guaranteed debt to replace maturing senior unsecured debt as a result of market disruptions or other circumstances beyond the entity's control, the participating entity may, with the FDIC's prior approval under paragraph (h) of this section, issue FDIC-guaranteed debt after October 31, 2009, and on or before April 30, 2010. Any such issuance is subject to all of the terms and conditions imposed by the FDIC in its approval decision as well as all of the provisions of this part, including without limitation, the payment of the applicable assessment and compliance with the disclosure requirements.

* * * * *

■ 4. Amend § 370.5 as follows:

■ a. Revise paragraph (f); and

■ b. Revise paragraph (h)(2), to read as follows:

§ 370.5 Participation.

* * * * *

(f) Except as provided in paragraphs (g), (j), and (k) of § 370.3, participating entities are not permitted to select which newly issued senior unsecured debt is guaranteed debt; all senior unsecured debt issued by a participating entity up to its debt guarantee limit must be issued and identified as FDIC-guaranteed debt as and when issued.

* * * * *

(h) * * *

(2) Each participating entity that is either an insured depository institution, an entity that has issued FDIC-guaranteed debt before April 1, 2009, an entity that has been approved pursuant to § 370.3(h) to issue FDIC-guaranteed debt after June 30, 2009, and on or before October 31, 2009, or a participating entity that has been approved pursuant to § 370.3(k) to issue FDIC-guaranteed debt after October 31, 2009, must include the following disclosure statement in all written materials provided to lenders or creditors regarding any senior unsecured debt that is issued by it during the applicable issuance period and that is guaranteed under the debt guarantee program:

This debt is guaranteed under the Federal Deposit Insurance Corporation's Temporary Liquidity Guarantee Program and is backed by the full faith and credit of the United States. The details of the FDIC guarantee are provided in the FDIC's regulations, 12 CFR Part 370, and at the FDIC's Web site, http://www.fdic.gov/tlgp. [If the debt being issued is mandatory convertible debt, add: *The expiration date of the FDIC's guarantee is the earlier of the mandatory conversion date or December 31, 2012*]. [If the debt being issued is any other senior unsecured debt, add: *The expiration date of the FDIC's guarantee is the earlier of the maturity date of the debt or December 31, 2012.*]

* * * * *

■ 5. Amend § 370.6 as follows:

■ a. Revise paragraph (d)(1); and

■ b. Add paragraph (i), to read as follows:

§ 370.6 Assessments under the Debt Guarantee Program.

* * * * *

(d) *Amount of assessments for debt within the debt guarantee limit*

(1) *Calculation of assessment.* Subject to paragraphs (d)(3) and (h) of this section, and except as provided in paragraph (i) of this section, the amount of assessment will be determined by multiplying the amount of FDIC-guaranteed debt times the term of the debt or, in the case of mandatory convertible debt, the time period from issuance to the mandatory conversion date, times an annualized assessment rate determined in accordance with the following table.

For debt with a maturity or time period to conversion date of—	The annualized assessment rate (in basis points) is—
180 days or less (excluding overnight debt)	50
181–364 days	75
365 days or greater	100

* * * * *

(i) *Assessment for debt issued under the Emergency Guarantee Facility.* The amount of the assessment for FDIC-guaranteed debt issued pursuant to § 370.3(k) of this part is equal to the amount of the debt times the term of the debt (or in the case of mandatory convertible debt, the time period to conversion) times an annualized assessment rate of 300 basis points, or such greater rate as the FDIC may determine in its decision approving such issuance.

By order of the Board of Directors.

Dated at Washington, DC, this 20th day of October 2009.

Robert E. Feldman,

Executive Secretary, Federal Deposit Insurance Corporation.

[FR Doc. E9–25555 Filed 10–22–09; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2009–N–0436]

New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations regarding new animal drug applications (NADAs). Specifically, this direct final rule is being issued to provide that NADAs shall be submitted in the described form, as appropriate for the particular submission. Currently, the regulation requires that all NADAs contain the same informational sections and does not explicitly provide the appropriate flexibility needed to address the development of all types of new animal drug products. This amendment will allow the agency to appropriately review safety and effectiveness data submitted to support the approval of new animal drug products. FDA is amending the regulations in accordance with its direct final rule procedures.

Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule. The companion proposed rule and this direct final rule are substantively identical.

DATES: This rule is effective March 8, 2010. Submit written comments on or before January 6, 2010. If FDA receives no significant adverse comments within the specified comment period, the agency will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0436 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Urvi Desai, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8297, e-mail: *urvi.desai@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

This direct final rule is being issued to amend § 514.1 (21 CFR 514.1) so as to provide that NADAs shall include the information described in the section, as appropriate for the particular submission. Currently, the regulation requires that all NADAs contain the same informational sections and does not explicitly provide the appropriate flexibility needed to address the development of all types of new animal drug products. This amendment will allow the agency to appropriately review safety and effectiveness data submitted to support the approval of new animal drug products. In addition, the amendment is similar to the current provisions of the human new drug application regulations at 21 CFR 314.50 and thus will make the new human and new animal drug regulations more consistent.

II. Direct Final Rulemaking

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures.'' This guidance document may be accessed at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.* FDA believes that this rule is appropriate for direct final rulemaking because it is intended to make non-controversial changes to existing regulations. We anticipate no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule. The companion proposed rule provides the procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

FDA is providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If FDA receives any significant adverse comment, we intend to withdraw this direct final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of the direct final rule, a document withdrawing the direct final rule. If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule using the usual notice-and-comment procedures under the APA (5 U.S.C. 552 *et seq.*). If we receive no significant adverse comment during the specified comment period, we intend to publish a document in the **Federal Register** confirming the effective date within 30 days after the comment period ends.

III. Legal Authority

FDA's authority to issue this direct final rule is provided by section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(b)(1)). This section states that any person may file with the Secretary of Health and Human Services an application with respect to any intended use or uses of a new animal drug and sets forth the specific information that must be included in such an application. In addition, section 701(a) of the act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the act. FDA is issuing this direct final rule under these authorities.

IV. Environmental Impact

FDA has carefully considered the potential environmental impacts of this rule and determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Economic Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory

alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the direct final rule would not impose any direct or indirect costs on industry or government through the amendment, but rather would only clarify that sponsors must include in their applications the information described in § 514.1 that is appropriate for their particular submission, the agency certifies that the direct final rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This direct final rule refers to previously approved collections of information found in FDA regulations. The direct final rule amends these previously approved collections of information by clarifying that NADAs must contain the information appropriate for the particular submission. Further, this amendment is based upon the Center for Veterinary Medicine's previous experience with these submissions. Thus, § 514.1 as amended, does not constitute a new or additional paperwork burden requiring Office of Management and Budget (OMB) approval.

Collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 514.1 have been approved under OMB Control No. 0910–0032. This approval expires April 30, 2011. An agency may not conduct and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 514 is amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 356a, 360b, 371, 379e, 381.

■ 2. In § 514.1, revise the first sentence of paragraph (a) and the introductory text of paragraph (b) to read as follows:

§ 514.1 Applications.

(a) Applications to be filed under section 512(b) of the act shall be submitted in the form and contain the information described in paragraph (b) of this section, as appropriate to support the particular submission. * * *

(b) Applications for new animal drugs shall be submitted in triplicate and assembled in the manner prescribed by paragraph (b)(15) of this section, and shall include the following information, as appropriate to support the particular submission: * * *

* * * * *

Dated: October 19, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25517 Filed 10–22–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

[DOD–2009–OS–0141; RIN 0790–AI59]

32 CFR Part 279

Retroactive Stop Loss Special Pay Compensation

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Interim final rule.

SUMMARY: This part provides for Retroactive Stop Loss Special Pay as authorized and appropriated in The Supplemental Appropriations Act, 2009.

The prompt implementation of the Interim Final Rule is of critical importance as Congress dictated the program be implemented within 120 days following the signing of the ''The Supplemental Appropriations Act, 2009. It was signed June 24, 2009. Additionally, this program is of short duration, from October 21, 2009 to October 21, 2010. The last day for submission of claims to the Secretaries of the Military Departments for Retroactive Stop Loss Special Pay is October 21, 2010. The Secretaries concerned are not authorized to make payments on claims submitted after October 21, 2010. The statutory deadline provides good cause, pursuant to 5 U.S.C. 553(d)(3), to make this rule effective immediately upon publication.

DATES: This rule is effective October 21, 2009. Comments must be received by December 22, 2009.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.