§ 120.225 How to implement an alcohol testing program.

(a) * * *

(2) Send this information in the form and manner prescribed by the Administrator, in duplicate to the appropriate address below:

(i) For § 91.147 operators: The Flight Standards District Office nearest to your principal place of business.

(ii) For all others: The Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM–800), 800 Independence Avenue, SW., Washington, DC 20591.

* * * * *

§ 120.119 Annual reports.

(b) As an employer, you must use the Management Information System (MIS) form and instructions as required by 49 CFR part 40 (at 49 CFR 40.26 and appendix H to 49 CFR part 40). You may also use the electronic version of the MIS form provided by DOT. The Administrator may designate means (e.g., electronic program transmitted via the Internet) other than hard-copy, for MIS form submission. For information on where to submit MIS forms and for the electronic version of the form, see: http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/dmg tested alcoholic.

* * * * *

§ 120.211 Applicable Federal regulations.

(b) * * *

(5) § 135.1—Applicability

§ 120.225 How to implement an alcohol testing program.

(e) * * *

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(i) For § 91.147 operators: The Flight Standards District Office nearest to your principal place of business.

(ii) For all others: The Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM–800), 800 Independence Avenue, SW., Washington, DC 20591.

* * * * *

§ 120.117 Implementing a drug testing program.

(a) * * *

(2) An operator as defined in § 91.147 of this chapter

§ 120.31, 120.33, 120.35, 120.37, and 120.39 of this chapter; and with the provisions of part 136, subpart A, and § 91.147 of this chapter by September 11, 2007.

* * * * *

Pamela Hamilton-Powell,
Director, Office of Rulemaking.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Children’s Products Containing Lead; Exemptions for Certain Electronic Devices

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) is issuing a final rule concerning certain electronic devices for which it is not technologically feasible to meet the lead limits as required under section 101 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).1

DATES: Effective Date: This final rule is effective on January 20, 2010.

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail khatlelid@cpsc.gov; telephone (301) 504–7254.

SUPPLEMENTARY INFORMATION:

A. Background

The Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110–314, 122 Stat. 3016, provides for specific lead limits in children’s products. Section 101(a) of the CPSIA provides that, by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. The limit

1 The Commission voted 5–0 to publish this final rule, with changes, in the Federal Register. Chairman Inez M. Tenenbaum, and Commissioners Thomas H. Moore, Nancy Nord, Robert Adler, and Anne Northup voted to publish the notice with changes. Commissioner Northup issued a statement, and the statement can be found at http://www.cpsc.gov/PN/northup01062010devices.pdf.
will be further reduced to 100 ppm after three years, or August 14, 2011, unless the Commission determines that it is not technologically feasible to meet this lower limit. Section 3(a)(16) of the Consumer Product Safety Act, as amended by section 235(a) of the CPSIA, defines “children’s product” as a “consumer product designed or intended primarily for children 12 years of age or younger.”

B. Statutory Authority
Section 101(b)(2) of the CPSIA provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children’s activities, and the aging of the product, as determined by the Commission. Paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child. Section 101(b)(2)(B) of the CPSIA further provides that the Commission shall promulgate a rule providing guidance with respect to what product components or classes of components will be considered to be inaccessible. An interpretative rule providing guidance on inaccessibility (inaccessibility rule) was published in the Federal Register on August 7, 2009 (74 FR 39535).

In addition, if the Commission determines that it is not technologically feasible for certain electronic devices to comply with the lead limits, section 101(b)(4) of the CPSIA provides that the Commission shall issue requirements by regulation to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices, and establish a schedule for achieving full compliance unless the Commission determines that full compliance with the lead limits is not technologically feasible within such a schedule. Under section 101(d) of the CPSIA, technological feasibility is based on the commercial availability of products, technology, or other practices that will allow compliance with the lead limits.

On January 15, 2009, the Commission issued a notice of proposed rulemaking on requirements for certain electronic devices that could not comply with the lead limits due to technological infeasibility (74 FR 2435). The notice of proposed rulemaking was withdrawn on February 12, 2009 (74 FR 7021). On that date, the Commission issued an interim final rule (74 FR 6991) to provide certain exemptions for children’s electronic devices including:
- Inaccessible lead-containing component parts;
- Accessible lead-containing components parts that cannot be produced without lead due to the lack of technologically feasible substitutions and which require lead for the proper functioning of the component part; and
- Lead-containing spare parts or other removable components which are inaccessible when the product is assembled in functional form or is otherwise granted an exemption.

The interim final rule also directed Commission staff to reevaluate and report to the Commission on the technical feasibility of compliance with the lead limits, including the technological feasibility of making accessible component parts inaccessible, and the status of the exemptions no less than every five years after publication of a final rule in the Federal Register. Comments on the interim final rule were due on March 16, 2009.

C. Discussion of Comments to the Interim Final Rule
The Commission received seven comments from consumer groups, electronics associations, companies, and individuals. In general, most comments sought to narrow or expand the scope of the exemptions.

1. Summary of the Law—Section 1500.88(a)
Section 1500.88(a), in essence, summarized the lead content limits in children’s products under section 101 of the CPSIA and how, over time, the limits decrease from 600 ppm to 100 ppm by August 14, 2011 unless the Commission determines that it is not technologically feasible to meet this lower limit. Section 1500.88(a) also stated that, “Paint, coatings, or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child.”

We did not receive any comment on this provision. However, we have, on our own initiative, revised the last sentence by adding, “Section 101(b)(2) of the CPSIA further provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children’s activities, and the aging of the product, as determined by the Commission.”

2. Technological Feasibility—Section 1500.88(b)
Section 1500.88(b) explained that if the Commission determines that it is not technologically feasible for certain electronic devices, the Commission must issue requirements by regulation to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices and establish a schedule by which such electronic devices shall be in full compliance unless the Commission determines that full compliance is not technologically feasible for such devices within a schedule set by the Commission.

We have, on our own initiative, modified this section to add “within a schedule set by the Commission” after “such devices.” This modification reflects the statutory language at section 101(b)(4)(B) of the CPSIA.

One commenter requested guidance regarding the definition of “electronic devices.” The CPSIA does not provide a definition for electronic devices. However, we believe a reasonable definition of an electronic device is “a device that generates, stores, distributes, or converts electrical energy into another energy form.” Examples of children’s electronic devices include, but are not limited to, products with batteries or power cords (or that use solar power or other power sources), such as music players, headphones, some toys and games, some calculators, and certain computers or similar electronic learning products.

3. Certain Lead-Containing Component Parts—Section 1500.88(c)
Section 1500.88(c) provided that certain lead-containing component parts in electronic devices that are unable to meet the lead limits would be granted exemptions provided that the use of lead is necessary for the proper functioning of the component part and it is not technologically feasible for the component part to meet the lead content limits.

On our own initiative, we have modified this section to add the word “accessible” in between “certain” and “lead-containing component parts,” to make clear that the exemptions in the rule are applicable only to accessible component parts. Inaccessible component parts are already excluded from the lead limits under section 101(b)(2) of the CPSIA.
One commenter stated that the exemptions should be narrowed to cover only components of electrical goods. This commenter asserted that the language in the interim final rule could be read to exclude general materials that contain metal alloys and enable manufacturers to add lead although it may not be technologically necessary to do so.

The rule was intended to be limited to the materials and components necessary for the electronic functioning of children’s electronic devices. In response to the comments, we have revised § 1500.88(c) by adding the word “electronic” before the word “functioning.” In addition, we have further clarified § 1500.88(d) to add the word “electronic” before “component parts” in the first sentence. Non-functional uses of lead in children’s electronic devices remain subject to the lead content limits under section 101(a) of the CPSIA. For example, if the metal component part was purely decorative, such as a cell phone charm or wrist accessory sold with, or attached to, a child’s phone, that charm or accessory is not necessary to the proper electronic functioning of the component part and is subject to the lead content limits.

Another commenter requested that the exemptions for the metal alloy components in children’s electronic devices be extended to products whose mechanical functions require the use of material containing lead, such as a brass collar on the wheel of a toy. The commenter also asserted that the exemption for “lead-bronze bearing shells and bushings” are not primarily used for the transmission of electrical current, but are mechanical devices.

Section 101(b)(4) of the CPSIA allows exemptions to the lead content limits if the Commission finds that it is not technologically feasible to remove the lead from the electronic devices. This section does not provide for exemptions for other types of products that are unrelated to electronic devices. The exemptions under this rule include bearing shells and bushings only when those bearing shells and bushings are integral to the operation of certain electronic devices, such as electric motors. For this reason, lead-bronze bearing shells and bushings are allowed in children’s electronic devices. However, the exemption does not extend to bearing shells and bushings in children’s products that are unrelated to electronic operations because they do not fall within the scope of these exemptions. The components must comply with the CPSIA’s lead content limits. We note that if such components are inaccessible to a child, they would not be subject to the CPSIA lead content limits under 16 CFR 1500.87.

One commenter stated that the health implications of lead exposure from the electronic products have not been considered and that the interim final rule does not provide an incentive to improve technology to reduce lead content. The commenter also stated that exempted products should be labeled as lead content. Another commenter stated that no exemptions should be granted given the dangerous effects of lead in children.

As discussed in the preamble to the interim final rule (74 FR at 6992), the complete elimination of lead, or the reduction in lead content to the lead content limits specified in the CPSIA, is currently not technologically feasible for certain components of children’s electronic products. Accordingly, the final rule provides for exemptions from the lead limits for a limited number of components of electronic devices that must be manufactured using lead, including in certain metal alloys. Such component parts could include power cord pins, cathode-ray tubes, and electrical connectors. Children are not expected to experience significant exposures to lead from these few applications. The lead containing components that are being exempted are components that one would not expect children to mouth, swallow, or handle for significant periods under normal and reasonably foreseeable conditions. Moreover, with few exceptions, many electronic devices in compliance with the lead limits under the CPSIA either because they already meet the lead content limits or because the lead-containing component part is inaccessible (74 FR at 6992).

Furthermore, we do not believe that labeling electronic devices for their lead content would add to the safety of these products. In the absence of the exemptions provided for in the CPSIA and this rule, certain electronics devices would be banned if they were intended primarily for children. The likely substitute for some of these products would be similar products that are intended for general consumer use. Thus, not providing these exemptions could result in increases in the children’s lead exposure from products intended for general consumer use that are not subject either to the lead limitations in the CPSIA or the alternate lead limits provided for in the exemptions under this rule.

We also disagree with the commenter’s assertion that the rule does not provide incentives for technological improvements. Congress recognized that certain electronic devices currently may not be able to meet the lead content limits. However, under section 101(b)(5) of the CPSIA, the Commission specifically was directed to periodically review and revise the regulations, as necessary, no less than every five years. The Commission intends to continue to evaluate the technological feasibility of making accessible component parts inaccessible, and to reevaluate the exemptions within that time frame as provided under § 1500.88(f) of this rule.

4. Exemptions for Lead—Section 1500.88(d)

This section set forth the specific exemptions for lead as used in certain component parts in children’s products. As discussed in part C.3 of this preamble, we have added the word “electronic” before “component parts” in the first sentence of § 1500.88(d) to make clear that this rule applies to materials and components necessary for the electronic functioning of children’s electronic devices.

Additionally, on our own initiative, we have revised § 1500.88(d)(1) to insert a comma between “electronic components” and “and fluorescent tubes” to clarify that electronic components and fluorescent tubes should be considered as separate items rather than as one item or as synonyms. We also have revised § 1500.88(d)(2) to replace “3,500 ppm” with “3,500 ppm,” for purposes of consistency with how the ppm levels are expressed elsewhere in the final rule. We also have revised § 1500.88(d)(8) to insert a comma between “the seal frit and frit ring” and “as well as in print pastes” to clarify that a seal frit and frit ring are distinct from print pastes.

Commenters representing the electronics industry manufacturers asserted that the list of exempted materials and components in the final rule is too limited. They requested that the rule incorporate all of the current exemptions of the use of lead in the European Union’s Restriction on Hazardous Substances (EU RoHS) directive to avoid inconsistencies and to harmonize with other standards. They claimed that while ongoing research aims to find alternatives and eliminate the use of lead, it is not yet technologically feasible to avoid all uses of lead. The commenters also asserted that testing for lead in electronic products is difficult and costly.

We do not believe that it is necessary to incorporate into the rule all of the exemptions listed in the EU RoHS directive (European Directive 2002/95/EC and amendments to the directive are available at http://eur-
For purposes of a petition request. 16 CFR 1051.6(a)(5). Commenters also requested that the rule explicitly state that exempted or inaccessible parts are not subject to the testing requirement of section 102 of the CPSIA.

With regard to inaccessible component parts, the preamble to the inaccessibility rule stated that a manufacturer currently is not required to provide third-party testing to demonstrate inaccessibility (74 FR at 39537). In addition, many of the exemptions provided under this rule do not require testing under section 102 of the CPSIA because there are no lead limits associated with the exemptions. However, the exemptions for the metal alloys are not blanket or absolute exemptions. Instead, they are presented as alternate lead limits. As such, those components, i.e., copper (less than 4 percent lead by weight), steel (less than 0.35 percent lead by weight), and aluminum (less than 0.4 percent lead by weight), must still be tested by the manufacturer to verify that these component parts comply with these higher lead limits under section 102 of the CPSIA.

The Commission intends to address component part testing and the establishment of protocols and standards for ensuring that children’s products are tested for compliance with applicable children’s products safety rules in an upcoming rulemaking. As for the other specific exemptions mentioned in §1500.88(d), such as lead used in compliant pin connector systems (§1500.88(d)(6)), lead used in optical and filter glass (§1500.88(d)(7)), lead oxide in plasma display panels and surface conduction electron emitter displays used in structural elements (§1500.88(d)(6)), and lead oxide in the glass envelope of Black Light Blue lamps (§1500.88(d)(9)), we did not receive comments on these provisions. Consequently, the final rule retains those provisions without change.

5. Removable or Replaceable Parts—Section 1500.88(e)

This section provided that components of electronic devices that are removable or replaceable, such as battery packs and light bulbs, are not subject to the lead content limits if they were otherwise granted an exemption, or are inaccessible when installed in the product, are not subject to the lead content requirements. When installed, such parts are inaccessible under 16 CFR 1500.87. In addition, these types of spare parts or replacement parts, including battery pack and light bulbs, are not intended primarily for children since such parts are available for general use by the public. While spare parts may sometimes be included with a children’s product, in many instances, the parts, necessary for the functioning of the electronic device, are to be installed by adults, and are inaccessible to children once installed.

One commenter requested guidance regarding whether a metal key sold with electrical electronic equipment would be subject to the lead content limits. According to the commenter, keys are made with copper alloy and aluminum and contain lead of up to 0.4%. The commenter stated that substitutes containing lead below 300 ppm are unavailable.

The definition of “children’s product” means a consumer product designed or intended primarily for children 12 years of age. A key used in connection with a child’s electronic device does not necessarily make the key a children’s product if the key is intended for an adult to use in safeguarding or monitoring the use of the electronic equipment. In such instances, the key would be in the possession of the adult at all times, and would not be considered a children’s product. In other instances, if a key is to be used primarily by a child in connection with an electronic device, an exemption from the lead content limits under the CPSIA would apply only in instances where such a key is necessary for the electronic functioning of the device.

Several commenters addressed removable and replaceable parts. Some commenters supported the exemption from the lead content limits for such parts on the basis that replacing or installing parts of a children’s electronic device is not a children’s activity. Other commenters opposed the exemption because children could access the lead-containing parts when they are not installed.

We decline to revise the rule as suggested by some commenters. We have determined that removable or replaceable parts, such as battery packs and light bulbs, that are inaccessible when installed in the product, are not subject to the lead content requirements. When installed, such parts are inaccessible under 16 CFR 1500.87. In addition, these types of spare parts or replacement parts, including battery pack and light bulbs, are not intended primarily for children since such parts are available for general use by the public. While spare parts may sometimes be included with a children’s product, in many instances, the parts, necessary for the functioning of the electronic device, are to be installed by adults, and are inaccessible to children once installed.

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children’s electronic devices, including the technological feasibility of making accessible component part inaccessible, and the status of the exemptions no less than every five years.

One commenter stated that the EU RoHS directive specifies that exemptions must be reviewed every four years. The commenter requested that the Commission adopt the same four year review cycle. As discussed in part C.4 of this preamble, we are not adopting all of the exemptions in the EU RoHS directive. Accordingly, the Commission’s review of the exemptions provided under this rule will be based on the application of lead in children’s electronic devices. Section 101(b)(5) of the CPSIA provides that reviews and possible revision must occur no less frequently than every five years. Thus, we do not believe that the rule needs to be revised at this time. However, to the extent technological advances are made in the next few years, such that the existing exemptions warrant revision or rescission, we will review such changes and consider revisions prior to the five year review period.

D. Impact on Small Businesses

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

In the preamble to the interim final rule (74 FR at 6992), the Commission’s Directorate for Economic Analysis determined that the exemption for certain specified materials from the requirements of section 101(a) of the CPSIA will not result in any increase in the costs of production for any firm. Its only effect on businesses, including small businesses, will be to reduce the costs associated with compliance with the lead content limits of the CPSIA. Based on the foregoing assessment, the Commission certifies that the rule would not have a significant impact on a substantial number of small entities.

E. Environmental Considerations

Generally, CPSC rules are considered to “have little or no potential for affecting the human environment,” and environmental assessments are not usually prepared for these rules (see 16 CFR 1500.84). The final rule is not expected to have an adverse impact on the environment, thus, the Commission concludes that no environmental assessment or environmental impact statement is required in this proceeding.

F. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this final rule is stated in section 18 of the Federal Hazardous Substances Act. 15 U.S.C. 1261n.

G. Effective Date

The Administrative Procedure Act requires that a substantive rule must be published not less than 30 days before its effective date, unless the rule relieves a restriction. 5 U.S.C. 553(d)(1). Because the final rule provides relief from existing testing requirements under the CPSIA and is virtually identical to an interim final rule that has been in effect since February 10, 2009, the effective date for the final rule is January 20, 2010.

List of Subjects in 16 CFR Part 1500


For the reasons stated above, the Commission amends chapter II of title 16 of the Code of Federal Regulations as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

1. The authority citation for part 1500 continues to read as follows:


2. Revise §1500.88 to read as follows:

§1500.88 Exemptions from lead limits under section 101 of the Consumer Product Safety Improvement Act for Certain Electronic Devices.

(a) The Consumer Product Safety Improvement Act (CPSIA) provides for specific lead limits in children’s products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger may not contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to meet this lower limit. Section 101(b)(2) of the CPSIA further provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children’s activities, and the aging of the product, as determined by the Commission.

Paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child.

(b) Section 101(b)(4) of the CPSIA provides that if the Commission determines that it is not technologically feasible for certain electronic devices to comply with the lead limits, the Commission must issue requirements by regulation to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices and establish a compliance schedule unless the Commission determines that full compliance is not technologically feasible within a schedule set by the Commission.

(c) Certain accessible lead-containing component parts in children’s electronic devices unable to meet the lead limits set forth in paragraph (a) of this section due to technological infeasibility are granted the exemptions that follow in paragraph (d) of this section below, provided that use of lead is necessary for the proper electronic functioning of the component part and it is not technologically feasible for the component part to meet the lead content limits set forth in paragraph (a) of this section.

(d) Exemptions for lead as used in certain electronic components parts in children’s electronic devices include:

1. Lead blended into the glass of cathode ray tubes, electronic components, and fluorescent tubes.

2. Lead used as an alloying element in steel. The maximum amount of lead shall be less than 0.35% by weight (3,500 ppm).

3. Lead used in the manufacture of aluminum. The maximum amount of lead shall be less than 0.4% by weight (4,000 ppm).

4. Lead used in copper-based alloys. The maximum amount of lead shall be less than 4% by weight (40,000 ppm).

5. Lead used in lead-bronze bearing shells and bushings.

6. Lead used in compliant pin connectors systems.

7. Lead used in optical and filter glass.
(8) Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring, as well as in print pastes. (9) Lead oxide in the glass envelope of Black Light Blue (BLB) lamps.

(e) Components of electronic devices that are removable or replaceable, such as battery packs and light bulbs that are inaccessible when the product is assembled in functional form or are otherwise granted an exemption, are not subject to the lead limits in paragraph (a) of this section.

(f) Commission staff is directed to reevaluate and report to the Commission on the technological feasibility of compliance with the lead limits in paragraph (a) of this section for children’s electronic devices, including the technological feasibility of making accessible component parts inaccessible, and the status of the exemptions, no less than every five years after publication of a final rule in the Federal Register on children’s electronic devices.

Dated: January 12, 2010.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

[FR Doc. 2010–877 Filed 1–19–10; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Change of Sponsor’s Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor’s name from Fort Dodge Animal Health, Division of Wyeth Holdings Corp. to Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, Inc. In a separate action, FDA is amending the animal drug regulations to reflect a change of sponsor’s name from Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc. to Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

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 in 21 CFR Part 510

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

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 part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

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


2. In § 510.600, in the table in paragraph (c)(1), revise the entries for “Fort Dodge Animal Health, Division of Wyeth Holdings Corp.” and “Fort Dodge Animal Health, Division of Wyeth” in the table in paragraph (c)(2), and in the table in paragraph (d) of this section, by inserting “Fort Dodge Animal Health, Division of Wyeth Holdings Corp.” in the table in paragraph (c)(1), the table in paragraph (c)(2), and “Fort Dodge Animal Health, Division of Wyeth Holdings Corp.” in the table in paragraph (d) of this section, by inserting “Fort Dodge Animal Health, Division of Wyeth” in the table in paragraph (c)(2), and “Fort Dodge Animal Health, Division of Wyeth” in the table in paragraph (d) of this section, by inserting “Fort Dodge Animal Health, Division of Wyeth” in the table in paragraph (c)(2), and “Fort Dodge Animal Health, Division of Wyeth” in the table in paragraph (d) of this section.

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

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Dated: January 8, 2010.

Elizabeth Rettie,
Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–930 Filed 1–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9475]

RIN 1545–BF83

Corporate Reorganizations; Distributions Under Sections 368(a)(1)(D) and 354(b)(1)(B); Correction

AGENCY: Internal Revenue Service (IRS), Treasury.