

# Rules and Regulations

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 1

[Docket No. FAA-2007-27160; Amendment No. 1-56]

RIN 2120-AI97

#### Changes to the Definition of Certain Light-Sport Aircraft

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Direct final rule; request for comments.

**SUMMARY:** This action corrects an unintended consequence created when we adopted the original Light-Sport Aircraft (LSA) Rule; we did not have sufficient information at that time to foresee this difficulty. This action amends the definition of an LSA in two areas. The changes will (1) permit development of lighter-than-air (LTA) LSA, and (2) allow retractable landing gear for LSA intended for operation on water. The LTA change will result in a common land-based LSA maximum takeoff weight limit and allow the LTA LSA industry to design and build safe, functional LTA aircraft. Allowing retractable landing gear for LSA intended for operation on water recognizes the realities of the operation of these LSA and will also enhance the growth of that industry.

**DATES:** Effective June 4, 2007.

Comments for inclusion in the Rules Docket must be received on or before May 21, 2007.

**FOR FURTHER INFORMATION CONTACT:** Larry Werth, Federal Aviation Administration, Aircraft Certification Service, Small Airplane Directorate, ACE-114, 901 Locust, Room 301, Kansas City, MO 64106; telephone 816-329-4147; fax: 816-329-4090; e-mail: [larry.werth@faa.gov](mailto:larry.werth@faa.gov).

**SUPPLEMENTARY INFORMATION:** Later in this preamble under the Additional Information section, we discuss how you can comment on this direct final rule and how we will handle your comments. Included in this discussion is related information about the docket. We also discuss how you can get a copy of this direct final rule and any related rulemaking documents.

#### Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart III, section 44701. Under that section, the FAA is charged with prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it establishes minimum standards required in the interest of safety for the design of aircraft.

#### Background

On July 27, 2004, the FAA issued the "Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft" final rule (69 FR 44772) (hereon referred to as The LSA/Sport Pilot Rule). That rule established a definition for the term "Light-Sport Aircraft" (LSA). Since we adopted that rule, the FAA has been working with the LSA industry in evaluating the overall LSA program. The past two years have seen remarkable growth in the overall LSA program. Over 600 new factory-built airplanes, powered parachutes, and weight-shift control aircraft have received airworthiness certificates. The exceptions to this rapid growth are lighter-than-air (LTA) LSA and LSA intended for operation on water.

In the first area, the FAA has determined the current LTA LSA maximum takeoff weight (MTW) of 660 pounds (300 kilograms) precludes the desired effect of industry design and development of safe LTA LSA. In the second area, the FAA has determined the physical differences between LSA intended for operation on water (amphibious LSA) and land-based LSA

justify allowing retractable landing gear for amphibious LSA. We discuss these determinations in the following paragraphs.

#### Lighter-Than-Air Light-Sport Aircraft

The LSA/Sport Pilot Rule, which became effective September 1, 2004, established an LTA LSA MTW of 660 pounds (300 kilograms). When the FAA originally considered LTA LSA, we determined that airships suitable for sport pilots do not need to meet all the requirements established in FAA-P-8110-2, "Airship Design Criteria".<sup>1</sup> We based the criteria on airship designs that conventionally use low molecular weight lifting gases rather than hot air. We based the weight limit in the final rule on a review of type-certificated free balloons not using hot air as a captive lifting gas. Since publication of the final rule, the FAA has received comments from the LTA aircraft community requesting the addition of aircraft using hot air as a lifting gas.

One commenter recommended the 660 pounds MTW in the current rule be redefined as a "Design Useful Load." The commenter reasons that, for designers of LTA aircraft, this definition would be a rational quantitative objective consistent with standards for sport pilot/light-sport aircraft. The commenter also said the definition would make the envelope volume/size differences between hot-air and low molecular weight lifting gas LSA irrelevant. The commenter provided information that counters the logic used to define weights for LTA aircraft.

Another commenter provided a table comparing envelope volume and maximum gross weight of 26 type-certificated hot air balloons designed for two-place use. The comparison table shows an average envelope volume of 58,615 cubic feet (ranging from 42,000 to 65,000 cubic feet), and an average maximum gross weight of 1,170 pounds (ranging from 870 to 1,433 pounds).

A commenter requested that the 660-pound design useful load be the LTA aircraft design weight criteria. The commenter also asked that existing two-place type-certificated hot air balloons be permitted to have maximum gross weights of at least 1,100 pounds. The commenter believes economics would naturally discourage a "larger" size

<sup>1</sup> Available in the docket.

airship with a useful load of 660 pounds.

We have reconsidered our decision to distinguish hot-air balloons and hot-air based airships from LSA in light of the facts and data presented by the light-sport community. We believe the characteristics and operation of these aircraft are within the standards for sport pilot/light-sport aircraft. Further, we erred in our determination of maximum weight for LTA aircraft as described in the preamble for the final rule. Based on the information presented by the LTA aircraft community, we have determined that the 1,320-pound MTW limit for LSA is applicable to LTA aircraft. This weight includes the structure, uninflated envelope, engine, burner system, fuel, installed equipment and systems, and two occupants. This increased weight limit permits LTA aircraft designers to provide better integrity for the structure that carries the sport pilot and passenger.

We do not agree with the recommendation to establish a definition for “design useful load” as the parameter for LTA aircraft weight. As stated in the notice of proposed rulemaking (NPRM) dated February 5, 2002 (67 FR 5376), and in the preamble for the final rule dated July 27, 2004 (69 FR 44794), the criteria in the LSA definition are intended to be objective characteristics that are easily measured. Design useful load would not be easily verified as a limiting measure.

Under the provisions of the Sport Pilot and Light-Sport Aircraft rule and revised Office of Management and Budget (OMB) Circular A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,” dated February 10, 1998, industry and the FAA have been working with ASTM International (originally formed as the American Society for Testing and Materials) to develop consensus standards for LSA. These consensus standards satisfy the FAA’s goal for airworthiness certification and establish a verifiable minimum safety level for LSA. In addition, use of the consensus standard process assures government and industry discussion and agreement on appropriate standards for the required level of safety.

We have reviewed the particular consensus standards developed for LTA LSA and note that these standards contain provisions for airships and balloons based on hot air or low molecular weight gas.

### **Retractable Landing Gear for LSA Intended for Operation on Water**

When we drafted the original proposal for LSA appropriate for sport pilots, we were concerned that LSA be simple in design and operation. For aircraft design, low performance within the constraints of light weight and structural integrity were important. For aircraft operation, simple mechanical systems within the constraint of sport pilot training requirements were important. As noted in the preamble to the rule, from an operations perspective, 14 CFR, part 61, § 61.31(e) provides a statement of the aircraft features that the FAA considers in assuring adequate training for a pilot to operate complex aircraft. From the aircraft operations perspective, § 61.31(e) does not dictate that retractable landing gear makes a seaplane complex.

We intended to allow for retractable landing gear for amphibious aircraft. We attempted to differentiate between retractable and repositionable landing gear, but that distinction has caused problems when implementing the rule. The term “repositionable landing gear” was defined in the preamble to the LSA/ Sport Pilot Rule as “\* \* \* wheeled landing gear that allows an aircraft designed for operation on water to takeoff and land from a hard surface and which may be retracted on the ground to permit takeoff and landing on water. Repositionable landing gear remains fixed in its position from takeoff through landing.” This definition did not fully recognize or account for the realities of operation of amphibious LSA. From the aircraft design perspective, we were concerned that malfunction or misuse of retractable landing gear on amphibious aircraft not impose a hazard to the aircraft occupants.

During the original rulemaking, we were willing to accept the prospect that aircraft structure designed for water loads for takeoff or landing would provide occupant protection in the event of a wheels up landing on the ground. Since the original rulemaking, the FAA has received data<sup>2</sup> from the industry showing that a wheels-down water landing accident sometimes results in minor injuries, but typically results in no injuries. The biggest challenge is escaping from the aircraft when a wheels-down landing accident results in the aircraft submerging in water. The simple two-place design configuration of a LSA facilitates easy

exit from the aircraft should such an accident occur.

Considering the relatively safe record of retractable landing gear on amphibious LSA and the physical differences between amphibious and land-based LSA, we believe use of retractable landing gear is appropriate for amphibious LSA. Our expectations for simple, mechanically operated retractable landing gear for sailplanes align with our expectations for operation of amphibious aircraft. (Sailplane fuselages are typically designed for landing loads similar to amphibious aircraft structural design criteria).

Finally, with the current § 1.1 LSA definition, most of the existing fleet of amphibious single- and two-seat ultralight-like aircraft in the LSA fleet cannot be issued an airworthiness certificate under § 21.191(i)(1). These aircraft do not meet the current definition of a LSA since most are equipped with retractable landing gear and not “repositionable” landing gear. Unless the LSA definition is changed to allow retractable landing gear for amphibious LSA before January 31, 2008, these aircraft will be unnecessarily excluded from this category of aircraft.

Czech Air Works (CZAW) petitioned the FAA for an exemption to allow retractable landing gear on its Mermaid amphibious airplane. As part of its request, CZAW provided information concerning the design and operation of amphibious LSA. The petition can be found in Docket No. FAA-2005-23030.

The FAA received approximately 450 comments from 260 commenters. Comments on the petition highlighted the overall benefits for an airplane to be capable of land and water landings. These comments also addressed structural design integrity of amphibious aircraft that provide added protection for aircraft occupants in the event of landing with the landing gear in the wrong position (gear up or down). One commenter pointed out that, without an exemption, manufacturers might sell the aircraft equipped with “beaching gear” (for use only when taxiing to land from water, and vice versa, using a ramp) instead of landing gear. This commenter suggested that pilots may be tempted to use the beaching gear as landing gear, which would compromise safety.

Several commenters objected to the petition for exemption. One commenter said changing gear position would increase risk to occupants of an amphibious LSA. Three commenters said that increasing complexity of LSA would increase risk. Four commenters

<sup>2</sup> See Docket Management System Docket Number FAA-2005-23030. Available at [dms.dot.gov](http://dms.dot.gov).

said the Mermaid aircraft would be seriously damaged if the pilot landed on water with the gear down. One commenter recommended allowing only one change of gear position each flight.

In granting the petition for exemption to allow retractable landing gear for amphibious LSA, the primary concern was to determine if the Mermaid aircraft is as safe as any other aircraft with LSA airworthiness certification. We reviewed the information provided by CZAW and the commenters to the petition for exemption. The FAA found the structural integrity of the Mermaid aircraft is enhanced by its "flying boat" design. This design offers increased protection for the occupants when landing with improperly positioned landing gear. We also found the simple method of actuating and monitoring the position of the landing gear is consistent with the design objectives for LSA.

We agree with the commenters who implied the safety of amphibious aircraft is better served by allowing for retractable rather than repositionable landing gear because of the manner in which amphibious aircraft are operated. We considered the comment that pilots might be tempted to use "beaching gear" (if equipped) as landing gear to be a persuasive argument. Using "beaching gear" as landing gear would compromise safety because it is not designed for landing impact loads.

Several commenters were concerned that retractable landing gear would add to the complexity of amphibious LSA. Commenters were divided on the need for landing gear position indicators for amphibious LSA. We find that a direct-action manual lever to mechanically operate the landing gear or a simple mechanical system is appropriate for amphibious LSA. Currently, sailplanes certificated as LSA are allowed to use a direct-action manual lever to mechanically operate the landing gear. We have determined that this revision to the definition of a LSA recognizes the operational requirements of amphibious LSA and is consistent with the stated design and safety objectives.

#### **The Direct Final Rule Process**

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. The two changes in the definition of LSA will be beneficial to and supported by the LSA industry. Increasing the LTA MTW will result in a common LSA limitation and eliminate the current unnecessary restrictions. Allowing retractable landing gear for amphibious LSA will be beneficial to that portion of the LSA

industry and will enhance the development of safe amphibious LSA.

Unless we receive a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** that indicates we received no adverse or negative comments and confirms the date the final rule will become effective. If the FAA receives, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, we will publish a document withdrawing the direct final rule in the **Federal Register**, and we may publish a notice of proposed rulemaking with a new comment period.

In evaluating any comments received, the FAA will consider only comments supported by valid and reasonable data. Adverse comments that dispute previously established and accepted FAA determinations or decisions will not be considered. Any written notice of intent to submit late comments must contain a reasonable estimate of when that comment will be submitted. We will not delay implementing these changes because comments were not submitted on time.

#### **Paperwork Reduction Act**

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the FAA to consider the impact of paperwork and other information collection burdens imposed on the public. We have determined that there are no current or new requirements for information collection associated with these amendments.

#### **International Compatibility**

The FAA has determined that there are no International Civil Aviation Organization (ICAO) Standards and Recommended Practices that correspond to this regulation.

#### **Regulatory Evaluation, Regulatory Flexibility Determination, International Trade Impact Assessment, and Unfunded Mandates Assessment**

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires agencies to analyze the economic impact of regulatory changes on small

entities. Third, the Trade Agreements Act (Pub. L. 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows.

We were too restrictive in two areas of the original LSA definition. With this rulemaking action, we are removing a restriction by allowing the LSA to use retractable landing gear when the aircraft is intended for operation on water. This rule will also create a common land-based LSA MTW limit, which will allow the LTA LSA industry to design and build safe, functional LTA aircraft.

The FAA has, therefore, determined that this final rule is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866, and is not "significant" as defined in DOT's Regulatory Policies and Procedures.

#### **Regulatory Flexibility Determination**

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354) (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their

actions to assure that such proposals are given serious consideration.” The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule will not impose any costs on small entities. We were overly restrictive in our original rule. We are removing restrictions to allow retractable landing gear for LSA intended for operation on water and are creating a common land-based LSA MTW limit, which will allow the LTA LSA industry to design and build safe, functional LTA aircraft. Therefore, as the FAA Administrator, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

#### International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and has determined that it will have a cost relieving impact on domestic and international entities and thus has a neutral trade impact.

#### Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (adjusted annually for inflation with the

base year 1995) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of \$128.1 million in lieu of \$100 million. This final rule does not contain such a mandate.

#### Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, we determined that this final rule does not have federalism implications.

#### Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this proposed rulemaking action qualifies for the categorical exclusion identified in paragraph 312f and involves no extraordinary circumstances.

#### Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 18, 2001). We have determined that it is not a “significant energy action” under the executive order because it is not a “significant regulatory action” under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

#### Additional Information

##### Commenting on This Direct Final Rule

You may send comments identified by Docket Number FAA–2007–27160 using any of the following methods:

- *DOT Docket Web site:* Go to <http://dms.dot.gov> and follow the instructions for sending your comments electronically.

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400

Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.

- *Fax:* 1–202–493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

#### Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

- (1) Searching the Department of Transportation’s electronic Docket Management System (DMS) Web page (<http://dms.dot.gov/search>);
- (2) Visiting the FAA’s Regulations and Policy Web page at [http://www.faa.gov/regulations\\_policies/](http://www.faa.gov/regulations_policies/); or
- (3) Accessing the Government Printing Office’s Web page at <http://www.gpoaccess.gov/fr/index.html>.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number, notice number, or amendment number of this rulemaking.

#### Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact your local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. You can find out more about SBREFA on the Internet at [http://www.faa.gov/regulations\\_policies/rulemaking/sbre\\_act/](http://www.faa.gov/regulations_policies/rulemaking/sbre_act/).

#### List of Subjects in 14 CFR Part 1

Air transportation.

#### The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends part 1 of Title 14, Code of Federal Regulations, as follows:

#### PART 1—DEFINITIONS AND ABBREVIATIONS

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

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

■ 2. Amend the definition of “light-sport aircraft” in § 1.1 by removing

paragraph (1)(i), redesignating (1)(ii) and (1)(iii) as (1)(i) and (1)(ii), respectively, and revising paragraph (12) to read as follows:

**§ 1.1 General definitions.**

\* \* \* \* \*  
*Light-sport aircraft* \* \* \*  
 \* \* \* \* \*

(12) Fixed or retractable landing gear, or a hull, for an aircraft intended for operation on water.

\* \* \* \* \*

Issued in Washington, DC, on April 9, 2007.

**Marion C. Blakey,**  
*Administrator.*

[FR Doc. E7-7453 Filed 4-18-07; 8:45 am]

BILLING CODE 4910-13-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 522**

**Implantation or Injectable Dosage Form New Animal Drugs; Withdrawal of Approval of NADAs; Estradiol Benzoate**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations that reflect approval of two new animal drug applications (NADAs) for a suspension implant of estradiol benzoate microspheres used in steers and heifers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency, and in suckling beef calves for increased rate of weight gain. In a notice published elsewhere in this issue of the **Federal Register**, FDA has withdrawn approval of the NADAs.

**DATES:** This rule is effective April 19, 2007.

**FOR FURTHER INFORMATION CONTACT:**

Pamela K. Esposito, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9067; e-mail: [pamela.esposito@fda.hhs.gov](mailto:pamela.esposito@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** PR Pharmaceuticals, Inc., 1716 Heath Pkwy., Fort Collins, CO 80524, has requested that FDA withdraw approval of NADA 141-040 for DURALEASE (estradiol benzoate), a suspension implant of estradiol benzoate

microspheres used in steers and heifers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency and NADA 141-041 for CELERIN-C (estradiol benzoate), a similar product used in suckling beef calves for increased rate of weight gain. This action is requested because the products are no longer manufactured or marketed.

In a notice published elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 141-040 and NADA 141-041 and all supplements and amendments thereto, were withdrawn, as of September 29, 2006.

Following the withdrawal of approval of these NADAs, PR Pharmaceuticals, Inc., is no longer a sponsor of an approved application. Therefore, 21 CFR 510.600(c) is amended to remove entries for this firm. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect the withdrawal of 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.

**List of Subjects**

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 522*

Animal drugs.

■ Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

**§ 510.600 [Amended]**

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “PR Pharmaceuticals, Inc.”; and in the table in paragraph (c)(2) remove the entry for “067210”.

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 522.841 [Removed]**

■ 4. Remove § 522.841.

Dated: April 9, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. E7-7458 Filed 4-18-07; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 558**

**New Animal Drugs For Use in Animal Feed; Withdrawal of Approval of NADAs; Pyrantel; Tylosin; Tylosin and Sulfamethazine**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) for intermediate premixes used to manufacture Type C medicated feeds. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADAs.

**DATES:** This rule is effective April 30, 2007.

**FOR FURTHER INFORMATION CONTACT:**

Pamela K. Esposito, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9067, e-mail: [pamela.esposito@fda.hhs.gov](mailto:pamela.esposito@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701, has requested that FDA withdraw approval of NADA 121-200 for Tylosin 10 Premix (tylosin), NADA 129-159 for TYLAN 40 Sulfa-G (tylosin and sulfamethazine), and NADA 137-484 for Swine Guard-BN (pyrantel). All are intermediate premixes used to manufacture Type C medicated feeds. This action is requested because the products are no longer manufactured or marketed.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA gives notice that approval of NADA