

some other Reserve Bank offices, as described in the May 2003 **Federal Register** document.

#### Administrative Procedure Act

The Board has not followed the provisions of 5 U.S.C. 553(b) relating to notice and public participation in connection with the adoption of this final rule. The revisions to the appendices are technical in nature, and the routing symbol revisions are required by the statutory and regulatory definitions of "check-processing region." Because there is no substantive change on which to seek public input, the Board has determined that the section 553(b) notice and comment procedures are unnecessary.

#### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board has reviewed the final rule under authority delegated to the Board by the Office of Management and Budget. This technical amendment to appendix A of Regulation CC will delete the reference to the San Antonio check processing office of the Federal Reserve Bank of Dallas and reassign the routing symbols listed under that office to the head office of the Federal Reserve Bank of Dallas. The depository institutions that are located in the affected check processing regions and that include the routing numbers in their disclosure statements would be required to notify customers of the resulting change in availability under § 229.18(e). However, because all paperwork collection procedures associated with Regulation CC already are in place, the Board anticipates that no additional burden will be imposed as a result of this rulemaking.

#### 12 CFR Chapter II

##### List of Subjects in 12 CFR Part 229

Banks, Banking, Reporting and recordkeeping requirements.

##### Authority and Issuance

■ For the reasons set forth in the preamble, the Board is amending 12 CFR part 229 to read as follows:

#### PART 229—AVAILABILITY OF FUNDS AND COLLECTION OF CHECKS (REGULATION CC)

■ 1. The authority citation for part 229 continues to read as follows:

*Authority:* 12 U.S.C. 4001 *et seq.*

■ 2. The Eleventh Federal Reserve District routing symbol list in appendix A is revised to read as follows:

#### Appendix A to Part 229—Routing Number Guide to Next-Day Availability Checks and Local Checks

\* \* \* \* \*

##### Eleventh Federal Reserve District

[Federal Reserve Bank of Dallas]

##### Head Office

1110	3110
1111	3111
1113	3113
1119	3119
1120	3120
1122	3122
1123	3123
1140	3140
1149	3149
1163	3163

##### Houston Branch

1130	3130
1131	3131

\* \* \* \* \*

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, May 4, 2004.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 04-10514 Filed 5-7-04; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

##### Implantation or Injectable Dosage Form New Animal Drugs; Insulin

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for the veterinary prescription use of an injectable suspension of zinc insulin of porcine origin for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

**DATES:** This rule is effective May 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: [melanie.berson@fda.gov](mailto:melanie.berson@fda.gov).

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., P.O. Box 318, 405 State St.,

Millsboro, DE 19966, filed NADA 141-236 for the veterinary prescription use of VETSULIN (porcine zinc insulin) Suspension for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus. The NADA is approved as of April 1, 2004, and the regulations are amended in part 522 (21 CFR part 522) by adding § 522.1160 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning April 1, 2004.

The agency has determined under 21 CFR 25.33(d)(1) 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.

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 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 part 522 is amended as follows:

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

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

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

■ 2. Section 522.1160 is added to read as follows:

##### § 522.1160 Insulin.

(a) *Specifications.* Each milliliter of porcine zinc insulin suspension

contains 40 international units (IU) of insulin.

(b) *Sponsor.* See No. 057926 in § 510.600 of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* (i) Administer by subcutaneous injection. An initial once-daily dose, administered by

subcutaneous injection concurrently with or right after a meal, is calculated as follows:

Body Weight	Initial Dose
<10 kg <sup>1</sup> (<22 lb <sup>2</sup> )	1 IU/kg + 1 IU
10 to 11 kg (22 to 24 lb)	1 IU/kg + 2 IU
12 to 20 kg (25 to 44 lb)	1 IU/kg + 3 IU
>20 kg (>44 lb)	1 IU/kg + 4 IU

<sup>1</sup> kg means kilograms.

<sup>2</sup> lb means pounds.

(ii) Adjust the once-daily dose described in paragraph (c)(1)(i) of this section at appropriate intervals based on clinical signs, urinalysis results, and glucose curve/spot check values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(2) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 23, 2004.

**Catherine P. Beck,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 04-10498 Filed 5-7-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Part 655

[Docket No. FHWA-2004-17321]

RIN 2125-AF02

#### National Standards for Traffic Control Devices; the Manual on Uniform Traffic Control Devices for Streets and Highways; Specific Service and General Service Signing for 24-Hour Pharmacies

**AGENCY:** Federal Highway Administration (FHWA), (DOT).

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

**SUMMARY:** This interim final rule amends the rule that prescribes the use of the 2003 edition of the Manual on

Uniform Traffic Control Devices (MUTCD) to permit the use of Specific Service and General Service signing to assist motorists in locating licensed 24-hour pharmacy services open to the public. These changes are designated as Revision No. 1 to the 2003 Edition of the MUTCD.

**DATES:** *Effective date:* This interim final rule is effective July 21, 2004. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of July 21, 2004.

*Comment date:* Comments relating to the technical details of the MUTCD amendment must be received on or before June 30, 2004.

**ADDRESSES:** Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590, or submit comments electronically at <http://dms.dot.gov/submit>, or fax comments to (202) 493-2251. Alternatively, comments may be submitted via the Federal eRulemaking Portal at <http://www.regulations.gov> (follow the on-line instructions for submitting comments). All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., *e.t.*, Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. All comments received into any docket may be searched in electronic format by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). Persons making comments may review U.S. DOT's complete Privacy Act Statement in the **Federal**

**Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477-78), or you may view the statement at <http://dms.dot.gov>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ernest Huckaby, Office of Transportation Operations (HOTO-1), (202) 366-9064, or Mr. Raymond Cuprill, Office of the Chief Counsel (202) 366-0791, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590-0001. Office hours are from 7:45 a.m. to 4:15 p.m., *e. t.*, Monday through Friday, except Federal holidays.

#### SUPPLEMENTARY INFORMATION:

##### Electronic Access and Filing

You may submit or retrieve comments online through the Document Management System (DMS) at: <http://dms.dot.gov/submit>. Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text File (RTF), American Standard Code Information Interchange (ASCII)(TXT), Portable Document Format (PDF), and WordPerfect (versions 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the web site.

An electronic copy of this document may also be downloaded by using a computer, modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may also reach the Office of the Federal Register's Home page at: [http://www.archives.gov/federal\\_register](http://www.archives.gov/federal_register) and the Government Printing Office's Web page at: <http://www.gpoaccess.gov>.

##### Background

On January 23, 2004, the President signed, thereby enacting into law, the Consolidated Appropriations Act, Fiscal Year 2004 (the Act), Public Law 108-199, 118 Stat. 3. Division F of the Act