Compliance: Required as indicated, unless accomplished previously.

To prevent collapse of the nose landing gear as a result of failure of the lock link bolt, accomplish the following:

(a) Within 24 months after the effective date of this AD, perform either a visual inspection or a records search to determine the serial number of the lock link bolt, part number (P/N) ACG7079–1, installed in the nose landing gear (NLG). If the visual inspection is accomplished, it must be conducted in accordance with procedures specified in McDonnell Douglas Service Bulletin DC10–32–242, dated November 1, 1995, for Model DC–10 series airplanes; or McDonnell Douglas Service Bulletin MD11–32–060, dated November 6, 1995, for Model MD–11 series airplanes.

(b) If the serial number of the lock link bolt is not AP001 through AP036 inclusive, or AP200 through AP344 inclusive: No further action is required by this AD.

(c) If the serial number of the lock link bolt is AP001 through AP036 inclusive, or AP200 through AP344 inclusive: Within 24 months after the effective date of this AD, replace the lock link bolt with a bolt, P/N ACG7079–1, that does not have one of those serial numbers.

(d) As of the effective date of this AD, no person shall install a lock link bolt, part number (P/N) ACG7079–1, having a serial number of AP001 through AP036 inclusive, or AP200 through AP344 inclusive, on any airplane.

(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, Los Angeles 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, Los Angeles ACO.

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

(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.

(g) The inspection shall be done in accordance with McDonnell Douglas Service Bulletin DC10–32–242, dated November 1, 1995, for Model DC–10 series airplanes; and McDonnell Douglas Service Bulletin MD11–32–060, dated November 6, 1995, for Model MD–11 series airplanes. 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 McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on August 13, 1996.

Issued in Renton, Washington, on June 27, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–16951 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

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14 CFR Part 39

[Docket No. 96–NM–133–AD; Amendment 39–9691; AD 96–14–07]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–11 and MD–11F Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain McDonnell Douglas Model MD–11 and MD–11F series airplanes, that currently requires repetitive inspections of the tail tank fuel pipe assembly and the associated mounting brackets in the aft fuselage compartment, and follow-on actions, if necessary. That AD also provides for an optional terminating modification for the repetitive inspections. This amendment deletes the optional terminating modification, and expands the applicability of the existing AD to include additional airplanes. This amendment is prompted by reports of cracking or bending of the fuel pipe mounting support and/or attaching bracket in the aft fuselage compartment due to a fuel pressure surge that caused repetitive loading of this area. The actions specified in this AD are intended to prevent such cracking/bending, which could expose the fuel pipe coupling O-ring. An exposed O-ring could lose its sealing effect and could allow a fuel leak in the aft fuselage compartment, which may result in a possible in-flight or ground fire.

DATES: Effective July 24, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 24, 1996.

Comments for inclusion in the Rules Docket must be received on or before September 9, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–133–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Raymond Vakili, Aerospace Engineer, Propulsion Branch, ANM–140L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5262; fax (310) 627–5210.

SUPPLEMENTARY INFORMATION: On November 4, 1991, the FAA issued AD 91–24–09, amendment 39–8095 (56 FR 61364, December 3, 1991), applicable to certain McDonnell Douglas Model MD–11 and MD–11F series airplanes. That AD requires repetitive visual inspections of the tail tank fuel pipe assembly and the associated mounting brackets located in the aft fuselage compartment to verify the correct position of the pipe flange and to detect damaged brackets. It also requires various follow-on actions, if any discrepancy is detected. That AD also provides for an optional terminating modification for the repetitive inspections. That action was prompted by a report of an uncontained fuel leak in the aft fuselage compartment on an in-service airplane, which was the result of migration of the tail tank fuel pipe assembly, and consequent exposure of the O-ring that provides the seal between the pipe assembly and the coupling shroud assembly. The actions required by that AD are intended to prevent a fuel leak in the aft fuselage compartment area, and the possibility of an in-flight or ground fire.

Actions Since Issuance of Previous Rule

Since the issuance of that AD, the FAA has received several reports of cracking or bending of the fuel pipe mounting support and/or attaching bracket at station Y=2033.750 in the aft

fuselage compartment on McDonnell Douglas Model MD–11 series airplanes. A section of the fuel pipe assembly and support bracket of some of these airplanes had been replaced in accordance with the optional terminating modification specified in AD 91–24–09. Additionally, this replacement had been accomplished during production on certain other airplanes on which these incidents occurred.

Investigation revealed that a fuel pressure surge during transfer of the tail tank fuel caused repetitive loading of the fuel pipe mounting support and/or attaching bracket, which resulted in the subject cracking/bending. Although none of the reported events have resulted in a fuel leak in the aft fuselage compartment, the FAA has determined that severe deformation of the bracket could allow the pipe to migrate, which could also expose the O-ring that provides the seal between the fuel pipe and coupling. If the O-ring is exposed, it could lose its sealing effect, and allow a fuel leak in the aft fuselage compartment, which could result in a possible in-flight or ground fire.

In light of these recent incidents, which are similar to the incident that prompted the issuance of AD 91–24–09, the FAA finds that the optional and on-condition terminating modifications (i.e., replacement of a section of the fuel pipe assembly and support bracket, an FAA-approved repair procedure, and replacement of the shroud assembly) specified in AD 91–24–09 do not adequately preclude the addressed unsafe condition identified as in-flight or ground fire. Therefore, the FAA finds that repetitive visual inspections to detect discrepancies (i.e., cracks, or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment, and to verify the correct position of the fuel pipe flange are necessary. These actions will ensure that the unsafe condition presented by fuel surge during transfer of tail tank fuel is corrected, and provide an acceptable level of safety.

Explanation of Relevant Service Information

The FAA has reviewed and approved McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. The alert service bulletin describes procedures for repetitive visual inspections to detect discrepancies (i.e., cracks, or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment; and to verify the correct position of the fuel pipe flange, and various follow-on actions. These follow-on actions include replacing the O-ring, repositioning the tail tank fuel pipe, and installing a temporary phenolic support block assembly. Installation of a phenolic support block assembly between the tail tank fuel pipe and adjoining structure as a temporary restraint will minimize the possibility of migration of the tail tank fuel pipe.

In addition, the visual inspections and certain of the follow-on actions of Alert Service Bulletin MD11–28A082 are essentially identical to those described in McDonnell Douglas MD–11 Alert Service Bulletin A28–22, Revision 4, dated September 16, 1991 (which was referenced in AD 91–24–09). However, the effectivity listing of Alert Service Bulletin MD11–28A082 includes additional airplanes that were not included in the effectivity listing of Alert Service Bulletin A28–22. These additional airplanes have been found to be subject to the addressed unsafe condition.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of this same type design, this AD supersedes AD 91–24–09 to require repetitive visual inspections to detect discrepancies (i.e., cracks or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment and to verify the correct position of the fuel pipe flange, and various follow-on actions. This AD also expands the applicability of the existing AD to include additional airplanes.

This is considered to be interim action. The manufacturer has advised that it currently is developing a modification that will positively address the unsafe condition addressed by this AD. Once this modification is developed, approved, and available, the FAA may consider additional rulemaking.

Determination of Rule's Effective Date

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 shall 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 rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–133–AD.'' The postcard will be date stamped and returned to the commenter.

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 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 that it 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 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8095 (56 FR 61364, December 3, 1991), and by adding a new airworthiness directive (AD), amendment 39–9691, to read as follows:

96–14–07 McDonnell Douglas: Amendment 39–9691, Docket 96–NM–133–AD. Supersedes AD 91–24–09, Amendment 39–8095.

Applicability: Model MD–11 and MD–11F series airplanes, manufacturer's fuselage numbers 0447 through 0599 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 the possibility of an in-flight or ground fire due to fuel leaking from the fuel pipe coupling, accomplish the following:

(a) Perform a visual inspection to detect discrepancies (i.e., cracks or deformation) of the fuel pipe of the fuel transfer system of the tail tank and associated mounting bracket located in the aft fuselage compartment; and to verify the correct position of the fuel pipe flange, in accordance with McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996; at the time specified in paragraph (a)(1) or (a)(2) of this AD, as applicable.

(1) For airplanes on which the modification specified in McDonnell Douglas Service Bulletin 28–22, dated September 24, 1991, has been accomplished; or that have been repaired in accordance with an FAA-approved repair procedure, as specified in paragraph (a)(3) of AD 91–24–09, amendment 39–8095; or on which the shroud assembly has been replaced with a serviceable part: Prior to the accumulation of 600 flight hours, or within 60 days after the effective date of this AD, whichever occurs later.

(2) For airplanes on which the modification specified in McDonnell Douglas Service Bulletin 28–22, dated September 24, 1991, has not been accomplished: Prior to the accumulation of 600 flight hours, or within 60 days since accomplishment of the last visual inspection in accordance with AD 91–24–09, whichever occurs first.

(b) *CONDITION 1.* If no discrepancy is detected during any visual inspection required by paragraph (a) of this AD, accomplish either paragraph (b)(1) or (b)(2) of this AD.

(1) *OPTION 1.* Repeat the visual inspection required by paragraph (a) of this AD thereafter at intervals not to exceed 600 flight hours or 60 days, whichever occurs later. Or

(2) *OPTION 2.* Prior to further flight, install a temporary phenolic support block assembly, shim, clamp, and bracket between the tail tank fuel pipe and station Y=2033.750 bulkhead, in accordance with Condition 1, Option 2, of McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. Within 6 months after accomplishment of this installation, perform a one-time inspection to verify the correct position of the temporary support block assembly installation in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin.

(i) If the assembly is found to be positioned properly, repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(ii) If the assembly is found to be improperly positioned, prior to further flight, reposition the fuel pipe in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin. Repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(c) *CONDITION 2.* If any discrepancy is detected, and the fuel pipe is found to be improperly positioned, but the O-ring is not exposed, during any visual inspection required by paragraph (a) of this AD, prior to further flight, accomplish either paragraph (c)(1) or (c)(2) of this AD.

(1) *OPTION 1.* Repeat the visual inspection in paragraph (a) of this AD thereafter at intervals not to exceed 600 flight hours or 60 days, whichever occurs later. Or

(2) *OPTION 2.* Prior to further flight, install a temporary phenolic support block assembly, shim, clamp, and bracket between the tail tank fuel pipe and station Y=2033.750 bulkhead; and reposition the fuel pipe assembly, as applicable; in accordance with Condition 2, Option 2, of McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. Within 6 months after accomplishment of this installation, perform a one-time inspection to verify the correct position of the temporary support block assembly installation in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin.

(i) If the assembly is found to be positioned properly, repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(ii) If the assembly is found to be improperly positioned, prior to further flight, reposition the fuel pipe in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin. Repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(d) *CONDITION 3.* If any discrepancy is detected, and the fuel pipe is found to be improperly positioned, and the O-ring is exposed, during any visual inspection required by paragraph (a) of this AD, prior to further flight, replace the O-ring with a new O-ring, and install a temporary phenolic support block assembly, shim, clamp, and bracket between the tail tank fuel pipe and station Y=2033.750 bulkhead, in accordance with McDonnell Douglas Alert Service Bulletin MD11–28A082, dated May 14, 1996. Within 6 months after accomplishment of the replacement and installation, perform a one-time inspection to verify the correct position of the temporary support block assembly installation in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin.

(1) If the assembly is found to be positioned properly, repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(2) If the assembly is found to be improperly positioned, prior to further flight, reposition the fuel pipe in accordance with Figure 2 (Sheet 2 of 3) of the alert service bulletin. Repeat the verification of the correct position of the fuel pipe flange, as specified in paragraph (a) of this AD, thereafter at intervals not to exceed 15 months.

(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, Los Angeles 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, Los Angeles ACO.

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

(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.

(g) The actions shall be done in accordance with McDonnell Douglas Alert Service

Bulletin MD11–28A082, dated May 14, 1996. 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 McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on July 24, 1996.

Issued in Renton, Washington, on July 1, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–17217 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Chlortetracycline

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 five supplemental new animal drug applications (NADA's) filed by Hoffmann-LaRoche, Inc., Pfizer, Inc., ALPHARMA, Inc., ADM Animal Health & Nutrition Div., and PennField Oil Co. The supplemental NADA's provide for the safe and effective use of Type A medicated articles containing chlortetracycline (CTC) in the feed of chickens, turkeys, swine, sheep, and calves, beef and nonlactating dairy cattle for improved production efficiency and for control and treatment of certain bacterial diseases susceptible to CTC. The approvals reflect compliance with results of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) evaluation of the drug's effectiveness, and FDA's conclusions concerning that evaluation.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: The following sponsors have submitted supplements to their approved NADA's:

- Hoffmann-LaRoche, Inc., Nutley, NJ 07110 (formerly held by American Cyanamid Co.), to NADA 48–761, which covers the Type A medicated articles: Aureomix® 293 (50 grams of chlortetracycline hydrochloride per pound (g CTC HCl/lb)) and Aureomycin® 50, 70, 80, 90, and 100 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- Pfizer, Inc., 235 East 42d St., New York, NY 10017, to NADA 92–286, which covers the Type A medicated articles CLTC® 10, 20, 30, 50, and 70 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl) and to NADA 92–287, which covers the Type A medicated articles CLTC® 50 MR and 100 MR (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ALPHARMA, Inc. (formerly A. L. Laboratories), One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, to NADA 46–699, which covers the Type A medicated articles: CTC 100 MR (100 g CTC HCl/lb) and CTC 10, CTC 50, CTC 65, CTC 70, and Micro CTC 100 (contains CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ADM Animal Health & Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801–2508 (formerly Feed Specialties Co., Inc.), to NADA 48–480, which covers the Type A medicated article Chloratet™ 50 (contains CTC calcium complex equivalent to 50 g CTC HCI/lb); and
- PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68137, to NADA 138–935, which covers the Type A medicated articles: Chlortetracycline Premixes 50, 60, 70, 80, 100 (all contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl), and 100 MR (100 g CTC HCl/lb).

The drug products were the subject of a NAS/NRC DESI evaluation of effectiveness (DESI 0113NV). The findings were published in the Federal Register of July 21, 1970 (35 FR 11646). NAS/NRC evaluated the drug products as probably effective for growth promotion and feed efficiency and for the treatment of animal diseases caused by pathogens sensitive to chlortetracycline. NAS/NRC stated that:

(1) Claims made regarding ''for prevention of'' or ''to prevent'' should be replaced with ''as an aid in the control of'' or ''to aid in the control of'''; (2) claims for growth promotion or stimulation are disallowed and claims for faster gains and/or feed efficiency should be stated as ''may result in faster gains and/or improved feed efficiency under appropriate conditions''; (3) each disease claim should be properly qualified as ''appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)''; if the disease cannot be so qualified the claim must be dropped; (4) claims pertaining to egg production and hatchability should be changed to ''May aid in maintaining egg production and hatchability, under appropriate conditions, by controlling pathogenic microorganisms''; (5) the labels should warn that treated animals must actually be consuming enough medicated water or medicated feed to provide a therapeutic dosage under the conditions that prevail and, as a precaution, state the desired oral dose per unit of animal weight per day for each species as a guide to effective usage of the preparation in drinking water or feed; and (6) effective blood levels are required for each recommended dosage.

FDA concurred with the NAS/NRC findings, interpreting the phrase ''* * * cannot be so qualified * * *'' in above item (3) to mean ''* * * is not supported by adequate data * * *'' FDA reviewed all available effectiveness data of products subject to the evaluation and concluded that the data supported effectiveness for the control and treatment of certain bacterial diseases susceptible to CTC in chickens, turkeys, swine, sheep, calves, and cattle.

The NAS/NRC DESI evaluation is concerned only with the drugs' effectiveness and safety to the treated animal. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites in food products derived from treated animals.

The five subject sponsors filed supplements that revised the labeling of their products to comply with the findings of the NAS/NRC review and FDA's conclusions concerning those findings. The supplemental NADA's were approved as of February 16, 1996. The revisions to § 558.128 (21 CFR 558.128) list the NAS/NRC and FDA-approved conditions of use for CTC-containing Type A medicated articles.

Products which comply with the NAS/NRC findings and FDA's conclusions regarding those findings are eligible for copying under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (see the eighth in a series of policy letters issued to facilitate implementation of GADPTRA that published in the Federal Register of August 21, 1991 (56 FR 41561). Accordingly, sponsors may now