

1999; and Table I, page 12 of Boeing Process Specification BAC 5946, Revision (AA), dated July 9, 2001.

(1) If no ribs are made from 7079-T6 material, no further action is required by this AD.

(2) If any ribs are made from 7079-T6 material, do paragraph (b) of this AD.

Follow-on Repetitive Inspections

(b) At the applicable times specified in paragraph (b)(1) or (b)(2) of this AD: Perform a detailed inspection for corrosion or cracking of all elevator hinge support ribs made from 7079-T6 material, according to Boeing Alert Service Bulletin 727-55A0091, including Appendix A, dated August 16, 2001.

Note 2: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

(1) For airplanes with no more than one elevator hinge support rib made of 7079-T6 material on each side of the horizontal stabilizer: Do the initial inspection for cracking or stress corrosion within 18 months after the effective date of this AD, and repeat this inspection every 18 months, until paragraph (d) of this AD has been done.

(2) For airplanes with more than one elevator hinge support rib made of 7079-T6 material on either side of the horizontal stabilizer: Do the initial inspection for corrosion or cracking within 180 days after the effective date of this AD, and repeat this inspection every 180 days, until paragraph (d) of this AD has been done.

Repair

(c) If any corrosion or cracking is found during any inspection required by paragraph (b) of this AD: Before further flight, repair according to Boeing Alert Service Bulletin 727-55A0091, including Appendix A, dated August 16, 2001, as applicable; or according to a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or according to data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. Where applicable repair procedures are not included in the section of the Boeing Structural Repair Manual referred to in the service bulletin, and the service bulletin specifies to write to Boeing for repair instructions, repair according to a method approved by the Manager, Seattle ACO, or according to data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved as required by this paragraph, the approval letter must specifically reference this AD.

Note 3: Boeing Alert Service Bulletin 727-55A0091, including Appendix A, dated August 16, 2001, refers to Boeing 727 Structural Repair Manual Chapter 55, Subject 55-10-4, as a source of service information for repair of certain cracks.

Replacement

(d) For airplanes on which any ribs made from 7079-T6 material are found: Within 60 months after the effective date of this AD, replace all elevator hinge support ribs made from 7079-T6 material with new, improved ribs, according to a method approved by the Manager, Seattle ACO, or according to data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically reference this AD. Such replacement terminates the repetitive inspections required by paragraph (b) of this AD.

Spares

(e) After the effective date of this AD, no one may install an elevator hinge support rib made from 7079-T6 material on any airplane.

Alternative Methods of Compliance

(f) 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 ACO. 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 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(g) 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.

Incorporation by Reference

(h) Except as provided by paragraphs (c) and (d) of this AD, the actions shall be done in accordance with Part 6, Section 51-00-00, Figure 20, of Boeing Document D6-48875, Boeing 727 Non Destructive Test Manual, dated December 5, 1999; Table I, page 12 of Boeing Process Specification BAC 5946, Revision (AA), dated July 9, 2001; and Boeing Alert Service Bulletin 727-55A0091, including Appendix A, dated August 16, 2001; as applicable. Boeing Document D6-48875, Boeing 727 Non Destructive Test Manual, contains the following list of effective pages:

Page title and number	Date shown on page
List of Effective Pages Pages 1, 2, 2A	April 5, 2002

Boeing Process Specification BAC 5946 contains the following list of effective pages:

Page number	Revision level shown on page	Date shown on page
Contents Pages 2, 3	(AA)	July 9, 2001

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 Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. 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.

Effective Date

(i) This amendment becomes effective on July 31, 2002.

Issued in Renton, Washington, on June 12, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02-15366 Filed 6-25-02; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001-NM-69-AD; Amendment 39-12783; AD 2002-12-11]

RIN 2120-AA64

Airworthiness Directives; Bombardier Model DHC-8-100, -200, and -300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Bombardier Model DHC-8-100, -200, and -300 series airplanes, that requires revision of the applicable maintenance program manual, repetitive inspections for corrosion or cracking of the hook roller shafts of the flap carriage, and eventual replacement of the hook roller shafts with new or serviceable hook roller shafts. This replacement extends the interval for the repetitive inspections. This action is necessary to prevent cracking of the hook roller shafts of the flap carriage and consequent reduced structural integrity of the flap, which could result in jamming of the flap. This

action is intended to address the identified unsafe condition.

DATES: Effective July 31, 2002.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 31, 2002.

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. 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 FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Parrillo, Aerospace Engineer, Airframe and Propulsion Branch, ANE-172, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256-7505; fax (516) 568-2716.

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 Bombardier Model DHC-8-100, -200, and -300 series airplanes was published in the **Federal Register** on March 21, 2002 (67 FR 13108). That action proposed to require revision of the applicable maintenance program manual; repetitive inspections for corrosion or cracking of the hook roller shafts of the flap carriage; and eventual replacement of the hook roller shafts with new or serviceable hook roller shafts, which would extend the interval for the repetitive inspections.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Explanation of Change to Final Rule

The FAA has revised paragraph (a) of the final rule to clarify that the maintenance manual revision must be accomplished according to the applicable temporary revision listed in paragraph (a)(1), (a)(2), or (a)(3) of the AD.

Conclusion

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

Cost Impact

The FAA estimates that 183 airplanes of U.S. registry will be affected by this AD.

It will take approximately 4 work hours per airplane to accomplish the required inspection, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the required inspection on U.S. operators is estimated to be \$43,920, or \$240 per airplane, per inspection cycle.

It will take approximately 4 work hours per airplane to accomplish the required replacement, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$460 per airplane. Based on these figures, the cost impact of the required replacement on U.S. operators is estimated to be \$128,100, or \$700 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect 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, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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 Rules 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. 106(g), 40113, 44701.

§ 39.13 [Amended]

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

2002-12-11 Bombardier, Inc. (Formerly de Havilland, Inc.): Amendment 39-12783. Docket 2001-NM-69-AD.

Applicability: Model DHC-8-100, -200, and -300 series airplanes; serial numbers 3 through 555 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent cracking of the hook roller shafts of the flap carriage and consequent reduced structural integrity of the flap, which could result in jamming of the flap, accomplish the following:

Revision of Maintenance Program Manual

(a) Within 30 days after the effective date of this AD, accomplish paragraph (a)(1), (a)(2), or (a)(3) of this AD according to the service information specified, as applicable.

(1) For Model DHC-8-100 series airplanes: Insert de Havilland Inc. Dash 8 Airworthiness Limitations List Temporary Revisions (TRs) AWL-75 and AWL-76, both dated July 14, 2000, into de Havilland Inc. Dash 8 Series 100 Maintenance Program Manual PSM 1-8-7.

(2) For Model DHC-8-200 series airplanes: Insert de Havilland Inc. Airworthiness Limitations List TR AWL 2-19, dated July 14, 2000, into de Havilland Inc. Dash 8 Series 200 Maintenance Program Manual PSM 1-82-7.

(3) For Model DHC-8-300 series airplanes: Insert de Havilland Inc. Airworthiness Limitations List TR AWL 3-83, dated July 14, 2000, into de Havilland Inc. Dash 8 Series 300 Maintenance Program Manual PSM 1-83-7.

Repetitive Inspections

(b) Do a detailed inspection for corrosion or cracking of the hook roller shafts of the flap carriage, at the times specified in paragraph (b)(1), (b)(2), or (b)(3) of this AD, as applicable; and according to the service information in paragraph (b)(1), (b)(2), or (b)(3) of this AD, as applicable.

Note 2: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

(1) For Model DHC-8-100 series airplanes: For Pre Mod 8Q101103 roller shafts having part number (P/N) 85750362-103 or 85750362-105, do the initial inspection at the compliance time specified in the "Threshold" column of the table in de Havilland Inc. Airworthiness Limitations List TRs AWL-75 and AWL-76, both dated July 14, 2000, or within 12 months after the effective date of this AD, whichever occurs later; according to de Havilland Inc. Dash 8 Series 100 Maintenance Program Manual PSM 1-8-7. Thereafter, repeat the inspection at the applicable interval specified in the "Initial Interval" column of the table in TR AWL-75 and AWL-76, until the airplane reaches the applicable threshold listed in the "Repeat Cut-In" column of the table in TR AWL-75 and AWL-76. Thereafter, repeat the inspections at the applicable interval listed in the "Repeat Interval" column of the table in TR AWL-75 and AWL-76, until paragraph (c) of this AD has been accomplished on all affected hook roller shafts. Where the TR specifies compliance intervals in "flights," for the purposes of this AD, "flights" means "flight cycles."

(2) For Model DHC-8-200 series airplanes: For Pre Mod 8Q101103 hook roller shafts having part number (P/N) 85750362-103 or 85750362-105, do the initial inspection at the compliance time specified in the "Threshold" column of the table in de Havilland Inc. Airworthiness Limitations List TR AWL 2-19, dated July 14, 2000, or within 12 months after the effective date of this AD,

whichever occurs later; according to de Havilland Inc. Dash 8 Series 200 Maintenance Program Manual PSM 1-82-7. Thereafter, repeat the inspection at the applicable interval specified in the "Initial Interval" column of the table in TR AWL 2-19, until the airplane reaches the applicable threshold listed in the "Repeat Cut-In" column of the table in TR AWL 2-19. Thereafter, repeat the inspections at the applicable interval listed in the "Repeat Interval" column of the table in TR AWL 2-19, until paragraph (c) of this AD has been accomplished on all affected hook roller shafts. Where the TR specifies compliance intervals in "flights," for the purposes of this AD, "flights" means "flight cycles."

(3) For Model DHC-8-300 series airplanes: For Pre Mod 8Q101103 hook roller shafts having part number (P/N) 85750362-103 or 85750362-105, do the initial inspection at the compliance time specified in the "Threshold" column of the table in de Havilland Inc. Airworthiness Limitations List TR AWL 3-83, or within 12 months after the effective date of this AD, whichever occurs later; according to de Havilland Inc. Dash 8 Series 300 Maintenance Program Manual PSM 1-83-7, dated July 14, 2000. Thereafter, repeat the inspection at the applicable interval specified in the "Initial Interval" column of the table in TR AWL 3-83, until the airplane reaches the applicable threshold listed in the "Repeat Cut-In" column of the table in TR AWL 3-83. Thereafter, repeat the inspections at the applicable interval listed in the "Repeat Interval" column of the table in TR AWL 3-83 until paragraph (c) of this AD has been accomplished on all affected hook roller shafts. Where the TR specifies compliance intervals in "flights," for the purposes of this AD, "flights" means "flight cycles."

Replacement

(c) At the applicable time specified in paragraph (c)(1) or (c)(2) of this AD, replace hook roller shafts having P/N 85750362-103 or 85750362-105 with new or serviceable hook roller shafts having P/N 85750362-107, according to Sections 57-50-44 and 57-50-53 of the de Havilland Inc. Dash 8 Aircraft Maintenance Manual, as applicable. Replacement of all hook roller shafts, P/N 85750362-103 or 85750362-105, with new hook roller shafts, P/N 85750362-107, ends the repetitive inspections at the intervals required by paragraph (b) of this AD.

(1) For hook roller shafts on which any corrosion or crack is found during any inspection per paragraph (b) of this AD: Do the replacement before further flight.

(2) For uncracked or uncorroded hook roller shafts: Do the replacement within 20,000 flight cycles or 5 years after the effective date of this AD, whichever is first.

Post-Replacement Inspections

(d) Following the replacement of hook roller shafts according to paragraph (c) of this AD, do the Structural Inspection Program for the hook roller shafts of the flap carriage, as specified in paragraph (d)(1), (d)(2), or (d)(3) of this AD, as applicable.

(1) For Model DHC-8-100 series airplanes: Using the criteria for Mod 8Q101103 hook

roller shafts having P/N 85750362-107, do the initial inspection at the compliance time specified in the "Threshold" column of the table in de Havilland Inc. Airworthiness Limitations List TR AWL-75 and AWL-76, both dated July 14, 2000, according to de Havilland Inc. Dash 8 Series 100 Maintenance Program Manual PSM 1-8-7. Thereafter, repeat the inspection at the applicable interval specified in the "Initial Interval" column of the table in TRs AWL-75 and AWL-76, until the airplane reaches the applicable threshold listed in the "Repeat Cut-In" column of the table in TRs AWL-75 and AWL-76. Thereafter, repeat the inspections at the applicable interval listed in the "Repeat Interval" column of the table in TRs AWL-75 and AWL-76. Where the TR specifies compliance intervals in "flights," for the purposes of this AD, "flights" means "flight cycles."

(2) For Model DHC-8-200 series airplanes: Using the criteria for Mod 8Q101103 hook roller shafts having P/N 85750362-107, do the initial inspection at the compliance time specified in the "Threshold" column of the table in de Havilland Inc. Airworthiness Limitations List TR AWL 2-19, dated July 14, 2000, according to de Havilland Inc. Dash 8 Series 200 Maintenance Program Manual PSM 1-82-7. Thereafter, repeat the inspection at the applicable interval specified in the "Initial Interval" column of the table in TR AWL 2-19, until the airplane reaches the applicable threshold listed in the "Repeat Cut-In" column of the table in TR AWL 2-19. Thereafter, repeat the inspections at the applicable interval listed in the "Repeat Interval" column of the table in TR AWL 2-19. Where the TR specifies compliance intervals in "flights," for the purposes of this AD, "flights" means "flight cycles."

(3) For Model DHC-8-300 series airplanes: Using the criteria for Mod 8Q101103 hook roller shafts having P/N 85750362-107, do the initial inspection at the compliance time specified in the "Threshold" column of the table in de Havilland Inc. Airworthiness Limitations List TR AWL 3-83, dated July 14, 2000, according to de Havilland Inc. Dash 8 Series 300 Maintenance Program Manual PSM 1-83-7. Thereafter, repeat the inspection at the applicable interval specified in the "Initial Interval" column of the table in TR AWL 3-83, until the airplane reaches the applicable threshold listed in the "Repeat Cut-In" column of the table in TR AWL 3-83. Thereafter, repeat the inspections at the applicable interval listed in the "Repeat Interval" column of the table in TR AWL 3-83. Where the TR specifies compliance intervals in "flights," for the purposes of this AD, "flights" means "flight cycles."

Alternative Methods of Compliance

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

Note 3: Information concerning the existence of approved alternative methods of

compliance with this AD, if any, may be obtained from the New York ACO.

Special Flight Permits

(f) 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.

Incorporation by Reference

(g) The maintenance program manual revision shall be done in accordance with de Havilland Inc. Dash 8 Airworthiness Limitations List Temporary Revision AWL-75, dated July 14, 2000; de Havilland Inc. Dash 8 Airworthiness Limitations List Temporary Revision AWL-76, dated July 14, 2000; de Havilland Inc. Airworthiness Limitations List Temporary Revision AWL 2-19, dated July 14, 2000; and de Havilland Inc. Airworthiness Limitations List Temporary Revision AWL 3-83, dated July 14, 2000; as applicable. 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 Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in Canadian airworthiness directive CF-1999-10R2, dated September 12, 2000.

Effective Date

(h) This amendment becomes effective on July 31, 2002.

Issued in Renton, Washington, on June 7, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02-15367 Filed 6-25-02; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket Nos. 76N-0080 and 00N-1610]

RIN 0910-AC12

Digoxin Products for Oral Use; Revocation of Conditions for Marketing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking the regulation establishing conditions for marketing digoxin products for oral use. This regulation is no longer necessary because the products, which are new drugs, can be regulated under the approval process for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) as set forth in the Federal Food, Drug, and Cosmetic Act (the act).

DATES: This rule is effective July 26, 2002. FDA does not plan to take regulatory action against currently marketed unapproved digoxin elixir products before June 28, 2004. Any unapproved digoxin elixir introduced after June 26, 2002, will be subject to regulatory action on July 26, 2002. Any unapproved digoxin tablet will be subject to regulatory action on July 26, 2002.

FOR FURTHER INFORMATION CONTACT:

Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 24, 2000 (65 FR 70538), FDA proposed to revoke § 310.500 (21 CFR 310.500), which established conditions for marketing digoxin products for oral use (tablets and elixir). The regulation: (1) Declared all digoxin products for oral use (tablets and elixir) to be new drugs, (2) required submission of ANDAs and bioavailability tests for all oral digoxin products (the requirement for the submission of ANDAs was stayed indefinitely (41 FR 43135, September 30, 1976)), (3) required a mandatory FDA certification program for digoxin tablets based on dissolution testing by the National Center for Drug Analysis, (4) required a recall of any previously marketed batch of digoxin tablets found to fail United States Pharmacopeia (USP) dissolution specifications, and (5) set forth a labeling requirement for all oral digoxin products.

In the preamble to the proposed rule, FDA described actions that have occurred since § 310.500 was published that render the regulation unnecessary. The agency discussed the 1997 approval of NDA 20-405 for Lanoxin (digoxin) Tablets and described the indications for the tablets, which differ from the indications for oral digoxin drug products set forth in § 310.500. The agency explained that because of the approval of NDA 20-405, digoxin tablets are now eligible for ANDAs

under section 505 of the act (21 U.S.C. 355).

The agency also noted that the dissolution requirements specified in § 310.500 are no longer used as standards in the certification program and are therefore obsolete. The agency concluded that regulation of these products under batch certification was no longer warranted.

The proposed rule referenced a companion notice published elsewhere in the **Federal Register** of November 24, 2000 (65 FR 70573), reaffirming the new drug status of oral digoxin products and requiring approved applications for marketing. In that notice, FDA lifted the stay for submitting ANDAs for digoxin products for oral use.

II. Comments and the Agency's Response

Interested persons were given until February 22, 2001, to submit comments on the proposal. FDA received comments from four manufacturers of drug products subject to the proposal.

(Comment 1) Three of the four submitted comments agreed that the agency should revoke § 310.500. One comment identified several public health reasons to revoke § 310.500. Those reasons are described in section II of this document and incorporated into the agency's response to the one comment that opposed revocation of § 310.500.

A. Opposition to Proposed Rule

(Comment 2) One comment opposed the agency's proposed rule to revoke § 310.500, contending that the batch certification procedure is sufficient for FDA to regulate digoxin tablets and that the proposed rule is inadequate because FDA failed to identify a public health reason or change of facts or circumstances to justify revoking its regulation of digoxin tablets under batch certification.

FDA disagrees with this comment. The integrity of the batch certification process, the principal concern of the comment, is not the relevant issue. The relevant issue is whether the certification procedure is still warranted in light of new information or changing circumstances. FDA concludes it is not warranted and, as explained in section II of this document, has determined that revocation of § 310.500 is rationally related to FDA's statutory obligation to ensure that marketed oral digoxin drug products are safe, effective, and properly labeled as reflected by current scientific knowledge and information.

In its November 2000 proposed rule and a companion notice published in the same issue of the **Federal Register**,