

of the modification of the nacelle strut and wing structure required by this paragraph.

(b) Perform the inspections and checks specified in paragraph III, NOTES 8, 9, 10, and 11 of the Accomplishment Instructions on page 129 of Boeing Alert Service Bulletin

747-54A2158, dated November 30, 1994, concurrently with the modification of the nacelle strut and wing structure required by paragraph (a) of this AD. Prior to further flight, correct any discrepancies found in accordance with the alert service bulletin.

(c) Accomplishment of the modification of the nacelle strut and wing structure in accordance with Boeing Alert Service Bulletin 747-54A2158, dated November 30, 1994, constitutes terminating action for the inspections required by the following AD's:

AD No.	Amend- ment No.	Federal Register citation	Date of publication
94-22-08	39-9057	59 FR 58761	Nov. 15, 1994.
93-17-07	39-8678	58 FR 45827	Aug. 31, 1993.
93-03-14	39-8518	58 FR 14513	Mar. 18, 1993.
92-24-51	39-8439	57 FR 60118	Dec. 18, 1992.
90-20-20	39-6725	55 FR 37859	Sept. 14, 1990.
89-07-15	39-6167	54 FR 11693	Mar. 22, 1989.
87-04-13 R1	39-5836	53 FR 2005	Jan. 26, 1988.
86-23-01	39-5450	51 FR 37712	Oct. 24, 1986.
86-08-03	39-5289	51 FR 12836	Apr. 16, 1986.
86-07-06	39-5270	51 FR 10821	Mar. 31, 1986.
86-05-11 R1	39-5334	51 FR 21900	June 17, 1986.
80-08-02	39-3738	45 FR 24450	Apr. 10, 1980.
79-17-07	39-3533	44 FR 50033	Aug. 27, 1979.

(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, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

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

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

(f) The modification, inspections, checks, and correction of discrepancies shall be done in accordance with Boeing Alert Service Bulletin 747-54A2158, dated November 30, 1994. 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 Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on July 28, 1995.

Issued in Renton, Washington, on June 16, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95-15299 Filed 6-27-95; 8:45 am]

BILLING CODE 4910-13-U

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94-NM-224-AD; Amendment 39-9286; AD 95-13-06]

Airworthiness Directives; Boeing Model 747 Series Airplanes Equipped With General Electric Model CF6-80C2 Series Engines or Pratt & Whitney Model PW4000 Series Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 747 series airplanes, that requires modification of the nacelle strut and wing structure, inspections and checks to detect discrepancies, and correction of discrepancies. This amendment is prompted by the development of a modification of the strut and wing structure that improves the damage tolerance capability and durability of the strut-to-wing attachments, and reduces reliance on non-routine inspections of those attachments. The actions specified by this AD are intended to prevent failure of the strut and subsequent loss of the engine.

DATES: Effective July 28, 1995.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 28, 1995.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This

information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Tim Backman, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone (206) 227-2776; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Boeing Model 747 series airplanes was published in the **Federal Register** on January 6, 1995 (60 FR 2033). That action proposed to require modification of the nacelle strut and wing structure, inspections and checks to detect discrepancies in the adjacent structure, and correction of discrepancies.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the proposed rule.

Revision of Descriptive Language

One commenter provides additional information to describe the purpose of the proposed modification of the nacelle strut and wing structure. This commenter suggests that the rule should specify that the modification not only significantly improves the load-carrying and durability of the strut-to-wing

attachments, but "reduces the reliance on non-routine inspections," as well. The FAA concurs with this suggestion and has revised the Summary section of the preamble to the final rule to include relevant wording.

This same commenter notes that the description of the unsafe condition that appeared in the Discussion section of the preamble to the notice refers to "the structural fail-safe capability of the strut-to-wing attachment." The commenter states that this description is inaccurate since it implies that the strut-to-wing attachment is inadequate.

The commenter suggests that a more accurate description would be "damage tolerance capability of the strut-to-wing attachment." The FAA acknowledges that the commenter's wording is more accurate. The pertinent wording in the preamble to the final rule has been revised to reflect this change. Furthermore, the FAA considers that the new structure of the strut meets the damage tolerance requirements of amendment 45 of section 25.571, "Damage—tolerance and fatigue evaluation of structure," of the Federal Aviation Regulations (14 CFR 25.571, amendment 45), which provides an even higher level of safety than simply fail-safe requirements.

This commenter also provides further clarification of the description of the requirements of the existing AD's that address unsafe conditions associated with the strut attachment assemblies on Model 747 series airplanes equipped with General Electric Model CF6-80C2 series engines or Pratt & Whitney Model PW4000 series engines. The description in the Discussion section of the preamble to the proposal states that the existing AD's require "inspection of the strut, midspan fittings, diagonal brace, and midspan fuse pins." The commenter states that a more complete description of the existing AD's would be "inspection of the strut midspan fittings, spring beam lugs, diagonal brace, and midspan fuse pins." The FAA acknowledges that the commenter's description of the requirements of the existing AD's is more succinct. However, since the Discussion section is not restated in this final rule, no change to the final rule is necessary.

Further, this commenter states that the description of the modification that appeared in the Explanation of Service Information section of the preamble to the proposal is detailed differently from the wording that appears in the alert service bulletin that is referenced in the proposal as the appropriate source of service information. The FAA acknowledges that paragraph I.C., Description, on page 6 of Boeing Alert

Service Bulletin 747-54A2156, dated December 15, 1994, provides another description of the actions involved in accomplishing the subject modification. However, although the service bulletin's description is worded somewhat differently, its intent is comparable to and consistent with the description that appeared in the preamble to the proposal.

Clarification of Note 1

One commenter requests that Note 1 of the proposal be clarified since it is too vague to determine exactly when FAA approval of alternative methods of compliance (AMOC) is necessary. The FAA concurs. Although every effort is made to keep the language simple and clear, it is apparent that some additional explanation is necessary to clarify the intent of Note 1. Performance of the requirements of this final rule is "affected" if an operator is unable to perform those requirements in the manner described in this AD. For example, if an AD requires a visual inspection in accordance with a certain service bulletin, and the operator cannot perform that inspection because of the placement of a repair doubler over the structure to be inspected, then "performance of the AD is affected."

In addition, performance of the requirements of an AD is "affected" if it is physically possible to perform the requirements, but the results achieved are different from those specified in the AD. For example, if the AD requires an NDT inspection in accordance with a certain service bulletin, and the operator is able to move the NDT probe over the specified area in the specified manner, but the results are either meaningless or inaccurate because of the repair doubler over that area, then "performance of the AD is affected."

While Note 1 itself is not capable of addressing every possible situation, "affected" is normally an easy standard to apply: either it is possible to perform the requirements as specified in the AD and achieve the specified results, or it is not possible. Therefore, if the requirements of this AD cannot be performed, then operators must submit a request for an approval of an AMOC from the FAA, in accordance with the provision of paragraph (d) of this final rule.

Accomplishment of any modification requirement of an AD, such as the modification of the nacelle strut and wing structure required by this final rule, does not "affect performance of the AD;" it is performance of the AD. Every AD includes a provision, with which operators are familiar, that states, "Compliance required as indicated,

unless accomplished previously." If an operator performs such a requirement before the AD is issued, the FAA is confident that the operator will recognize that it has already complied with the AD and no further action (including obtaining approval of an AMOC) is required. This is consistent with current law and practice, which Note 1 is not intended to change.

Compliance Time for Modification

One commenter requests that the compliance time of proposed paragraph (a), which requires modification of the nacelle strut and wing structure, be extended by 4 months. The commenter notes that a 4-month extension of the compliance time would coincide with the time recommended in the referenced Boeing Alert Service Bulletin 747-54A2156 for that modification. Further, this commenter alleges that a difference of 4 months will "significantly impact" its operations.

The FAA does not concur with the commenter's request. In developing an appropriate compliance time for this action, the FAA considered not only the degree of urgency associated with addressing the subject unsafe condition, but the manufacturer's recommendation as to an appropriate compliance time, the availability of required parts, and the practical aspect of installing the required modification within a maximum interval of time allowable for all affected airplanes to continue to operate without compromising safety. Further, the FAA took into account the 7-year compliance time recommended by the manufacturer, as well as the number of days required for the rulemaking process; in consideration of these factors, the FAA finds that 80 months after the effective date of this final rule will fall approximately at the same time for compliance as recommended by the manufacturer.

However, under the provisions of paragraph (b) of the final rule, any operator may submit requests for adjustments to the compliance time along with data demonstrating that such requests will not compromise safety. In evaluating such requests for adjustments to the compliance time, the FAA will closely examine the operator's explanation of why an extension is needed. The FAA will also consider the operator's good faith attempt at complying within the compliance time contained in this final rule, which can be demonstrated by accomplishing the modification on a significant percentage of the airplanes in the operator's fleet prior to submitting a request for adjustment to the compliance time. The FAA will take into consideration the

number of airplanes in the operator's fleet on which the modification has been accomplished and the number of unmodified airplanes remaining in the operator's fleet. Additionally the operator would be asked to submit a schedule for accomplishing the modification on the airplanes remaining in its fleet.

Requirements Redundant to Part 121

One commenter requests that proposed paragraph (b) be deleted since the proposed inspection and repair of components (referenced in Notes 8, 9, and 10 of the Accomplishment Instructions on page 91 of Boeing Alert Service Bulletin 747-54A2156, dated December 15, 1994) are redundant to the requirements of part 121 of the Federal Aviation Regulations (14 CFR 121).

The FAA does not concur with the commenter that the requirements of paragraph (b) should be deleted from the final rule. According to section 39.1 of the Federal Aviation Regulations (14 CFR 39.1), the issuance of an AD is based on the finding that an unsafe condition exists or is likely to develop in aircraft of a particular type design.

Further, it is within the FAA's authority to issue an AD to require actions to address unsafe conditions that are not otherwise being addressed (or addressed inadequately) by normal maintenance procedures. The FAA points out that fatigue cracking and corrosion in the strut-to-wing attachments have resulted in several incidents and catastrophic accidents. Although 14 CFR 121 addresses damage found on components during other maintenance activities, the FAA has determined that the catastrophic consequences of the unsafe condition are such that reiterating the necessity of performing inspections and repairs when any damage or corrosion is found while performing the modification of the nacelle strut and wing structure is warranted and necessary. The AD is the appropriate vehicle for mandating such actions.

Clarification of Note 11 in the Alert Service Bulletin

This same commenter also notes that a torque check would be more appropriate to detect loose fasteners of the diagonal brace fittings (referenced in Note 11 of the alert service bulletin). Further, the commenter asserts that these torque checks should be accomplished in accordance with the actual Accomplishment Instructions of the Boeing Alert Service Bulletin 747-54A2156, rather than in accordance with a Note that precedes the actual

Accomplishment Instructions as stated in proposed paragraph (b).

The FAA concurs that a torque check would be more appropriate to detect loose fasteners. The FAA's intent was to require a torque check and the follow-on corrective action indicated in Note 11 of the alert service bulletin. Obviously, the torque check was inadvertently omitted from that version of the alert service bulletin; however, the follow-on action to "torque any loose fasteners" was included in that version of the alert service bulletin. The manufacturer has notified the FAA that Revision 1 of the alert service bulletin, planned for release later this year, will correct this omission. However, the FAA does not consider that delaying this action until after the release of the revision of the service bulletin is warranted. Therefore, paragraph (b) of the final rule has been revised to clarify that a torque check must be performed to detect loose fasteners.

Clarification of Cost Estimate Information

One commenter requests that the cost estimate be revised to include the cost of out-of-service time for each aircraft during the time that the modification is accomplished, and the additional fuel costs that would be incurred due to the additional weight added to each aircraft by the modification hardware. Another commenter, Boeing, requests that the cost estimate be revised to indicate that it will absorb the cost of labor to accomplish the proposed modification of the nacelle strut and wing structure. However, the commenter states that any costs in excess of those quoted in Boeing Alert Service Bulletin 747-54A2156, dated December 15, 1994, will be borne by the operator.

The FAA concurs that a revision to the cost estimate is necessary to remove the labor costs that the manufacturer will incur; therefore, the economic impact information, below, has been revised accordingly. However, the FAA does not concur that a revision is necessary to include the costs for out-of-service time or the costs for additional fuel. The appropriate number of hours required to accomplish the required actions, specified as 6,253 work hours in the economic impact information, below, was developed with data provided by the manufacturer.

Note: The manufacturer has informed the FAA that it will incur labor costs up to a maximum of 6,253 work hours.

This number represents the time required to gain access, remove parts, inspect, modify, install, and close up. The cost analysis in AD rulemaking

actions typically does not include out-of-service time for each aircraft or additional fuel costs, as was suggested by the commenter. These costs would be impossible to calculate accurately due to the differences in out-of-service time for each operator. Furthermore, the increase in fuel costs due to the weight added by the modification, would vary greatly from operator to operator, depending upon airplane utilization.

The Air Transport Association of America (ATA) requests that the FAA include costs "beyond just parts and labor costs" when calculating the estimated costs to accomplish the proposed actions. The ATA points out that the FAA should consider such costs to avoid requiring actions that the ATA considers inconsequential.

The FAA does not concur. Contrary to the ATA's assertion, in establishing the requirements of all AD's, the FAA does consider cost impact to operators beyond the estimates of parts and labor costs contained in AD preambles. For example, where safety considerations allow, the FAA attempts to impose compliance times that generally coincide with operator's maintenance schedules. However, because operators' schedules vary substantially, the FAA is unable to accommodate every operator's optimal scheduling in each AD. Each AD does allow individual operators to obtain approval for extensions of compliance times, based on a showing that the extension will not affect safety adversely. Therefore, the FAA does not consider it appropriate to attribute to the AD, the costs associated with the type of special scheduling that might otherwise be required.

Furthermore, because the FAA generally attempts to impose compliance times that coincide with operator's scheduled maintenance, the FAA considers it inappropriate to attribute the costs associated with aircraft "downtime" to the cost of the AD, because, normally, compliance with the AD will not necessitate any additional downtime beyond that of a regularly scheduled maintenance hold. Even if, in some cases, additional downtime is necessary for some airplanes, the FAA does not possess sufficient information to evaluate the number of airplanes that may be so affected or the amount of additional downtime that may be required. Therefore, attempting to estimate such costs would be futile.

The FAA points out that this AD is an excellent example of the fact that costs to operators are fully considered beginning at the earliest possible stages of AD development. In this case, the alert service bulletin that is referenced

in this final rule was developed by Boeing only after extensive and detailed consultations with large numbers of operators of Model 747 series airplanes. The compliance times and various optional means of compliance presented in his AD are based on those consultations, and were developed in order to minimize the economic impacts on operators to the extent possible consistent with the service bulletin's and this AD's safety objectives. Therefore, the costs that the ATA asserts were not considered by the FAA have, in fact, been a major consideration throughout this AD process; the fact that the FAA has not attempted to quantify speculative costs does not diminish the extent of this consideration.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 257 Model 747 series airplanes equipped with General Electric Model CF6-80C2 series engines or Pratt & Whitney Model PW4000 series engines of the affected design in the worldwide fleet. The FAA estimates that 36 airplanes of U.S. registry will be affected by this AD.

The full strut modification required by this AD will take approximately 6,253 work hours per airplane to accomplish, at an average labor cost of \$60 per work hour. The manufacturer will incur the cost of labor up to a maximum of 6,253 work hours per airplane. However, if the operator exceeds 6,253 work hours to accomplish the modification, the additional labor costs must be borne by the operator. The FAA does not have the ability to predict those additional work hours for operators to accomplish the modification. Therefore, attempting to estimate such costs would be futile. Required parts will be supplied by the manufacturer at no cost to the operators. Based on the above data, the requirements of this AD may have no cost impact to U.S. operators.

However, the cost impact, above, does not reflect the cost of the terminating actions described in the service bulletins listed in paragraph I.C., Table 2, "Prior or Concurrent Service Bulletins," on page 7 of Boeing Alert Service Bulletin 747-54A2156, dated

December 15, 1994, that are required to be accomplished prior to, or concurrently with, the modification of the nacelle strut and wing structure. Since some operators may have accomplished certain modifications on some or all of the airplanes in its fleet, while other operators may not have accomplished any of the modifications on any of the airplanes in its fleet, the FAA is unable to provide a reasonable estimate of the cost of accomplishing the terminating actions described in the service bulletins listed in Table 2 of the Boeing alert service bulletin.

Regulatory Impact

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 Federal 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) 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 final evaluation has been prepared for this action and it is contained in the Rule Docket. A copy of it 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 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

95-13-06 Boeing: Amendment 39-9286. Docket 94-NM-224-AD.

Applicability: Model 747 series airplanes having line positions 679 through 1046 inclusive, equipped with General Electric Model CF6-80C2 series engines or Pratt & Whitney Model PW4000 series engines; 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 use the authority provided in paragraph (d) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the strut and subsequent loss of the engine, accomplish the following:

(a) Within 80 months after the effective date of this AD, accomplish the modification of the nacelle strut and wing structure in accordance with Boeing Alert Service Bulletin 747-54A2156, dated December 15, 1994. All of the terminating actions described in the service bulletins listed in paragraph I.C., Table 2, "Prior or Concurrent Service Bulletins," on page 7 of Boeing Alert Service Bulletin 747-54A2156, dated December 15, 1994, must be accomplished in accordance with those service bulletins prior to, or concurrently with, the accomplishment of the modification of the nacelle strut and wing structure required by this paragraph.

(b) Perform the inspections and checks (including a torque check to detect loose fasteners) specified in paragraph III, Notes 8, 9, 10, and 11 of the Accomplishment Instructions on page 91 of Boeing Alert Service Bulletin 747-54A2156, dated December 15, 1994, concurrently with the modification of the nacelle strut and wing structure required by paragraph (a) of this AD. Prior to further flight, correct any discrepancies in accordance with the alert service bulletin.

(c) Accomplishment of the modification of the nacelle strut and wing structure in accordance with Boeing Alert Service Bulletin 747-54A2156, dated December 15, 1994, constitutes terminating action for the inspections required by the following AD's:

AD No.	Amendment No.	Federal Register citation	Date of publication
93-17-07	39-8678	58 FR 45827.	Aug. 31, 1993.
93-03-14	39-8518	58 FR 14513.	Mar. 18, 1993.
93-24-51	39-8439	57 FR 60118.	Dec. 18, 1992.

(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, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

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

(e) Special flight permits may be issued in accordance with §§ 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.

(f) The modification, inspections, checks, and correction of discrepancies shall be done in accordance with Boeing Alert Service Bulletin 747-54A2156, dated December 15, 1994. 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 Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on July 28, 1995.

Issued in Renton, Washington, on June 16, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95-15300 Filed 6-27-95; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Nicarbazin Type A Medicated Article

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Planalquimica Industrial Ltda. The ANADA provides for the use of a nicarbazin-containing Type A medicated article in making Type C medicated chicken feeds for the prevention of coccidiosis.

EFFECTIVE DATE: June 28, 1995.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION:

Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053-120, Campinas, Sao Paulo, Brazil, has filed ANADA 200-027, which provides for the use of a nicarbazin-containing Type A medicated article in making Type C medicated chicken feeds as an aid in preventing outbreaks of cecal and intestinal coccidiosis.

Planalquimica's ANADA 200-027 for a 113.5-gram-per-pound nicarbazin Type A medicated article (Nicarmix) is approved as a generic copy of Merck Research Laboratories' NADA 9-476 for Nicarb®. The ANADA is approved as of June 28, 1995, and the regulations are amended in 21 CFR 510.600(c) and 558.366(a) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen

in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Planalquimica Industrial Ltda." and in the table in paragraph (c)(2) by numerically adding a new entry for "060728" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *