undesignation by the seller is eliminated. Duke requests clarification that a slice of system undesignation by the seller would be appropriate in such circumstances.

Commission Determination

6. We confirm that, where an off-system buyer is buying system power from a seller that is a network customer on an adjacent transmission system, the buyer needs transmission service on both the system on which the seller is located and the system on which buyer is located, but that it remains the buyer's choice as to whether to procure network or point-to-point service. The Commission's reference in Order No. 890–C to the use of point-to-point service to take delivery of system power was not intended to restrict the buyer's choice to instead use network service. As Duke notes, there may be a situation in which a buyer and seller of capacity from a network resource both take network service on the same transmission system and the power is delivered under section 31.3 of the *pro forma* OATT to another transmission system on which the buyer's network load is located. In such a situation, both the buyer and seller of power are network customers of the transmission system on which the sale of power takes place. We clarify, to the extent necessary, that the seller in such a situation may support the transaction by undesignating its resources on a system basis.

7. In Order No. 890–C, the Commission noted that the Reliability Standards governing the calculation of ATC were pending Commission review. Concurrent with this order, the Commission in Docket No. RM08–19–000 is directing the North American Electric Reliability Corporation (NERC) to develop modifications to certain of these Reliability Standards to address the modeling of network resources and its impact on the calculation of ATC. To the extent Duke or other parties have concerns regarding the appropriate modeling of network resource designations on the calculation of ATC, the Commission encourages those parties to raise their concerns in NERC's standards development process.

II. Information Collection Statement

8. The Office of Management and Budget (OMB) regulations require that OMB approve certain information collection requirements imposed by an agency.[6] The revisions to the information collection requirements for transmission providers adopted in Order No. 890 were approved under OMB Control Nos. 1902–0233. This order does not substantively alter those requirements. OMB approval of this order is therefore unnecessary. However, the Commission will send a copy of this order to OMB for informational purposes only.

III. Document Availability

9. In addition to publishing the full text of this document in the **Federal Register,** the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington DC 20426.

10. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

11. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

IV. Effective Date and Congressional Notification

12. This order does not substantively alter the requirements of Order Nos. 890, 890–A, 890–B or 890–C and, therefore, will become effective as of the date of publication in the **Federal Register.**

By the Commission.

Kimberly D. Bose,

Secretary.

[FR Doc. E9–28216 Filed 11–24–09; 8:45 am]

BILLING CODE 6717–01–P

[6] 5 CFR 1320 (2007).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. FDA–1977–N–0013] (formerly Docket No. 1977–N–0094L)

RIN 0910–AF36

Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a final rule that appeared in the **Federal Register** of April 29, 2009 (74 FR 19385) (as amended in the **Federal Register** of June 30, 2009 (74 FR 31177). The final rule requires important new organ-specific warnings and related labeling for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products. The new labeling informs consumers about the risk of liver injury when using acetaminophen and the risk of stomach bleeding when using nonsteroidal anti-inflammatory drugs (NSAIDs). This document is intended to clarify some provisions in the final rule which may be unclear. Specifically, this document addresses how blister cards can be labeled to comply with the new required labeling, clarifies the length of time that the ''See new warnings'' flag is required to appear in the labeling, and provides some optional wording to clarify the liver injury warning on OTC acetaminophen products containing multiple active ingredients.

DATES: *Effective Date*: This final rule is effective April 29, 2010.

Compliance Date: The compliance date for all products subject to this final rule, including products with annual sales less than $25,000, is April 29, 2010.

FOR FURTHER INFORMATION CONTACT: Arlene Solbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending the final rule that was published in the **Federal Register** of

April 29, 2009, (the April 29, 2009, final rule) which requires important new organ-specific warnings and related labeling for OTC IAAA drug products. The new labeling informs consumers about the risk of liver injury when using acetaminophen and the risk of stomach bleeding when using NSAIDs. After the April 29, 2009, final rule was published, we received feedback from manufacturers stating that some of the requirements in the final rule are unclear (Refs. 1 and 2). We are amending the final rule to address these issues raised by the submissions (see section II of this document). One issue involves the liver injury and stomach bleeding warnings that must appear on immediate container labeling. Another issue concerns the posting of a ''See new warnings'' flag on the principal display panel (PDP) of the retail packaging. The third issue concerns the wording of the first bulleted statement in the liver injury warning.

Publication of this document constitutes final action on the change under the Administrative Procedures Act (5 U.S.C. 553). This technical amendment merely clarifies the intent of the final rule with respect to the three minor issues raised in the submissions. FDA therefore, for good cause shown, has determined that notice and public comment are unnecessary under 5 U.S.C. 553(b)(3)(B).

II. April 29, 2009, Final Rule Requirements Being Addressed in This Document

A. Immediate Container Labeling

In the final rule, we require that the new liver injury and stomach bleeding warnings appear on the outer and the immediate container of the retail packaging, where applicable (§ 201.326(a)(1)(iii)(A), (a)(1)(iv)(A)(*1*), (a)(1)(v)(A), (a)(2)(iii)(A), (a)(2)(iv)(A)(*1*), and (a)(2)(v)(A) (21 CFR 201.326(a)(1)(iii)(A), (a)(1)(iv)(A)(*1*), (a)(1)(v)(A), (a)(2)(iii)(A), (a)(2)(iv)(A)(*1*), and (a)(2)(v)(A)). We received feedback from manufacturers seeking clarification of these final rule requirements for blister card packaging (Ref. 1). We did not intend for the final rule to require liver injury or stomach bleeding warnings to appear on each blister unit on a blister card. Rather, we believe it is acceptable that the appropriate warning appear on the blister card in one place, as long as the warning stays intact and readable when drug product is removed from the blister card. Therefore, in this document, we are stating explicitly that the liver injury and stomach bleeding warnings are not required to appear on each blister unit of a blister card, as long as the appropriate warning appears on the blister card and remains intact and readable when drug is removed from the blister card. These modifications appear in § 201.326(a)(1)(iii)(A), (a)(1)(iv)(A)(*1*), (a)(1)(v)(A), (a)(2)(iii)(A), (a)(2)(iv)(A)(*1*), and (a)(2)(v)(A) in the regulatory text of this document.

We also received feedback that certain immediate containers, such as stick packs and sachets, also present space limitations for labeling and that we should not require the liver injury and stomach bleeding warnings to appear on these immediate container packages (Ref 1). We do not agree that these types of immediate containers should be exempt from the requirements in the final rule. Although these packages have limited labeling space, we believe that there is adequate space to accommodate the required warnings on these types of packages. We are also concerned that consumers may routinely remove these packages from the outer carton and, therefore, fail to see the liver injury and stomach bleeding warnings if they are only printed on the carton. For these reasons, we are not exempting these types of immediate containers from the final rule requirements.

B. ''See New Warnings'' Flag

In the April 29, 2009, final rule, we require a ''See new warnings'' flag on the PDP of all OTC drug products containing acetaminophen or NSAIDs to advise consumers of the new required warnings. In the final rule, we state that ''we will require that the 'See New Warnings' flag appear on the PDP for one year after the final rule is published, rather than for the 6 or 9 months suggested by the submission'' (74 FR 19385 at 19388). We explained that ''we continue to believe that educating consumers about the risks associated with OTC IAAA drug products is very important and more likely to be successful if the flag remains on products for 1 year'' (74 FR 19385 at 19388 through 19389). In § 201.326(b) (21 CFR 201.326(b)), the final rule states: ''The labeling of any drug product subject to this section that is initially introduced or initially delivered for introduction into interstate commerce before the effective date and within 12 months after the effective date of the final rule must bear on its PDP, as defined in § 201.60, the statement 'See new warnings information.'''

We intended this provision to require that the ''See new warnings'' statement appear on the PDPs of all OTC drug products containing acetaminophen or NSAIDs that are introduced into interstate commerce by the effective date of the final rule (i.e., by April 29, 2010). We did not intend to require the ''See new warnings'' statement for those products that are introduced into interstate commerce after the final rule effective date. We also intended the provision to require that the statement remain on the label for at least 1 year from the time the product is introduced into interstate commerce. We did not intend to require that the statement remain on the label for any longer than the 1-year period from the time of introduction into interstate commerce. For example, if the ''See new warnings'' flag is included on the PDP of a product introduced into interstate commerce 6 months after publication of the final rule (i.e., October 29, 2009), then the flag must remain on the PDP for a full year (i.e., until October 29, 2010). To make this requirement clear, we are modifying § 201.326(b) in the regulatory text of this document.

C. Liver Injury Warning for OTC Acetaminophen Products Containing Multiple Active Ingredients

In the April 29, 2009, final rule, we require a liver injury warning for all OTC drug products containing acetaminophen. The introductory sentence and first bulleted statement of this warning state: ''This product contains acetaminophen. Severe liver damage may occur if you take [bullet] more than the [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount * * *''. Our intention was that the warning would prevent consumers from taking more than 4 grams (g) of an OTC acetaminophen product daily, the proposed maximum safe daily dose for OTC acetaminophen. After the final rule was published, we received feedback from manufacturers of OTC acetaminophen products who were concerned that consumers may be confused about the warning on OTC acetaminophen containing multiple active ingredients (e.g., cold-cold/analgesic combination products) (Refs. 1 and 2). For some combination products, the maximum number of daily dosage units may be limited by an active ingredient other than acetaminophen in the products. In such cases, the maximum number of daily dosage units result in a maximum daily dose of acetaminophen which is significantly below 4 g. To clarify that the maximum number of daily dosage units may not be the maximal daily dose of acetaminophen, we are allowing the optional statement ''for this product'' at the end of the first bulleted statement: ''more than [insert maximum number of daily dosage units] in 24 hours, which

is the maximum daily amount'' [optional: ''for this product'']. We agree with manufacturers that this revision will clarify the warning for OTC acetaminophen products containing multiple active ingredients.

III. Request for Enforcement Discretion

We received feedback requesting that we exercise enforcement discretion for manufacturers of OTC combination acetaminophen products so that they could revise the first bulleted statement of the liver injury warning to clarify that the maximum number of daily dosage units may not be the maximal daily dose of acetaminophen for those products (Ref. 2). As discussed in section II.C of this document, we are allowing the optional statement ''for this product'' at the end of the first bulleted statement: ''more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount.'' The request asked us to exercise enforcement discretion until we revise this bulleted statement in the final rule. Because we are amending this bulleted statement in this document, the request that we exercise enforcement discretion is no longer applicable.

IV. Analysis of Impacts

We have examined the impacts of this 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). We believe that this 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. Our April 29, 2009, final rule requires important new organ-specific warnings (i.e., liver injury and stomach bleeding warnings) and related labeling for OTC drug products containing acetaminophen and NSAIDs to advise consumers of potential risks and when to consult a doctor (74 FR 19385). We are amending the final rule in this document to clarify some of the labeling requirements specified in the final rule. Three amendments are being made. One amendment specifies that manufacturers of OTC acetaminophen and NSAID drug products are not required to put the liver injury or stomach bleeding warning on each blister unit of a blister card as long as the appropriate warning appears on the blister card and remains intact and readable when drug is removed from the blister card (§ 201.326(a)(1)(iii)(A), (a)(1)(iv)(A)(*1*), (a)(1)(v)(A), (a)(2)(iii)(A), (a)(2)(iv)(A)(*1*), and (a)(2)(v)(A)). The second amendment specifies that the ''See new warnings'' flag (§ 201.326(b)) must remain on the label for at least 1 year from the time the manufacturer puts the statement on the PDP. The third amendment clarifies the liver injury warning on OTC acetaminophen products containing multiple active ingredients. We examined the impacts of the amended labeling requirements described in this document when we developed the April 29, 2009, final rule. We determined that the final rule would not have a significant impact on a substantial number of small entities. Because this amendment does not add any new requirements that were not considered in developing the final rule, we do not believe this rule will 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. We do not expect the final rule as amended to result in any 1-year expenditure that would meet or exceed this amount.

V. Paperwork Reduction Act of 1995

We conclude that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

We have determined under 21 CFR 25.31(a) 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.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' The sole statutory provision giving preemptive effect to the final rule is section 751 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379r).

We believe that we have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effects of this rule are consistent with Executive Order 13132.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA–1977–N–0013–0039.
2. FDA–1977–N–0013–0040.

List of Subjects in 21 CFR Part 201

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, 21 CFR part 201, (as added in the **Federal Registers** of April 29, 2009, and amended June 30, 2009), is amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Section 201.326, (as added at 74 FR 19385, April 29, 2009, and amended at 74 FR 31177, June 30, 2009) is further amended by revising paragraphs (a)(1)(iii)(A), (a)(1)(iv)(A)(*1*), (a)(1)(v)(A), (a)(2)(iii)(A), (a)(2)(iv)(A)(*1*), (a)(2)(v)(A), and (b) to read as follows:

§ 201.326 Over-the-counter drug products containing internal analgesic/antipyretic active ingredients; required warnings and other labeling.

(a) * * *

(1) * * *

(iii) * * *

(A) The liver warning states ''Liver warning [heading in bold type]: This product contains acetaminophen. Severe liver damage may occur if you take [bullet] more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount [optional: 'for this product'] [bullet] with other drugs containing acetaminophen [bullet] 3 or more alcoholic drinks every day while using this product''. This ''Liver'' warning must be the first warning under the ''Warnings'' heading. For products that contain both acetaminophen and aspirin, this ''Liver'' warning must appear after the ''Reye's syndrome'' and ''Allergy alert'' warnings in § 201.66(c)(5)(ii)(A) and (c)(5)(ii)(B) and before the ''Stomach bleeding'' warning in paragraph (a)(2)(iii)(A) of this section. If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers. If the immediate container is a blister card, the warning must appear on the blister card and remain intact and readable when drug product is removed from the blister card. The warning does not need to be included on each blister unit.

* * * * *

(iv) * * *

(A) * * *

(*1*) The liver warning states ''Liver warning [heading in bold type]: This product contains acetaminophen. Severe liver damage may occur if your child takes [bullet] more than 5 doses in 24 hours, which is the maximum daily amount [optional: 'for this product'] [bullet] with other drugs containing acetaminophen''. This ''Liver'' warning must be the first warning under the ''Warnings'' heading. If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers. If the immediate container is a blister card, the warning must appear on the blister card and remain intact and readable when drug product is removed from the blister card. The warning is not required to be included on each blister unit.

* * * * *

(v) * * *

(A) The liver warning states ''Liver warning [heading in bold type]: This product contains acetaminophen. Severe liver damage may occur if [bullet] adult takes more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount [optional: 'for this product'] [bullet] child takes more than 5 doses in 24 hours [bullet] taken with other drugs containing acetaminophen [bullet] adult has 3 or more alcoholic drinks everyday while using this product.'' If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers. If the immediate container is a blister card, the warning must appear on the blister card and remain intact and readable when drug product is removed from the blister card. The warning is not required to be included on each blister unit.

* * * * *

(2) * * *

* * * * *

(iii) * * *

(A) The stomach bleeding warning states ''Stomach bleeding warning [heading in bold type]: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you [bullet] are age 60 or older [bullet] have had stomach ulcers or bleeding problems [bullet] take a blood thinning (anticoagulant) or steroid drug [bullet] take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) [bullet] have 3 or more alcoholic drinks every day while using this product [bullet] take more or for a longer time than directed''. This ''Stomach bleeding'' warning must appear after the ''Reye's syndrome'' and ''Allergy alert'' warnings in § 201.66(c)(5)(ii)(A) and (c)(5)(ii)(B). For products that contain both acetaminophen and aspirin, the acetaminophen ''Liver'' warning in paragraph (a)(1)(iii) of this section must appear before the ''Stomach bleeding'' warning in this paragraph. If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers. If the immediate container is a blister card, the warning must appear on the blister card and remain intact and readable when drug product is removed from the blister card. The warning is not required to be included on each blister unit.

* * * * *

(iv) * * *

(A) * * *

(*1*) The stomach bleeding warning states ''Stomach bleeding warning [heading in bold type]: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if your child [bullet] has had stomach ulcers or bleeding problems [bullet] takes a blood thinning (anticoagulant) or steroid drug [bullet] takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) [bullet] takes more or for a longer time than directed''. The ''Stomach bleeding'' warning must appear after the ''Reye's syndrome'' and ''Allergy alert'' warnings in § 201.66(c)(5)(ii)(A) and (c)(5)(ii)(B). If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers. If the immediate container is a blister card, the warning must appear on the blister card and remain intact and readable when drug product is removed from the blister card. The warning is not required to be included on each blister unit.

* * * * *

(v) * * *

(A) The Stomach bleeding warning states ''Stomach bleeding warning [heading in bold type]: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if the user [bullet] has had stomach ulcers or bleeding problems [bullet] takes a blood thinning (anticoagulant) or steroid drug [bullet] takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) [bullet] takes more or for a longer time than directed [bullet] is age 60 or older [bullet] has 3 or more alcoholic drinks everyday while using this product''. The ''Stomach bleeding'' warning must appear after the ''Reye's syndrome'' and ''Allergy alert'' warnings in § 201.66(c)(5)(ii)(A) and (c)(5)(ii)(B). If there is an outer and immediate container of a retail package, this warning must appear on both the outer and immediate containers. If the immediate container is a blister card, the warning must appear on the blister card and remain intact and readable when drug product is removed from the blister card. The warning is not required to be included on each blister unit.

* * * * *

(b) *New warnings information statement.* The labeling of any drug product subject to this section that is initially introduced or initially delivered for introduction into interstate commerce before or on April 29, 2010, must bear on its PDP, as defined in § 201.60, the statement ''See new warnings information''. This statement must appear highlighted (e.g., fluorescent or color contrast) or in bold type, be in lines generally parallel to the base on which the package rests as it is designed to be displayed, and be in one

of the following sizes, whichever is greater:

(1) At least one-quarter as large as the size of the most prominent printed matter on the PDP, or

(2) At least as large as the size of the ''Drug Facts'' title, as required in § 201.66(d)(2). The new warnings information statement must remain on the PDP of the drug product for at least 1 year from the date the product is initially introduced into interstate commerce.

* * * * *

Dated: November 17, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28296 Filed 11–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Change of Sponsor

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 for 29 new animal drug applications (NADAs) and 2 abbreviated new animal drug applications (ANADAs) from Intervet, Inc., to Schering-Plough Animal Health Corp.

DATES: This rule is effective November 25, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 29 approved NADAs and 2 approved ANADAs to Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901: NADA 034–478, 034–621, 045–188, 102–380, 104–494, 111–278, 120–648, 121–473, 128–620, 131–310, 131–675, 132–872, 137–600, 138–612, 139–189, 140–856, 140–897, 140–927, 140–954, 140–992, 141–222, 141–236, 141–258, 141–269, 141–276, 141–278, 141–280, 141–282, 141–286; ANADA 200–134 and 200–239. Accordingly, the agency is amending the regulations in 21 CFR parts 520, 522 (21 CFR part 522), and 558 to reflect the transfer of ownership. In addition, § 522.1081 is being revised to reflect a current format.

Following these changes of sponsorship, Intervet, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Intervet, Inc.

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 Parts 520 and 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

■ 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, 520, 522, and 558 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 ''Intervet, Inc.''; and in the table in paragraph (c)(2), remove the entry for ''057926''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.48 [Amended]

■ 4. In paragraph (b) of § 520.48, remove ''057926'' and in its place add ''000061''.

§ 520.905a [Amended]

■ 5. In paragraph (b) of § 520.905a, remove ''057926'' and in its place add ''000061''.

§ 520.905b [Amended]

■ 6. In paragraph (b) of § 520.905b, remove ''057926'' and in its place add ''000061''.

§ 520.905c [Amended]

■ 7. In paragraph (b) of § 520.905c, remove ''057926'' and in its place add ''000061''.

§ 520.905d [Amended]

■ 8. In paragraph (b)(1) of § 520.905d, remove ''057926'' and in its place add ''000061''.

§ 520.905e [Amended]

■ 9. In paragraph (b) of § 520.905e, remove ''057926'' and in its place add ''No. 000061''.

§ 520.1010 [Amended]

■ 10. In paragraph (b)(2) of § 520.1010, remove ''057926'' and in its place add ''000061''.

§ 520.1200 [Amended]

■ 11. In paragraph (b) of § 520.1200, remove ''057926'' and in its place add ''000061''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.246 [Amended]

■ 13. In paragraph (b)(3) of § 522.246, remove ''057926'' and in its place add ''000061''.

§ 522.1010 [Amended]

■ 14. In paragraph (b)(4) of § 522.1010, remove ''057926'' and in its place add ''000061''.

§ 522.1078 [Amended]

■ 15. In paragraph (b) of § 522.1078, remove ''Nos. 050604, 057926, and 059130'' and in its place add ''Nos. 000061, 050604, and 059130''.

§ 522.1079 [Amended]

■ 16. In paragraph (b) of § 522.1079, remove ''057926'' and in its place add ''000061''.

■ 17. Revise § 522.1081 to read as follows:

§ 522.1081 Chorionic gonadotropin.

(a) *Specifications*. Each vial contains 5,000, 10,000 or 20,000 USP units of lyophilized powder for constitution with accompanying diluent to a 10-milliliter solution.