Alternative Methods of Compliance (AMOCs)

(i) You must request AMOCs as specified in 14 CFR part 39.19. All AMOCs must be approved by the Manager, Los Angeles Aircraft Certification Office, FAA.

Material Incorporated by Reference

(j) The FPIs must be done in accordance with Honeywell International Inc. ASB TPE331–A72–2102, dated March 28, 2002. Approval of incorporation by reference from the Office of the Federal Register is pending.

Related Information

(k) None.

Issued in Burlington, Massachusetts, on August 1, 2003.

Francis A. Favara,

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

[FR Doc. 03–20231 Filed 8–7–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 121 and 135

[Docket No. FAA–2003–14830; Special Federal Aviation Regulation (SFAR) No. 71]

RIN 2120–AH02

Air Tour Operators in the State of Hawaii

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to continue the existing safety requirements in Special Federal Aviation Regulation No. 71 (SFAR 71) and eliminate the termination date for SFAR 71. Currently, SFAR 71 is a final rule that will expire on October 26, 2003. Since 1994, the FAA has extended SFAR 71 for two 3-year periods. The procedural, operational, and equipment safety requirements of SFAR 71 would continue to apply to parts 91, 121, and 135 air tour operators in Hawaii. SFAR 71 does not apply to operations conducted under part 121 in airplanes with a passenger-seating configuration of more than 30 seats and a payload capacity of more than 7,500 pounds or to flights conducted in gliders or hot air balloons.

DATES: Comments must be received on or before September 8, 2003.

ADDRESSES: You may submit comments to FAA–2003–14830 by any of the following methods:

- *Web site: http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC between 9 am and 5 pm, Monday through Friday, except Federal Holidays.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to *http://dms.dot.gov,* including any personal information provided. Please see the Privacy Act heading under **SUPPLEMENTARY INFORMATION** and Regulatory Notices.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC between 9 am and 5 pm, Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Alberta Brown, Aviation Safety Inspector, Air Transportation Division, AFS–200, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; Telephone (202) 267–8321, or by email at *Alberta.Brown@faa.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons are invited to participate in this proposed rulemaking by submitting such data, views or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on a proposal. Comments are specifically invited on the overall regulatory, economic, environmental and energy-related aspects of the proposal. If you are submitting comments on paper, write docket number FAA–2003–14830 on your comments and submit them in duplicate. Submit your comments to the Docket Management System or through the internet at the addresses listed above.

Anyone who would like the FAA to acknowledge receipt of their comments must submit a self-addressed, stamped, postcard containing the statement ''Comments to Docket No. FAA–2003–14830.'' The postcard will be date/time stamped and returned. All communications received on or before the specified closing date for comments will be considered before taking action on this proposed rule. Comments filed after the closing date will be considered to the extent practicable. The proposal may be changed in light of the comments received.

All comments submitted will be available for examination in the public docket both before and after the closing date for comments. If any substantive contact with FAA personnel occurs concerning this proposal after its publication, a report summarizing that contact will be placed in the docket.

Privacy Act

Anyone is able to search the electronic form of all comments received into our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Statement in the **Federal Register** published on April 11, 2000 (volume 65, Number 70, pages 19477–78), or you may visit *http://dms.dot.gov.*

Availability of the Proposed Rule

You can download an electronic copy of this proposed rule through the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page *(http://dms.dot.gov/search);*

(2) Visiting the Office of Rulemaking's Web page at *http://www.faa.gov/avr/armhome.htm;* or

(3) Accessing the **Federal Register's** Web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

You also can get a copy by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure you put docket number FAA–2003–14830 on your request. to identify this rulemaking.

You may review the public docket containing this proposal, any comments

received, and any final disposition, in person in the Docket Management System office (*see* address above) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires the FAA to comply with small entities requests for information or advice about compliance with statutes and regulations within its jurisdiction. Internet users can find additional information on SBREFA on the FAA's Web page at *http://www.2faa.gov/avr/arm/sbrefa.htm.* Persons without internet access may call the office of rulemaking at (202) 267–8677 for more information.

Background

In 1994, the FAA issued SFAR 71 as an emergency rule because of safety concerns about the risks associated with air tours in Hawaii and the increase in the accident rate (59 FR 49138, September 26, 1994). Currently, SFAR 71 imposes special safety requirements for all air tours conducted in Hawaii under parts 91, 135, and certain part 121 operations.

Section 3 specifically addresses single engine helicopters operated beyond the shore of any island. Without regard to gliding distance, the helicopter must be equipped with floats adequate to accomplish a safe emergency ditching as well as flotation gear easily accessible to each occupant. If there are no floats on the helicopter, each occupant must wear the flotation gear.

Section 4 applies to all helicopter air tours, not just single engine helicopters or off shore air tours, and requires operators to complete a performance plan before each flight. The pilot in command must comply with the performance plan.

Section 5 requires that, except for approach to, and transition from a hover, the pilot in command of a helicopter air tour operate at a combination of height and forward speed (including hover) that would permit a safe landing in the event of engine power loss, in accordance with the height-speed envelope for that helicopter under current weight and aircraft altitude.

Section 6 requires minimum altitudes for air tours in Hawaii. No person may conduct an air tour in Hawaii below an altitude of 1,500 feet above the surface or closer than 1,500 feet to any person or property. There are exceptions for altitudes necessary for takeoff and landing, compliance with air traffic control clearances, and altitudes prescribed by federal statute or regulation. Section 6 also allows operators to obtain deviation authority from the FAA to operate at lower altitudes.

Section 7 requires that each pilot in command of an air tour flight of Hawaii, with a flight segment beyond the ocean shore of any island, ensure that passengers are briefed on water ditching procedures, use of flotation equipment, and how to exit from the aircraft in the event of a water landing.

The original SFAR would have expired 3 years after becoming effective in October 1994; however, the FAA extended the termination date in both 1997 and 2000 for additional 3-year terms. (62 FR 58854, October 30, 1997; 65 FR 58610, September 29, 2000.) Except for the date extensions, SFAR 71 has continued without change to its substantive or procedural safety requirements and has remained in effect for approximately 9 years.

As discussed in the two extensions, the FAA will continue to develop a national air tour safety standards notice of proposed rulemaking. The national rulemaking will be responsive to the NTSB and others who believe that air tour safety standards should be applicable nationwide.

There have been three lawsuits regarding SFAR 71 rulemaking. The Hawaii Helicopter Operators Association (HHOA) challenged the validity of the emergency rule issued in 1994, contending that the FAA had violated the notice and comment provisions of the Administrative Procedure Act (APA). The United States Court of Appeals for the Ninth Circuit upheld the promulgation of SFAR 71 as an emergency rule finding that the FAA had properly invoked the good cause exception to section 553(c) of the APA. Also, the Court rejected HHOA's claim that the SFAR's 1,500 foot minimum altitude requirement was arbitrary and capricious. *See Hawaii Helicopter Operators Association* v. *FAA,* 51 F. 3d 212 (9th Cir. 1995).

When the FAA extended SFAR 71 in 1997 and 2000, Safari Aviation, Inc., petitioned for review of both rules in the 9th Circuit. As to the 1997 interim rule, the Court held that the challenge was moot because the rule had expired. As to the 2000 rule extending SFAR 71 without change (except for the date) the Court found that the FAA adequately responded to the comments it received. The FAA was required to respond only to significant comments raising relevant points and which, if adopted, would require a change to the proposal. The Court found that the FAA had a rational basis for promulgating SFAR 71 and held that the rule was not arbitrary or capricious. The Court also held that the FAA-approved deviations from the altitude minimums in SFAR 71 were interpretive rules not subject to the notice and comment provisions of the APA. *See Safari Aviation* v. *FAA,* 300 F. 3d 1144 (9th Cir. 2002) *cert. denied.*

The Petition for Rulemaking

In October 2002, 15 helicopter air tour operators and their pilots who operate in Hawaii petitioned to amend SFAR 71. Each of the identical petitions was signed by air tour pilots. The petitions are available in docket number FAA–2002–13959 as well as this rulemaking docket. Petitioners state that the 1,500-foot minimum altitude requirement in SFAR 71, even with FAA approved specific deviation authority, ''is cumbersome and lacks flexibility in dynamic circumstances.'' They maintain that the altitude requirement in SFAR 71 is ''unnecessarily restrictive and compromises safety by taking away pilot options.'' Petitioners state that ''pilot judgment should dictate altitude and standoff distances in accordance with well-established FAA regulatory practice and helicopter industry experience.''

Petitioners agree that the 1,500-foot minimum altitude restriction should be maintained for habitable structures and congregations of persons. For other areas, however, they request that the FAA amend the altitude restriction for helicopters to align it with federal aviation regulation section 135.203 (14 CFR 135.203). The 300-ft. altitude restriction in 14 CFR 135.203 refers to VFR helicopter operations over congested areas; however, petitioners maintain that 300 feet is a reasonable minimum altitude to apply to helicopter tour operations in noncongested areas in Hawaii. They ask the FAA to amend SFAR 71 to allow air tour helicopter operations at 300 feet except when operating over habitable structures or congregations of people.

Petitioners maintain that allowing helicopter air tours as low as 300 feet would make ''SFAR 71 safer because pilot decision-making would no longer be compromised by pressure to maintain unreasonable altitudes in certain circumstances.'' They believe that ''the pilot would then have the latitude to determine the safe and most reasonable route of flight considering terrain and weather.''

Petitioners state that SFAR 71 causes helicopter tours to fly over, or very close to, communities concentrated along the coast of the windward side of the Hawaiian Islands in order to stay at 1,500 feet and remain under the cloud

ceiling. They state that general aviation airplanes fly low in this area to stay below the helicopter tour flights. They assert that this practice is ''contrary to common sense, increases the potential for mid-air collisions, and increases noise exposure for coastal communities.'' Finally, petitioners state that a review of the pre-SFAR helicopter accidents in Hawaii would disclose that ''a 300 foot restriction would have been equally effective in preventing almost every accident attributed to low altitude.''

In an identical addendum to the petition, some petitioners state that SFAR 71 should be rescinded and that the rules governing helicopter flight and equipment should be uniform throughout the United States. These petitioners maintain that parts 91 and 135 are established safety regulations acceptable to helicopter tour pilots and tour operators on a nationwide level. They contend that SFAR 71 was imposed because of a political outcry for increased regulations. They also maintain that the accident history used to support SFAR 71 shows that if the pilots and operators had complied with existing regulations, the accidents would not have occurred or the outcomes would have been different.

The FAA's Response

The FAA has considered the petitioners' views, arguments and information in formulating this notice of proposed rulemaking. During the years that SFAR 71 has been in effect, the FAA has received many comments about the minimum altitude requirement; it continues to be a contentious issue. When the FAA issued SFAR 71 in 1994 as an emergency rule, the National Transportation Safety Board and others criticized the minimum altitude requirement because of a concern that tour operations would be concentrated at that altitude increasing the risk of mid-air collisions and derogating safety. In practice, the FAA has granted deviations to a majority of the operators, which has mitigated this concern. By granting the deviations, the FAA has provided the majority of air tour operators with specific interpretations of how the minimum altitude requirement of SFAR 71 applies to them in light of their individual safety qualifications and differences in local terrain and prevailing conditions.

The petitions and addendums to the petitions raise issues again that are similar to comments received by the agency during the three rulemaking proceedings on this SFAR. The helicopter air tour operators do not agree with the 1,500-ft. altitude minimum and they want to fly lower at 300 feet over other than congested areas in Hawaii without obtaining an FAA authorized deviation. They acknowledge, however, that a minimum altitude of 300 feet would not have prevented all the pre-SFAR accidents attributable to low altitude. SFAR 71 limits the minimum altitude at which air tours may be conducted and, to that extent, the FAA agrees with petitioners that SFAR 71 has taken away a pilot option. An altitude of 1,500 feet provides a pilot with more distance, and thus time, to avoid an accident or to deal with an error.

In summary, SFAR 71 has been successful in reducing the air tour accident rate in Hawaii and does not compromise safety. Any FAA issued deviations from the altitude requirement will continue to be site specific because the public interest in safety requires a case-by-case and site-by-site assessment for each altitude deviation request.

The Proposal

The FAA proposes to continue the safety requirements of SFAR 71 without a termination date because of the success of SFAR 71 in reducing the air tour accident rate in Hawaii and the proven effectiveness of the SFAR's requirements.

Environmental Review

In accordance with FAA Order 1050.1D, the FAA has determined that this proposed rule is categorically excluded from environmental review under section 102(2)(C) of the National Environmental Policy Act. The original SFAR 71 established procedural, operational, and equipment safety requirements for air tour aircraft in the state of Hawaii. This proposal would maintain the same requirements. This rulemaking will not involve any significant impacts to the human environment and the FAA has determined that there are no extraordinary circumstances.

Regulatory Evaluation Summary

This regulatory evaluation estimates the benefits and costs of a proposed rule that would continue the existing safety requirements in SFAR 71 and eliminate its termination date. Currently, SFAR 71 is a final rule that will expire on October 26, 2003. Since 1994, the FAA has extended SFAR 71 for two 3-year periods. The procedural, operational, and equipment safety requirements of SFAR 71 would continue to apply to parts 91, 135, and certain 121 air tour operators in Hawaii. SFAR 71 does not apply to operations conducted under part 121 in airplanes with a passenger-seating configuration of more than 30 seats and a payload capacity of more than 7,500 pounds or to flights conducted in gliders or hot air balloons.

The FAA estimates the total cost of this proposed rule at $29.8 million or $20.9 million, discounted. The costs reflect maintenance and operating costs attributable to flotation devices and flotation gear, operating costs required for calculating helicopter performance plans and providing passenger briefing for emergency egress in the event of a water landing. Lost opportunity costs would also be incurred due to the minimum weather provisions.

The quantified monetary benefits of the proposed rule are estimated at $125.3 million. An estimated 39 fatalities would be avoided, if the rule were 100 percent effective and the rule would have to be less than 23 percent effective for the cost per fatality avoided to exceed the benchmark value of $3.0 million.

The FAA has determined that the benefits of the proposed rule would exceed the cost. The rule would not impact on international trade because the affected operators do not compete with foreign operators. The rule would not have an unfunded mandate exceeding $100 million annually on the private sector or state, local, and tribal governments. The FAA has determined that the proposed rule would have a significant impact on a substantial number of small air tour operators.

International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

In accordance with the above statute, the FAA has assessed the potential effect of this proposed rule and has determined that it would have only a domestic impact and therefore no affect on any trade-sensitive activity.

Paperwork Reduction Act

SFAR 71 contains information collection requirements. Those same requirements apply to this extension. OMB approval (No. 2120–0620) has been extended through January 31, 2004.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.''

This proposed rule does not contain such a mandate. The requirements of Title II do not apply.

Federalism Implications

The regulations herein will not have substantial direct effects on the State, 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, the FAA certifies that this regulation will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

14 CFR Part 91

Aircraft, Airmen, Aviation safety.

14 CFR Part 121

Air carriers, Aircraft, Airmen, Aviation safety, Charter flights, Safety, Transportation.

14 CFR Part 135

Air taxi, Aircraft, Airmen, Aviation safety.

The Amendment

The Federal Aviation Administration proposes to amend 14 CFR parts 91, 121, and 135 as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46502, 46504, 46506–46507, 47122, 47508, 47528–47531.

PART 121—OPERATING REQUIREMENTS: DOMESTIC FLAG, AND SUPPLEMENTAL OPERATIONS

2. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44901, 44903–44904, 44912, 46105.

3. Add SFAR No. 71 to part 121.

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON-DEMAND OPERATIONS

4. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

5. In parts 91, 121, and 135, SFAR NO. 71—Special Operating Rules For Air Tour Operators In The State of Hawaii, Section 8 is revised to read as follows:

SFAR NO. 71—Special Operating Rules for Air Tour Operators in the State of Hawaii

* * * * *

Section 8. *Termination date.* This SFAR NO. 71 shall remain in effect until further notice.

Issued in Washington, DC on August 4, 2003.

John M. Allen,

Acting Director, Flight Standards Service.

[FR Doc. 03–20277 Filed 8–5–03; 4:47 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. 2003N–0324]

New Animal Drugs; Removal of Obsolete and Redundant Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing removal of regulations that exempted certain new animal drugs administered in feed from batch certification requirements. FDA is also proposing removal of regulations that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofuran, and sulfonamide drugs administered in animal feed. The intended effect of this proposed rule is to remove regulations that are obsolete or redundant. Some of the products and combination uses subject to the listings in these regulations are subject to a notice of findings of effectiveness and an opportunity for hearing published elsewhere in this issue of the **Federal Register**. One approved product subject to the regulations proposed for removal is being codified elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the proposed rule by November 6, 2003.

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/ecomments*.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–1), 7519 Standish Pl., Rockville, MD 20855, 301–827–2954, e-mail: *abeaulie@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, the agency is announcing the effective conditions of use for some of the products or use combinations subject to the listings in parts 510 and 558 (21 CFR part 510 and 558), specifically, §§ 510.515 and/or 558.15, and the agency is proposing to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. One approved product subject to § 558.15 is being codified in part 558, subpart B in a final rule published elsewhere in this issue of the **Federal Register**. Concurrent with that announcement and final rule, the agency is proposing to remove these two sections of the Code of Federal Regulations (§§ 510.515 and 558.15) for the reasons described in sections II and III of this document.

II. Part 510, Subpart F Animal Use Exemptions From Certification and Labeling Requirements and § 510.515 Animal Feeds Bearing or Containing New Animal Drugs Subject to the Provisions of Section 512(n) of the Act

A. History of Part 510, Subpart F and § 510.515

In 1945, Congress added section 507 to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) requiring the agency to provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin (Public Law 79–139, 59 Stat. 463). No distinction was made