corrected, could result in loss of a blade due to blade shank and clamp cracks, which could result in loss of aircraft control.

Since the issuance of those ADs, the FAA has received reports of:

(1) 37 cracked blades in the past three years, including two blade separations with one resulting in a fatal accident;

(2) 4 cracked blade clamps, including one blade separation;

(3) 5 blade separations from hub fatigue cracks (only found in HC–8( )( ) series hubs).

The investigations into these occurrences revealed fatigue cracks in the following parts/areas:

(1) blade internal bearing bore (corrosion at origin) and blade retention radius;

(2) steel hub blade clamps; and

(3) steel hub blade retention radius (only found in HC–8( )( ) series hubs).

Additionally, the FAA has determined that the HC–(1,4,5,8)(2,3)(X,V)( )–( ) Series steel hub propellers have similar loading and load paths to the failed HC–8( )( ) series propellers and may develop fatigue cracks.

The FAA has reviewed and approved the technical contents of Hartzell Propeller Inc. Service Bulletin (SB) No. HC–SB–61–217, Revision 1, dated July 11, 1997, that describes procedures for fluorescent dye penetrant and eddy current inspections of the blade and an optical comparator inspection of the blade retention area, and, if necessary, replacement with serviceable parts. In addition, this SB describes procedures for visual and magnetic particle inspection of the blade clamp, dye penetrant inspection of the blade internal bearing bore and, if necessary, replacement with serviceable parts. For all HC–(1,4,5,8)(2,3)(X,V)( )–( ) steel hub propellers, this SB describes an additional visual and magnetic particle inspection of the hub, and, if necessary, replacement with serviceable parts.

Since an unsafe condition has been identified that is likely to exist or develop on other propellers of this same type design, this AD supersedes ADs 68–13–02, 68–19–04, 75–17–34, and 77–14–07 to require initial and repetitive fluorescent dye penetrant and eddy current inspections of the blade and an optical comparator inspection of the blade retention area, and, if necessary, replacement with serviceable parts. In addition, this AD requires an initial and repetitive visual and magnetic particle inspection of the blade clamp, dye penetrant inspection of the blade internal bearing bore and, if necessary, replacement with serviceable parts. Also, for all HC–(1,4,5,8)(2,3)(X,V)( )–( ) steel hub propellers, this AD requires an additional initial and repetitive visual and magnetic particle inspection of the hub and, if necessary, replacement with serviceable parts. Finally, this AD adds a reporting requirement to obtain additional data and determine if adjustment can be made to the repetitive inspection intervals, with possible relief. The actions are required to be accomplished in accordance with the SB described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this 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 under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the 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 AD 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 Number 96–ANE–40.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will 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 final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–614 (33 FR 9252, June 22, 1968), 39–868 (33 FR 12961, September 13, 1968), 39–868 (34 FR 18296, November 15, 1969), 39–2337 (40 FR 33433, August 8, 1975), and 39–2955 (42 FR 35638, July 11, 1977), and by adding a new airworthiness directive, Amendment 39–10112, to read as follows:

97–18–02 Hartzell Propeller Inc.: Amendment 39–10112. Docket 96–ANE–40. Supersedes AD 68–13–02, Amendment 39–614; AD 68–19–04, Amendment 39–868; AD 75–17–34, Amendment 39–2337; AD 77–14–07, Amendment 39–2955.

Applicability: Hartzell Propeller Inc. ()HC–()(2,3)(X,V)()–() series and HA-A2V20–1B series propellers with aluminum blades. These propellers are installed on but not limited to the following aircraft:

Manufacturer Aircraft Model
Aero Commander (Twin Commander)
500 AERO COMMANDER
500A AERO COMMANDER
500B, 500S, 500U AERO COMMANDER
520 AERO COMMANDER
560 AERO COMMANDER
560A, 560E AERO COMM.
680, 680E, 720 AERO COMM.
680F, FP, FL, FLR AERO COMMANDER
B1 (CALLAIR)
Aeromere
FALCO F.8.L
Aeronautica Macchi
AL60–F5
AM–3
Bauger
SAIL PLANE
Beech
35 SERIES BONANZA
35–C33 DEBONAIR
35–C33A, E33A, F33A
50 SERIES TWIN BONANZA
58P, 58TC BARON
95–55, 95–A55, 95–B55 BARON
65, A65, 65–(B)80, 65–A80, 70
A65–8200, 70
Bellanca
14–13
14–19
14–19–2
14–19–3
7GCA, 7GCB, 7GCC
DW–1 EAGLE
Camair
480
Cessna
170
170A
172 SKYHAWK
175
180, A, B, C, D, E, F, G, H
182, A, B, C, D, E
182F, G, H, J, K, L, M
210, A, B, C, 5, 5A
310, 310A
310B, 310C
310D, E, F, G, H, E310H
320, 320–1 SKYKNIGHT
320A, 320B
402 BUSINESSLINER
411
WREN 460
WREN 460H, J, K, L, M
deHavilland
DH104 DOVE
DH114 HERON
Dornier
DO27Q–6
DO28A–1
DO28B–1
Fuji
T–3, LM–2
GAF—Gov't. Aircraft Factories
N22B, N24A, N22S, N22C
Goodyear (Loral)
GA22A GOODYEAR BLIMP
GZ19, 19A GOODYEAR BLIMP
Great Lakes
2T–1A–2
Grumman
G44, G44A WIDGEON
G21C, D GOOSE
Helio
H–391 COURIER
H–391B COURIER
H–395A COURIER
Luscombe
11
11A
Mooney
M20
Multitech (Temco)
D16 TWIN NAVION
D16A TWIN NAVION
Nardi
FN–333
Navion
NAVION B
NAVION, NAVION A
Pacific Aerospace (Fletcher)
FU–24, FU–24A
Piaggio
P–149D
P136–L1 ROYAL GULL
P136–L2 ROYAL GULL
P149D
P166 ROYAL GULL
Pilatus
PC–3
PC–6; PC–6–H1, –H2 PORTER
Piper
PA–E23–250 AZTEC
PA14 FAMILY CRUISER
PA18(A)(S)–150 SUPER CUB
PA18A–150 SUPER CUB
PA22–150, PA22S–150
TRIPACER
PA23 SERIES APACHE
PA23–160 APACHE
PA23–235 AZTEC
PA23–250 AZTEC
PA24–250 COMANCHE
PA24–400 COMANCHE
PA24S COMANCHE
PA28 CHEROKEE
PA28–140 CHEROKEE
Prop Jets Inc.
200
200A,B,C
Republic (STOL Amphibian)
RC3 SEABEE
Scottish Aviation (BAE)
B.206 SERIES 2 BEAGLE
Stinson
L–5
108, –1, –2, –3
108–2–3
Sud Aviation (SOCATA)
GY.80–150 GARDAN
GY.80–160 GARDAN HORIZON
Swift
GC–1B
Taylorcraft
20
Texas Bullet
205
Windecker
EAGLE

Note 1: The above is not a complete list of aircraft which may contain the affected Hartzell Propeller Inc. ()HC–()(2,3)(X,V)()–() series and HA–A2V20–1B series propellers with aluminum blades because of installation approvals made by, for example, Supplemental Type Certificate or field approval under FAA Form 337 ''Major Repair and Alteration.'' It is the responsibility of the owner, operator, and person returning the aircraft to service to determine if an aircraft has an affected propeller.

Note 2: The parenthesis that appear in the propeller models indicate the presence or absence of additional letter(s) which vary the basic propeller hub model designation. This airworthiness directive is applicable regardless of whether these letters are present or absent on the propeller hub model designation.

Note 3: This AD applies to each propeller 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 propellers 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 (g) 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 blade separation due to cracked blades, hubs, or blade clamps, which can result in loss of control of the airplane, accomplish the following:

(a) On Hartzell propeller models with hub models ()HC–(1,4,5,8)(2,3)(X,V)()–() perform initial and repetitive inspections and, if necessary, replace with serviceable parts in accordance with Hartzell Propeller Inc. Service Bulletin (SB) No. HC–SB–61–217, Revision 1, dated July 11, 1997, as follows:

(1) Initially perform a fluorescent dye penetrant and eddy current inspection of the blade, an optical comparator inspection of the blade retention area, a dye penetrant inspection of the blade internal bearing bore, and a visual and magnetic particle inspection of the blade clamp and of the hub. The initial inspection is required within the following:

(i) 1,000 hours time since new (TSN) for propellers with less than 900 hours TSN on the effective date of this AD, provided that the initial inspections are performed within 60 calendar months TSN or 24 calendar months after the effective date of this AD, whichever calendar time occurs later, or

(ii) 100 hours time in service (TIS) for propellers with 900 or more hours TSN, or unknown TSN, on the effective date of this AD, provided that the initial inspections are performed within 24 calendar months after the effective date of this AD.

(2) Thereafter, perform repetitive fluorescent dye penetrant and eddy current inspection of the blade, an optical comparator inspection of the blade retention area, and a visual and magnetic particle inspection of the blade clamp. The repetitive inspection is required at intervals not to exceed 500 hours TIS or 60 calendar months, whichever occurs first, since last inspection.

(3) Thereafter, perform a repetitive visual and magnetic particle inspection of the hub. This repetitive hub inspection is required at intervals not to exceed 250 hours TIS or 60 calendar months, whichever occurs first, since last inspection.

(4) Thereafter, perform a repetitive dye penetrant inspection of the blade internal bearing bore. This repetitive blade internal bearing bore inspection is required at intervals not to exceed 60 calendar months since last inspection.

(b) On Hartzell propeller models with hub models ( )HC–(A,D)(2,3)(X,V) ( )–( ), and HA–A2V20–1B, except HC–A3VF–7( ), perform initial and repetitive inspections and, if necessary, replace with serviceable parts in accordance with Hartzell SB No. HC–SB–61–217, Revision 1, dated July 11, 1997, as follows:

(1) Initially perform a fluorescent dye penetrant and eddy current inspection of the blade, an optical comparator inspection of the blade retention area, a visual and magnetic particle inspection of the blade clamp, and a dye penetrant inspection of the blade internal bearing bore. The initial inspection is required within the following:

(i) 1,000 hours TSN for propellers with less than 800 hours TSN on the effective date of this AD, provided that the initial inspections are performed within 60 calendar months TSN or 24 calendar months after the effective date of this AD, whichever calendar time occurs later, or

(ii) 200 hours TIS for propellers with 800 or more hours TSN, or unknown TSN, on the effective date of this AD, provided that the initial inspections are performed within 24 calendar months after the effective date of this AD.

(2) Thereafter, perform repetitive fluorescent dye penetrant and eddy current inspection of the blade, an optical comparator inspection of the blade retention area, and a visual and magnetic particle inspection of the blade clamp. The repetitive inspection is required at intervals not to exceed 500 hours TIS or 60 calendar months, whichever occurs first, since last inspection.

(3) Thereafter, perform repetitive dye penetrant inspections of the blade internal bearing bore. This repetitive blade internal bearing bore inspection is required at intervals not to exceed 60 calendar months since last inspection.

(c) On Hartzell propeller models with hub models HC–A3VF–7( ) perform initial and repetitive inspections and, if necessary, replace with serviceable parts in accordance with Hartzell SB No. HC–SB–61–217, revision 1, dated July 11, 1997, as follows:

(1) Initially perform a fluorescent dye penetrant and eddy current inspection of the blade, an optical comparator inspection of the blade retention area, a visual and magnetic particle inspection of the blade clamp, and a dye penetrant inspection of the blade internal bearing bore. The initial inspection is required within the following:

(i) 3,000 hours TSN for propellers that have never been overhauled and have less than 2,500 hours TSN on the effective date of this AD, provided that the initial inspections are performed within 60 calendar months TSN or 24 calendar months after the effective date of this AD, whichever calendar time occurs later, or

(ii) 3,000 hours TIS since last overhaul for propellers that have been overhauled but have less than 2,500 hours TIS since last overhaul on the effective date of this AD, provided that the initial inspections are performed within 60 calendar months TIS since last overhaul or 24 calendar months after the effective date of this AD, whichever calendar time occurs later, or

(iii) 500 hours TIS, for propellers that have never been overhauled and have 2,500 or more hours TSN on the effective date of this AD, or propellers which have been overhauled and have 2,500 or more hours TIS since last overhaul on the effective date of this AD, or propellers with unknown TSN, provided that the initial inspections are performed within 24 calendar months after the effective date of this AD.

(2) Thereafter, perform repetitive fluorescent dye penetrant and eddy current inspection of the blade, an optical comparator inspection of the blade retention area, and a visual and magnetic particle inspection of the blade clamp. The repetitive inspection is required at intervals not to exceed 3000 hours TIS or 60 calendar months, whichever occurs first, since last inspection.

(3) Thereafter, perform repetitive dye penetrant inspections of the blade internal bearing bore. This repetitive blade internal bearing bore inspection is required at intervals not to exceed 60 calendar months since last inspection.

(d) The initial inspection of the internal blade bearing bore required by paragraphs (a)(1), (b)(1), or (c)(1) of this AD need not be accomplished again if previously accomplished in accordance with page 4 of Hartzell SB No. HC–SB–61–217, Revision 1, dated July 11, 1997.

(e) If not previously accomplished, shot peen the propeller blade shank area during the initial inspection required by paragraphs (a)(1), (b)(1), or (c)(1), as appropriate, and perform the shot peening in accordance with Hartzell SB No. HC–SB–61–217, Revision 1, dated July 11, 1997. Re-shot peening of the propeller blade shank area during the repetitive inspections required by paragraphs (a)(2), (b)(2), or (c)(2), as appropriate, is required only if the propeller blade shank area has been repaired or has excessive wear or damage in accordance with Hartzell SB No. HC–SB–61–217, Revision 1, dated July 11, 1997.

(f) Report inspection results to the Manager, Chicago Aircraft Certification Office, FAA, Small Airplane Directorate, 2300 East Devon Ave., Des Plaines, IL 60018, within 15 working days of the inspection. Reporting requirements have been approved by the Office of Management and Budget (OMB) and assigned OMB control number 2120–0056.

(g) 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, Chicago Aircraft Certification Office. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Chicago Aircraft Certification Office.

Note 4: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Chicago Aircraft Certification Office.

(h) 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.

(i) The actions required by this AD shall be done in accordance with the following Hartzell Propeller Inc. SB:

Document No.	Revision	Pages	Date
HC–SB–61–217 ..... Total pages: 16.	1	1–16	July 11, 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 Hartzell Propeller Inc., One Propeller Place, Piqua, OH 45356–2634, ATTN: Product Support; telephone (937) 778–4200, fax (937) 778–4321. Copies may be inspected at the FAA, New England Region, Office of the Assistant Chief 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.

(j) This amendment becomes effective on September 11, 1997.

Issued in Burlington, Massachusetts, on August 15, 1997.

James C. Jones,

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

[FR Doc. 97–22677 Filed 8–26–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 89N–0474]

RIN 0910–AA25

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of ''Geriatric Use'' Subsection in the Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the content and format of labeling for human prescription drug products, including biological products, to include information pertinent to the appropriate use of drugs in the elderly (persons aged 65 years and over) and to facilitate access to this information by establishing a ''Geriatric use'' subsection in the labeling. The final rule is one of several measures FDA has taken in response to the special concerns associated with prescription drug use in elderly patients. FDA believes that improving access to information that is important to the elderly will facilitate the safe and effective use of prescription drugs in older populations.

DATES: This final rule becomes effective on August 27, 1998. Submit written comments on the collection of information provisions by October 27, 1997. See section IV of this document for the implementation dates of this final rule for drug classes and drug products.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5621.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 1, 1990 (55 FR 46134), FDA proposed to amend its prescription drug labeling regulations (§ 201.57) to establish in the ''Precautions'' section a subsection on the use of drugs in elderly or geriatric patients (aged 65 years and over). The final rule requires, in a new ''Geriatric use'' subsection of prescription drug labeling, that sponsors describe available information pertinent to the appropriate use of drugs in elderly patients. In cases where none of the provisions of the ''Geriatric use'' subsection are applicable, FDA may permit omission of the subsection or approve an accurate and appropriate alternate statement.

The final rule recognizes the special concerns associated with the geriatric use of prescription drugs and acknowledges the need to communicate important information so that drugs can be used safely and effectively in older patients. The medical community has become increasingly aware that prescription drugs can produce effects in elderly patients that are significantly different from those produced in younger patients. Although both young and old patients can exhibit a range of responses to drug therapy, factors contributing to different responses are comparatively more common among the elderly. For example, elderly patients are more likely to have impaired mechanisms of drug excretion (e.g., decreased kidney function), to be on other medications that can interact with a newly prescribed drug, or to have another medical condition that can affect drug therapy.

Geriatric labeling information is of increasing importance because of the growing proportion of the population that is over 65 years of age, and the significant use of medications by this age group. People over age 65 constitute only 12 percent of the U.S. population, but they consume over 30 percent of the prescription drug products sold in this country. The elderly are expected to constitute 22 percent of the U.S. population by the year 2030.

The final rule is one of several actions taken by FDA to promote safe and effective prescription drug use in the elderly. FDA has encouraged sponsors to include more elderly subjects, especially those over 75 years of age, in clinical studies. In the **Federal Register** of March 5, 1990 (55 FR 7777), FDA announced the availability of a guideline entitled ''Guideline for the Study of Drugs Likely to be Used in the Elderly.'' The guideline emphasizes FDA's recommendation that drugs should be studied in the full range of patients who will receive them, including the elderly, and that efforts should be made to discover differences in pharmacokinetics related to age, or to conditions associated with age (e.g., decreased renal function, concomitant drugs, concomitant illness), and that clinical data should be analyzed to see whether the drug has different effects, favorable or unfavorable, in the old and young. The guideline provides detailed advice on how to evaluate new drugs in older patients and is intended to encourage routine and thorough evaluation of the effects of drugs in elderly populations so that sufficient information can be provided to physicians. The guideline did not call for, or anticipate, an increase in the number of patients or the number of clinical studies needed to evaluate a new therapy. Patients over 65 years of age already represented a significant portion of study subjects in most cases, based on several FDA surveys. The principal new steps called for were to not exclude the very old, to analyze the data already collected, and to obtain modest additional pharmacokinetic data. Only in special cases (e.g., drugs especially targeted for older patients or where age-related differences or problems are anticipated) were separate studies in the elderly recommended.

In the **Federal Register** of August 2, 1994 (59 FR 39398), FDA published a guideline regarding the use of drugs in geriatric populations entitled ''Studies in Support of Special Populations: Geriatrics.'' The guideline was prepared by the Efficacy Expert Working Group of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, which is concerned with the harmonization of technical requirements among the European Union, Japan, and the United States. The guideline reflects sound scientific principles for testing drugs in geriatric populations and for submitting