cause of any visual loss in order to receive disability benefits under either title XVI or title II, including disability benefits based on blindness under title II. The commenter indicated that these differences, as well as the fact that there is no duration requirement for benefits based on blindness under title XVI while there is such a requirement under title II, penalize individuals who receive title II disability benefits based on blindness. The commenter also recommended that if the title XVI eligibility requirements are statutory and cannot be changed, we should apply them when we determine whether individuals are disabled based on blindness under title II.

Response: These rules are required by the Act. ''Blindness'' and ''disability'' are separate categories under title XVI, whereas under title II blindness is considered a type of ''disability.'' The statutory requirements for eligibility based on blindness under title XVI are different from the statutory requirements for eligibility based on disability under title II and title XVI. As a matter of law, we cannot apply the title XVI eligibility requirements for statutory blindness to title II claims for disability.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these rules meet the requirements for a significant regulatory action under Executive Order 12866, as amended by Executive Order 13258. Thus, they were subject to OMB review.

Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities because they will affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These rules do not impose any new or revised reporting or recordkeeping requirements on the public.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: November 27, 2006.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ For the reasons set out in the preamble, we are amending subpart P of part 404 and subpart I of part 416 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

■ 2. Revise § 404.1513(a)(3) to read as follows:

§ 404.1513 Medical and other evidence of your impairment(s).

(a) * * *

(3) Licensed optometrists, for purposes of establishing visual disorders only (except, in the U.S. Virgin Islands, licensed optometrists, for the measurement of visual acuity and visual fields only);

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I—[Amended]

■ 3. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383(b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

■ 4. Revise § 416.913(a)(3) to read as follows:

§ 416.913 Medical and other evidence of your impairment(s).

(a) * * *

(3) Licensed optometrists, for purposes of establishing visual disorders only (except, in the U.S. Virgin Islands, licensed optometrists, for the measurement of visual acuity and visual fields only). (See paragraph (f) of this section for the evidence needed for statutory blindness);

* * * * *

[FR Doc. E7–3577 Filed 2–28–07; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

New Animal Drugs; Maropitant

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 two new animal drug applications (NADAs) filed by Pfizer, Inc. The NADAs provide for the veterinary prescription use of maropitant citrate tablets and maropitant citrate injectable solution for the management of vomiting in dogs.

DATES: This rule is effective March 1, 2007.

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.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–262 for CERENIA (maropitant citrate) Tablets. The NADA provides for the veterinary prescription use of maropitant citrate tablets in dogs for the prevention of acute vomiting and for the prevention of vomiting due to motion sickness. The application is approved as of January 29, 2007, and 21 CFR part 520 is amended by adding new § 520.1315 to reflect the approval.

Pfizer, Inc., also filed NADA 141–263 for CERENIA (maropitant citrate) Injectable Solution, used by veterinary prescription in dogs for the prevention and treatment of acute vomiting. The application is approved as of January 29, 2007, and 21 CFR part 522 is amended by adding new § 522.1315 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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 (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this original approval of NADA 141–262 qualifies for 5 years of marketing exclusivity beginning January 29, 2007.

Under section 512(c)(2)(F)(ii) of the act, this original approval of NADA 141–263 qualifies for 3 years of marketing exclusivity beginning January 29, 2007.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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 Parts 520 and 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 520 and 522 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. Section 520.1315 is added to read as follows:

§ 520.1315 Maropitant.

(a) *Specifications.* Each tablet contains 16, 24, 60, or 160 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount.* For the prevention of acute vomiting, administer a minimum of 2.0 mg per kilogram (/kg) body weight once daily for up to 5 consecutive days. For the prevention of vomiting due to motion sickness, administer a minimum of 8.0 mg/kg body weight once daily for up to 2 consecutive days.

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

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.

■ 4. Section 522.1315 is added to read as follows:

§ 522.1315 Maropitant.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 1.0 mg per kilogram body weight by subcutaneous injection once daily for up to 5 consecutive days.

(2) *Indications for use.* For the prevention and treatment of acute vomiting.

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

Dated: February 16, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–3402 Filed 2–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

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 supplemental abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for the addition of tylosin tartrate to an approved subcutaneous implant containing trenbolone and estradiol used for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter.

DATES: This rule is effective March 1, 2007.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *eric.dubbin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200–346 for COMPONENT TE–200 with TYLAN (trenbolone acetate and estradiol with tylosin tartrate), a subcutaneous implant used for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter. The supplemental ANADA provides for the addition of a pellet containing 29 milligrams (mg) tylosin tartrate to the approved COMPONENT TE–200 implant for steers and heifers fed in confinement for slaughter. The supplemental application is approved as of January 26, 2007, and the regulations are amended in 21 CFR 522.2477 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)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning January 26, 2007.

The agency has determined under 21 CFR 25.33(a)(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.