

addition to the Wild and Scenic Rivers System;

(I) A sole source aquifer recharge area;
(J) A State water quality standard (including designated and/or existing beneficial uses and anti-degradation requirements); or

(K) The release or disposal of regulated substances above the levels set forth in a permit or license issued by an appropriate regulatory authority.

(5) *Responsibilities and procedures for preparation of an environmental assessment.* (i) the Executive Director will request that the Lender and Borrower provide information concerning all potentially significant environmental impacts of the Borrower's proposed project pursuant to 13 CFR 400.206. The Executive Director, consulting at his discretion with CEQ, will review the information provided by the Lender and Borrower. Though no specific format for an environmental assessment is prescribed, it shall be a separate document, suitable for public review and should include the following in conformance with 40 CFR 1508.9:

(A) *Description of the environment.* The existing environmental conditions relevant to the Board's analysis determining the environmental impacts of the proposed project, should be described. The no action alternative also should be discussed;

(B) *Documentation.* Citations to information used to describe the existing environment and to assess environmental impacts should be clearly referenced and documented. These sources should include, as appropriate, but not be limited to, local, tribal, regional, State, and Federal agencies, as well as, public and private organizations and institutions;

(C) *Evaluating environmental consequences of proposed actions.* A brief discussion should be included of the need for the proposal, of alternatives as required by 42 U.S.C. 4332(2)(E) and their environmental impacts. The discussion of the environmental impacts should include measures to mitigate adverse impacts and any irreversible or irretrievable commitments of resources to the proposed project.

(ii) The Executive Director, in preparing an environmental assessment, may:

(A) Tier upon the information contained in a previous EIS, as described in 40 CFR 1502.20;

(B) Incorporate by reference reasonably available material, as described in 40 CFR 1502.21; and/or

(C) Adopt a previously completed EIS reasonably related to the project for which the proceeds of the loan sought

to be guaranteed under the Program will be used, as describe in 40 CFR 1506.3.

(iii) Because of the statute's admonition to the Board to make its decisions as soon as possible after receiving applications, the Board will not:

(A) Publish notice of intent to prepare an environmental assessment, as describe in 40 CFR 1501.7;

(B) Conduct scoping, as described in 40 CFR 1501.7; and

(C) Seek comments on the environmental assessment, as described in 40 CFR 1503.1.

(iv) If, on the basis of an environmental assessment, it is determined that an EIS is not required, a FONSI, as described in 40 CFR 1508.13 will be prepared. The FONSI will include the environmental assessment or a summary of it and be available to the public from the Board. The Executive Director shall remain a record of these decisions, making them available to interested parties upon request. Requests should be directed to the Executive Director, Emergency Steel Guarantee Loan Program, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Prior to a final loan guarantee decision, a copy of the NEPA documentation shall be sent to the Board for consideration.

(6) *Responsibilities and procedures for preparation of an environmental impact statement.* (i) If after an environmental assessment has been completed, it is determined that an EIS is necessary, it and other related documentation will be prepared by the Executive Director in accordance with section 102(2)(c) of NEPA, this section, and 40 CFR parts 1500 through 1508. The Executive Director may seek additional information from the applicant in preparing the EIS. Once the document is prepared, it shall be submitted to the Board. If the Board considers a document unsatisfactory, it shall be returned to the Executive Director for revision or supplementation prior to a loan guarantee decision; otherwise the Board will transmit the document to the Environmental Protection Agency.

(ii)(A) The following procedures, as discussed in 40 CFR parts 1500 through 1508, will be followed in preparing an EIS:

(1) The format and contents of the draft and final EIS shall be as discussed in 40 CFR 1502.

(2) The requirements of 40 CFR 1506.9 for filing of documents with the Environmental Protection Agency shall be followed.

(3) The Executive Director, consulting at his discretion with CEQ, shall

examine carefully the basis on which supportive studies have been conducted to assure that such studies are objective and comprehensive in scope and in depth.

(4) NEPA requires that the decision making "utilize a systematic, interdisciplinary approach that will ensure the integrated use of the natural and social sciences and the environmental design arts." 42 U.S.C. 4332(A). If such disciplines are not present on the Board staff, appropriate use should be made of personnel of Federal, State, and local agencies, universities, non-profit organizations, or private industry.

(B) Until the Board issues a record of decision as provided in 40 CFR 1502.2 no action concerning the proposal shall be taken which would:

(1) Have an adverse environmental impact; or

(2) Limit the choice of reasonable alternatives.

(3) 40 CFR 1506.10 places certain limitations on the timing of Board decisions on taking "major Federal actions." A loan guarantee shall not be made before the times set forth in 40 CFR 1506.10.

(iii) A public record of decision stating what the decision was; identifying alternatives that were considered, including the environmentally preferable one(s); discussing any national considerations that entered into the decision; and summarizing a monitoring and enforcement program if applicable for mitigating the environmental effects of a proposal; will be prepared. This record of decision will be prepared at the time the decision is made.

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EMERGENCY OIL AND GAS GUARANTEED LOAN BOARD

13 CFR Part 500

RIN 3003-ZA00

Loan Guarantee Decision; Availability of Environmental Information

AGENCY: Emergency Oil and Gas Guaranteed Loan Board.

ACTION: Interim final rule; request for comments.

SUMMARY: In accordance with the Council on Environmental Quality's regulations implementing the National Environmental Policy Act ("NEPA"), the Emergency Oil and Gas Guaranteed Loan Board ("Board") is adopting NEPA procedures. Environmental data or

documentation concerning the use of the proceeds of any loan guaranteed under this Program must be provided by the Lender to the Board to assist the Board in meeting its legal responsibilities under NEPA. The purpose of these procedures is to ensure that environmental information is available to the Board as it makes decisions concerning applications for loan guarantees. In addition to setting forth the Board's NEPA procedures, these amendments make three changes. First, language is added to clarify the collateral and security interests necessary for each guarantee. Second, language is added creating a tiered system for the submission of financial statements for Borrowers based on the type of qualified oil and gas company applying and the amount of the loan sought. Third, these amendments extend the deadline for the submission of applications.

DATES: *Effective Date:* This rule is effective December 23, 1999.

Comments: Comments may be submitted no later than February 22, 2000.

ADDRESSES: Comments may be submitted to: Charles E. Hall, Executive Director, Emergency Oil and Gas Guaranteed Loan Board, U.S. Department of Commerce, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Charles E. Hall, Executive Director, Emergency Oil and Gas Guaranteed Loan Board, U.S. Department of Commerce, Washington, DC 20230, (202) 219-0584.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Council on Environmental Quality's regulations 40 CFR Parts 1500 to 1508, implementing the National Environmental Policy Act ("NEPA"), the Emergency Oil and Gas Guaranteed Loan Board is adopting NEPA procedures. The NEPA process is intended to help public officials make decisions based on an understanding of the environmental consequences of their actions. The purpose of the Board's procedures is to ensure that necessary environmental information is available to the Board as it makes loan guarantee decisions.

Pursuant to the Emergency Oil and Gas Guaranteed Loan Program, 13 CFR 500.206, each application for a Guarantee under the Program must be accompanied by information necessary for the Board to meet the requirements of NEPA. Environmental data or documentation concerning the use of the proceeds of any loan guaranteed

under this Program must be provided by the Lender to the Board. Once this information is received, an environmental assessment of the proposed project will be completed by the Board. This information will accompany each applicant's loan guarantee application during the Board's review and selection process.

These procedures enumerate the types of actions that will trigger the Board's NEPA procedures. Any action classified as a "major Federal action" is subject to NEPA review. Typically, a government loan guarantee involving actions such as any project involving construction and/or installations; any project involving ground disturbing activities; and any project supporting renovation, other than remodeling, are considered major Federal actions. Such actions will require the preparation of an environmental assessment providing a description of the existing environment, a description of the future of the environment without the project, supporting documentation concerning the project and its environmental affects, an analysis of viable alternatives throughout the proposed project area, and mitigation measures designed to alleviate the environmental consequences of the proposed project. However, the Board has determined that certain actions, that are otherwise major Federal actions, normally do not have a significant impact on the quality of the human environment and are, therefore, categorically excluded from the environmental impact statement requirements of NEPA. For instance, guarantees for loans for the working capital needs of the Borrower and guarantees for the refinancing of outstanding indebtedness of the Borrower are categorically excluded from the need to prepare an environmental assessment or an environmental impact statement under NEPA.

In addition to setting forth the Board's NEPA procedures, these amendments make three changes to the substantive program regulations contained in Subpart C of part 500. First, as currently written, the Board's regulations could be interpreted to require a borrower to provide a security interest in all of its property, even if the value of that property far exceeds the amount of the loan. These amendments clarify that the Board requires a first lien on any property purchased, refinanced, or substantially improved with the proceeds of the guaranteed loan and a minimum security interest of equal status with the highest security interest in any other property of the Borrower's pledged to secure that loan. The

borrower would have discretion to determine which of its other property it would pledge. A key factor in the Board's decision-making will be the priority of the security interest in collateral, as well as the quality of the collateral. Thus, applications giving the government a higher security interest on higher quality collateral will be evaluated higher in the application review process than those applications providing a lesser level of security interest.

Second, the Board's current regulations require the submission of three years of independently audited financial statements as part of the application. While public companies are required to have independent audits performed annually, many small private companies do not have such audits performed. Some lenders may not require audited financial statements to determine that a borrower is credit worthy. To address this issue, the Board is amending its regulations to create a tiered system for the submission of financial statements for Borrowers based on the type of qualified oil and gas company applying and the amount of the loan sought. For independent oil and gas companies, a two tiered system is created. For loan proposals under \$5 million, the Applicant is required to submit three years for financial statements for the Borrower reviewed by a certified public accountant prepared following generally accepted accounting principles (GAAP). For loan proposals greater than \$5 million, the Applicant is required to submit a financial statement for the Borrower of the most recent year audited by an independent certified public accountant and financial statements from the two prior years reviewed by a certified public accountant prepared following GAAP. Service companies, in contrast, will be required to submit consolidated financial statements for the previous three years audited by an independent certified public accountant. Failure to submit full audited statements for the three years historical period may affect the risk assigned to a loan and will be part of the evaluation criteria the Board uses in making their decisions.

Third, in response to industry concerns over the time frame for the submission of completed applications, the deadline for the submission of applications has been extended to January 31, 2000. The current regulations establish a deadline of December 30, 1999, for the filing of complete application with the Board.

Administrative Law Requirements*Executive Order 12866*

This interim final rule has been determined not to be a significant for purposes of Executive Order 12866.

Administration Procedure Act

This rule is exempt from the requirement to provide prior notice and an opportunity for public comment pursuant to 5 U.S.C. 553(b)(A), as it involves a matter relating to Board procedures and practice. Similarly, because this rule of procedure does not have a substantive effect on the public, it is not subject to a 30 day delay in effective date, as normally is required under 5 U.S.C. 553(d). However, the Board is interested in receiving public comment and is, therefore, issuing this rule as interim final.

Regulatory Flexibility Act

Because this rule is not subject to a requirement to provide prior notice and an opportunity for public comment pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Congressional Review Act

This rule has been determined to be not major for purposes of the Congressional Review Act, 5 U.S.C. 801 *et seq.*

Intergovernmental Review

No intergovernmental consultations with State and local officials is required because the rule is not subject to the provisions of Executive Order 12372 or Executive Order 12875.

Unfunded Mandate Reform Act of 1995

This rule contains no Federal mandates, as that term is defined in the Unfunded Mandates Reform Act, on State, local and tribal governments or the private sector.

Executive Order 13132

This rule does not contain policies having federalism implications requiring preparataion of a Federalism Assessment.

Executive Order 12630

This rule does not contain policies that have takings implications.

List of Subjects in 13 CFR Part 500

Administrative practice and procedure, Environmental impact statement, Freedom of Information,

Loan Programs—Oil and Gas, Reporting and recordkeeping requirements.

Charles E. Hall,

Executive Director, Emergency Oil and Gas Guaranteed Loan Board.

For the reasons set forth in the preamble, the Emergency Oil and Gas Guaranteed Loan Board amends 13 CFR part 500 as follows:

PART 500—[AMENDED]

1. The authority citation for part 500 continues to read as follows:

Authority: Pub. L. 106–51, 113 Stat. 255 (15 U.S.C. 1841 note).

2. Section 500.204(c)(2) is revised to read as follows:

§ 500.204 Loan terms.

* * * * *

(c) * * *

(2) Without limiting the Lender's or Borrower's obligations under paragraph (c) of this section, at a minimum, the loan shall be secured by:

(i) A fully perfected and enforceable security interest and or lien, with first priority over conflicting security interests or other liens in all property acquired, improved, or derived from the loan funds; and

(ii) A fully perfected and enforceable security interest and or lien in any other property of the Borrower's pledged to secure the loan, including accessions, replacements, proceeds, or property given by a third party as Security for the loan, the priority of which shall be, at a minimum, equal in status with the existing highest voluntarily granted or acquired interest or lien;

* * * * *

3. Section 500.205 is amended by revising paragraphs (a) and (b)(8) to read as follows:

§ 500.205 Application process.

(a) *Application process.* An original application and three copies must be received by the Board no later than 8 p.m. EST, January 31, 2000, in the U.S. Department of Commerce, Washington, DC 20230. Applications which have been provided to a delivery service on or before January 30, 2000, with "delivery guaranteed" before 8 p.m. on January 30, 2000, will be accepted for review if the Applicant can document that the application was provided to the delivery service with delivery to the address listed in this section guaranteed prior to the closing date and time. A postmark of January 30, 2000, is not sufficient to meet this deadline as the application must be received by the required date and time. Applications will not be accepted via facsimile

machine transmission or electronic mail.

(b) * * *

(8)(i) An independent oil and gas company, as defined in section 201(c)(3)(A)(i) of the Act, is required to submit:

(A) For loans less than \$5 million, three years of financial statements reviewed by a certified public accountant following generally accepted accounting principles, as well as any interim financial statements; or

(B) For loans of \$5 million or greater, three years of financial statements must be submitted. The most recent year's statement must be audited by an independent certified public accountant. Statements from the prior two years must be reviewed by a certified public accountant following generally accepted accounting principles. In addition, any interim financial statements and associated notes must be submitted as well.

(ii) A service company, as defined in section 201(c)(3)(A)(ii) of the Act, is required to submit consolidated financial statements of the Borrower for the previous three years that have been audited by an independent certified public accountant, including any associated notes, as well as any interim financial statements and associated notes.

* * * * *

4. Section 500.206 is amended by removing paragraphs (b) and (c), redesignating paragraph (d) as paragraph (b), adding paragraph (c) and revising paragraph (a) to read as follows:

§ 500.206 Environmental requirements.

(a)(1) *In General.* Environmental assessments of the Board's actions will be conducted in accordance with applicable statutes, regulations, and Executive Orders. Therefore, each application for a Guarantee under the Program must be accompanied by information necessary for the Board to meet the requirements of applicable law.

(2) *Actions requiring compliance with NEPA.* (i) The types of actions classified as "major Federal actions" subject to NEPA procedures are discussed generally in 40 CFR parts 1500 through 1508.

(ii) With respect to this Program, these actions typically include:

(A) Any project, permanent or temporary, that will involve construction and/or installations;

(B) Any project, permanent or temporary, that will involve ground disturbing activities; and

(C) Any project supporting renovation, other than interior remodeling.

(3) *Environmental information required from the Lender.* (i) Environmental data or documentation concerning the use of the proceeds of any loan guaranteed under this Program must be provided by the Lender to the Board to assist the Board in meeting its legal responsibilities. The Lender may obtain this information from the Borrower. Such information includes:

(A) Documentation for an environmental threshold review from qualified data sources, such as a Federal, State or local agency with expertise and experience in environmental protection, or other sources, qualified to provide reliable environmental information;

(B) Any previously prepared environmental reports or data relevant to the loan at issue;

(C) Any environmental review prepared by Federal, State, or local agencies relevant to the loan at issue;

(D) The information required for the completion of Form XYZ, "Environmental Assessment and Compliance Findings for Related Environmental Laws;" and

(E) Any other information that can be used by the Board to ensure compliance with environmental laws.

(ii) All information supplied by the Lender is subject to verification by the Board.

* * * * *

(c) *National Environmental Policy Act.* (1) *Purpose.* The purpose of this paragraph (c) is to adopt procedures for compliance with the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, by the Board. This paragraph supplements regulations at 40 CFR Chapter V.

(2) *Definitions.* For purposes of this section, the following definitions apply:

Categorical exclusion means a category of actions which do not individually or cumulatively have a significant effect on the human environment and for which neither an environmental assessment nor an environmental impact statement is required.

Environmental assessment means a document that briefly discusses the environmental consequences of a proposed action and alternatives prepared for the purposes set forth in 40 CFR 1508.9.

EIS means an environmental impact statement prepared pursuant to section 102(2)(C) of NEPA.

FONSI means a finding of no significant impact on the quality of the

human environment after the completion of an environmental assessment.

NEPA means the National Environmental Policy Act, 42 U.S.C. 4321, *et seq.*

Working Capital Loan means money used by an ongoing business concern to fund its existing operations.

(3) *Delegations to Executive Director.*

(i) All incoming correspondence from Council on Environmental Quality (CEQ) and other agencies concerning matters related to NEPA, including draft and final EIS, shall be brought to the attention of the Executive Director. The Executive Director will prepare or, at his or her discretion, coordinate replies to such correspondence.

(ii) With respect to actions of the Board, the Executive Director will:

(A) Ensure preparation of all necessary environmental assessments and EISs;

(B) Maintain a list of actions for which environmental assessments are being prepared;

(C) Revise this list at regular intervals, and send the revisions to the Environmental Protection Agency;

(D) Make the list available for public inspection;

(E) Maintain a list of EISs; and

(F) Maintain a file of draft and final EISs.

(4) *Categorical exclusions.* (i) This paragraph describes various classes of Board actions that normally do not have a significant impact on the human environment and are categorically excluded. The word "normally" is stressed; there may be individual cases in which specific factors require contrary action.

(ii) Subject to the limitations in paragraph (c)(4)(iii) of this section, the actions described in this paragraph have been determined not to have a significant impact on the quality of the human environment. They are categorically excluded from the need to prepare an environmental assessment or an EIS under NEPA.

(A) Guarantees of working capital loans; and

(B) Guarantees of loans for the refinancing of outstanding indebtedness of the Borrower, regardless of the purpose for which the original indebtedness was incurred.

(iii) Actions listed in paragraph (c)(4)(ii) of this section that otherwise are categorically excluded from NEPA review are not necessarily excluded from review if they would be located within, or in other cases, potentially affect:

(A) A floodplain;

(B) A wetland;

(C) Important farmlands, or prime forestlands or rangelands;

(D) A listed species or critical habitat for an endangered species;

(E) A property that is listed on or may be eligible for listing on the National Register of Historic Places;

(F) An area within an approved State Coastal Zone Management Program;

(G) A coastal barrier or a portion of a barrier within the Coastal Barrier Resources System;

(H) A river or portion of a river included in, or designated for, potential addition to the Wild and Scenic Rivers System;

(I) A sole source aquifer recharge area;

(J) A State water quality standard (including designated and/or existing beneficial uses and anti-degradation requirements); or

(K) The release or disposal of regulated substances above the levels set forth in a permit or license issued by an appropriate regulatory authority.

(5) *Responsibilities and procedures for preparation of an environmental assessment.* (i) The Executive Director will request that the Lender and Borrower provide information concerning all potentially significant environmental impacts of the Borrower's proposed project pursuant to 13 CFR 500.206. The Executive Director, consulting at his discretion with CEQ, will review the information provided by the Lender and Borrower. Though no specific format for an environmental assessment is prescribed, it shall be a separate document and should include the following in conformance with 40 CFR 1508.9:

(A) *Description of the environment.* The existing environmental conditions relevant to the Board's analysis determining the environmental impacts of the proposed project, should be described. The no action alternative also should be discussed;

(B) *Documentation.* Citations to information used to describe the existing environment and to assess environmental impacts should be clearly referenced and documented. Such references should include, as appropriate, but not be limited to, local, tribal, regional, State, and Federal agencies, as well as, public and private organizations and institutions;

(C) *Evaluating environmental consequences of proposed actions.* A brief discussion should be included of the need for the proposal, of alternatives as required by 42 U.S.C. 4332(2)(E) and their environmental impacts. The discussion of the environmental impacts should include measures to mitigate adverse impacts and any irreversible or

irretrievable commitments of resources to the proposed project.

(ii) The Executive Director, in preparing an environmental assessment, may:

(A) Tier upon the information contained in a previous EIS, as described in 40 CFR 1502.20;

(B) Incorporate by reference reasonably available material, as described in 40 CFR 1502.21; and/or

(C) Adopt a previously completed EIS reasonably related to the project for which the proceeds of the loan sought to be guaranteed under the Program will be used, as described in 40 CFR 1506.3.

(iii) Because of the statute's admonition to the Board to make its decisions as soon as possible after receiving applications, the Board will not:

(A) Publish notice of intent to prepare an environmental assessment, as described in 40 CFR 1501.7;

(B) Conduct scoping, as described in 40 CFR 1501.7; and

(C) Seek comments on the environmental assessment, as described in 40 CFR 1503.1.

(iv) If, on the basis of an environmental assessment, it is determined that an EIS is not required, a FONSI, as described in 40 CFR 1508.13 will be prepared. The FONSI will include the environmental assessment or a summary of it and be available to the public from the Board. The Executive Director shall maintain a record of these decisions, making them available to interested parties upon request. Requests should be directed to the Executive Director Emergency Oil and Gas Guarantee Loan Program, 14th Street and Constitution Avenue, NW., Washington DC 20230. Prior to a final loan guarantee decision, a copy of the NEPA documentation shall be sent to their Board for consideration.

(6) *Responsibilities and procedures for preparation of an environmental impact statement.* (i) If after an environmental assessment has been completed, it is determined that an EIS is necessary, it and other related documentation will be prepared by the Executive Director in accordance with section 102(2)(c) of NEPA, this section, and 40 CFR parts 1500 through 1508. The Executive Director may seek additional information from the applicant in preparing the EIS. Once the document is prepared, it shall be submitted to the Board. If the Board considers a document unsatisfactory, it shall be returned to the Executive Director for revision or supplementation prior to a loan guarantee decision; otherwise the Board will transmit the

document to the Environmental Protection Agency.

(ii)(A) The following procedures, as discussed in 40 CFR parts 1500 through 1508, will be followed in preparing an EIS:

(1) The format and contents of the draft and final EIS shall be as discussed in 40 CFR 1502.

(2) The requirements of 40 CFR 1506.9 for filing of documents with the Environmental Protection Agency shall be followed.

(3) The Executive Director, consulting at his discretion with CEQ, shall examine carefully the basis on which supportive studies have been conducted to assure that such studies are objective and comprehensive in scope and depth.

(4) NEPA requires that the decision making "utilize a systematic, interdisciplinary approach that will ensure the integrated use of the natural and social sciences and the environmental design arts." 42 U.S.C. 4332(A). If such disciplines are not present on the Board staff, appropriate use should be made of personnel of Federal, State, and local agencies, universities, non-profit organizations, or private industry.

(B) Until the Board issues a record of decision as provided in 40 CFR 1502.2 no action concerning the proposal shall be taken which would:

(1) Have an adverse environmental impact; or

(2) Limit the choice of reasonable alternatives.

(3) 40 CFR 1506.10 places certain limitations on the timing of Board decisions on taking "major Federal actions." A loan guarantee shall not be made before the times set forth in 40 CFR 1506.10.

(iii) A public record of decision stating what the decision was; identifying alternatives that were considered, including the environmentally preferable one(s); discussing any national considerations that entered into the decision; and summarizing a monitoring and enforcement program if applicable for mitigating the environmental effects of a proposal; will be prepared. This record of decision will be prepared at the time the decision is made.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Diclazuril

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations for medicated feed applications to add an entry stating the maximum Type B level and assay limits for diclazuril Type B and C medicated feeds. The **Federal Register** document that reflected approval of Schering-Plough Animal Health Corp.'s new animal drug application (NADA) for use of diclazuril Type A medicated articles for making Type C medicated broiler feeds failed to provide that entry.

DATES: This regulation is effective December 23, 1999.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 2, 1999 (64 FR 35923), FDA published a final rule that reflected the approval of Schering-Plough Animal Health Corp.'s NADA 141-951. The NADA provides for use of a Type A medicated article containing 0.2 percent of diclazuril (CLINACOX™) to make Type C broiler feeds used for the prevention of coccidiosis. The final rule added 21 CFR 556.175 and 558.198 to reflect the approval, but failed to amend § 558.4 (21 CFR 558.4) to add an entry stating the maximum Type B level and assay limits for diclazuril Type B and C medicated feeds. At this time, § 558.4 is amended in paragraph (d) in the table "Category I" accordingly.

As provided in 21 CFR part 20 and 514.11(e)(2)(ii), a freedom of information summary of safety and effectiveness data and information required to support approval of the application was placed on file in the Dockets Management Branch, Food and Drug Administration, upon publication of the approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.