to which it applies. We do not believe that a one-year extension would impose a burden on competition. We also believe the extension of the filing accommodation would continue to promote efficiency and capital formation by permitting ABS issuers to disclose static pool information in a format that is more useful to investors and cost-effective and not unduly burdensome for asset-backed issuers.

We request comment on whether the proposed amendment, if adopted, would promote efficiency, competition, and capital formation. Commenters are requested to provide empirical data and other factual support for their view to the extent possible.

VI. Regulatory Flexibility Analysis Certification

The Commission hereby certifies pursuant to 5 U.S.C. 605(b) that the proposed amendment contained in this release, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposal relates to the disclosure requirements for ABS in Securities Act registration statements. Securities Act Rule 157 [26] defines an issuer, other than an investment company, to be a ''small business'' or ''small organization'' if it had total assets of $5 million or less on the last day of its most recent fiscal year. In 2004, when we proposed the new and amended rules and forms to address the registration, disclosure and reporting requirements for ABS, we certified that the proposals would not have a significant economic impact on a substantial number of small entities. As the depositor and issuing entity are most often limited purpose entities in an ABS transaction, we focused on the sponsor in analyzing the potential impact of the proposals under the Regulatory Flexibility Act. The staff analyzed sponsors that conducted registered public offerings of ABS during 2003. No sponsor had total assets of $5 million or less.[27] Based on staff experience, we continue to believe that few, if any, sponsors are small entities. In addition, even if some sponsors are small entities, the proposed amendment to Rule 312 would not have a significant economic impact on any such entities because it only extends a temporary filing accommodation that is currently in effect. As discussed above in Section III, we do not believe the proposed extension would impose any new or increased costs on ABS issuers. Accordingly, we do not believe that the extension, if adopted, would have a significant economic impact on a substantial number of small entities.

We solicit written comments regarding this certification. We request comment on whether the proposals could have an effect that we have not considered. We request that commenters describe the nature of any impact on small entities and provide empirical data to support the extent of the impact.

VII. Statutory Authority and Text of the Proposed Amendment

The amendment described is being proposed under the authority set forth in Sections 6, 7, 10, 19 and 28 of the Securities Act of 1933 (15 U.S.C. 77f, 77g, 77j, 77s and 77z–3).

List of Subjects in 17 CFR Part 232

Reporting and recordkeeping requirements, Securities.

Text of the Proposed Amendment

For the reasons set out in the preamble, the Commission proposes to amend title 17, chapter II, of the Code of Federal Regulations as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for part 232 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.*; and 18 U.S.C. 1350.

* * * * *

§ 232.312 [Amended]

2. Amend § 232.312 by removing ''December 31, 2009'' and in its place adding ''December 31, 2010'' in the first sentence of paragraph (a).

* * * * *

Dated: October 19, 2009.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. E9–25496 Filed 10–22–09; 8:45 am]

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[26] 17 CFR 230.157.

[27] *Asset-Backed Securities,* Release No. 33–8419 (May 3, 2004) [69 FR 26650] (proposing release related to Regulation AB and other new rules and forms related to asset-backed securities).

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations regarding new animal drug applications (NADAs). Specifically, this proposed rule is being issued to provide that NADAs shall be submitted in the form and containing the information described, 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. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on or before January 6, 2010. If FDA receives any significant adverse comments, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

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 way:

- 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 proposed rule is being issued to amend § 514.1 (21 CFR 514.1) so as to provide that NADAs shall contain 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 proposed 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. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural framework to finalize the rule in the event that a significant adverse comment is received in response to the direct final rule and it is withdrawn. FDA is publishing the direct final rule because we believe the rule is non-controversial, and we do not anticipate receiving any significant adverse comments. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead we will publish a document confirming the effective date within 30 days after the comment period ends, confirming when the direct final rule will go into effect.

If we receive any significant adverse comment regarding the direct final rule, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures under the Administrative Procedures Act (APA) (5 U.S.C. 552a *et seq*.). The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule, and vice versa. We will not provide additional opportunity for comment.

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 a 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 APA (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant 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.

In the **Federal Register** of November 21, 1997 (62 FR 62466), you can find additional information about FDA's direct final rulemaking procedures in 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*.

III. Legal Authority

FDA's authority to issue this proposed 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 proposed 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 Impacts

FDA has examined the impacts of the proposed 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 proposed 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 proposed 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 proposes to certify that the rule will 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 proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this proposed 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 proposed rule refers to previously approved collections of information found in FDA regulations. The proposed rule would amend 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.

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, it is proposed that 21 CFR part 514 be 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. E9–25518 Filed 10–22–09; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–AW72

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast (NE) Multispecies Fishery; Amendment 16

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of a fishery management plan amendment; request for comments.

SUMMARY: NMFS announces that the New England Fishery Management Council (Council) has submitted Amdnement 16 to the NE Multispecies Fishery Management Plan (FMP) and its associated draft Final Environmental Impact Statement (FEIS) for Secretarial review and is requesting comments from the public. Amendment 16 was developed by the Council as part of the biennial adjustment process in the FMP to update status determination criteria for all regulated NE multispecies or ocean pout stocks; to adopt rebuilding programs for NE multispecies stocks newly classified as being overfished and subject to overfishing; and to revise management measures, including significant revisions to the Sector management and allocation measures, necessary to end overfishing, rebuild overfished regulated NE multispecies or ocean pout stocks, and mitigate the adverse economic impacts of increased effort controls. Amendment 16 would also implement new requirements for establishing allowable biological catch (ABC), annual catch limits (ACLs), and accountability measures (AMs) for each stock managed by the FMP, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Finally, this action would add Atlantic wolffish to the list of species managed by the FMP. This action is necessary to address the results of the most recent stock assessment, which indicate that several additional NE multispecies regulated species are overfished and subject to overfishing and that some stocks currently classified as overfished require additional reductions in fishing mortality to rebuild by the end of their rebuilding periods.