

application for title II Social Security benefits, which you may be entitled to, unless you tell us otherwise.

(c) *What if I file a claim with the Department of Veterans Affairs (DVA)?* If you file an application with the DVA on one of its forms for survivors' dependency and indemnity compensation (see section 3005 of title 38 U.S.C.), we will consider this an application for Social Security survivors' benefits, except for the lump sum death payment.

PART 422—ORGANIZATION AND PROCEDURES

Subpart F—[Amended]

■ 4. The authority citation for subpart F of part 422 continues to read as follows:

Authority: Secs. 205 and 702(a)(5) of the Social Security Act (42 U.S.C. 405 and 902(a)(5)). Section 422.512 is also issued under 30 U.S.C. 901 *et seq.*

■ 5. Section 422.505 is revised to read as follows:

§ 422.505 What types of applications and related forms are used to apply for retirement, survivors, and disability insurance benefits?

(a) *Applications.* Prescribed applications include our traditional pre-printed forms, and applications our employees complete on computer screens based on information you give us. We then print a copy on paper, have you sign it and process the signed application electronically. You may also use SSA's Internet website to submit an SSA-approved application to us. You can complete an Internet application on a computer (or other suitable device, such as an electronic kiosk) and electronically transmit the form to us using an SSA-approved electronic signature. If, however, we do not have an approved electronic signature established when you file your Internet application, you must print and sign the completed application and deliver the form to us.

(b) *Related forms.* The following are some related forms:

SSA-3—Marriage Certification. (For use in connection with Application for Wife's or Husband's Insurance Benefits, (Form SSA-2))

SSA-11—Request to be Selected as Payee. (For use when an individual proposing to be substituted for the current payee files an application to receive payment of benefits on behalf of disabled child, or a child under 18, or an incapable or incompetent beneficiary or for himself/herself if he/she has a payee.)

SSA-21—Supplement to Claim of Person Outside of the United States. (To

be completed by or on behalf of a person who is, was, or will be outside the United States.)

SSA-25—Certificate of Election for Reduced Spouse's Benefits. (For use by a wife or husband age 62 to full retirement age who has an entitled child in his or her care and elects to receive reduced benefits for months during which he or she will not have a child in his or her care.)

SSA-721—Statement of Death by Funeral Director. (This form may be used as evidence of death (see § 404.704 of this chapter).)

SSA-760—Certificate of Support (Parent's, Husband's or Widower's). (For use in collecting evidence of support.)

SSA-766—Statement of Self-Employment Income. (For use by a claimant to establish insured status based on self-employment income in the current year.)

SSA-783—Statement Regarding Contributions. (This form may be used as evidence of total contributions for a child.)

SSA-787—Physician's/Medical Officer's Statement of Patient's Capability to Manage Benefits. (This form may be used to request evidence of capability from various medical sources.)

SSA-824—Report on Individual with Mental Impairment. (For use in obtaining medical evidence from medical sources when the claimant has been treated for a mental impairment.)

SSA-827—Authorization for Source to Release Information to the Social Security Administration. (To be completed by a disability claimant to authorize release of medical or other information.)

SSA-1002—Statement of Agricultural Employer (Years Prior to 1988). (For use by employer to provide evidence of annual wage payments for agricultural work.)

SSA-1372—Student's Statement Regarding School Attendance. (For use in connection with request for payment of child's insurance benefits for a child who is age 18 through 19 and a full-time student.)

SSA-1388—Report of Student Beneficiary at End of School Year. (For use in confirming continuing eligibility to benefits or indicating the need for suspension or termination action.)

SSA-1724—Claim for Amount Due in the Case of a Deceased Beneficiary. (For use in requesting amounts payable under title II to a deceased beneficiary.)

SSA-3368—Disability Report—Adult. (For use in recording information about the claimant's condition, source of medical evidence and other information

needed to process the claim to a determination or decision.)

SSA-3369—Disability Report—Work History. (For use in recording work history information.)

SSA-3826-F4—Medical Report—General. (For use in helping disability claimants in obtaining medical records from their doctors or other medical sources.)

SSA-3827—Medical Report—(Individual with Childhood Impairment). (For use in requesting information to determine if an individual's impairment meets the requirements for payment of childhood disability benefits.)

SSA-4111—Certificate of Election for Reduced Widow(er)s Benefits. (For use by applicants for certain reduced widow's or widower's benefits.)

SSA-7156—Farm Self-Employment Questionnaire. (For use in connection with claims for benefits based on farm income to determine whether the income is covered under the Social Security Act.)

SSA-7160—Employment Relationship Questionnaire. (For use by an individual and the alleged employer to determine the individual's employment status.)

SSA-7163—Questionnaire about Employment or Self-Employment Outside the United States.

(To be completed by or on behalf of a beneficiary who is, was, or will be employed or self-employed outside the United States.)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Nitazoxanide Paste

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 IDEXX Pharmaceuticals, Inc. The NADA provides for veterinary prescription use of an nitazoxanide oral paste for the treatment of equine protozoal myeloencephalitis (EPM).

DATES: This rule is effective January 6, 2004.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

IDEXX Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed NADA 141-178 for veterinary prescription use of NAVIGATOR (32 percent nitazoxanide) Antiprotozoal Oral Paste for the treatment of EPM caused by *Sarcocystis neurona*. The NADA is approved as of November 18, 2003, and 21 CFR part 520 is amended by adding new § 520.1498 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 (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning November 18, 2003.

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 520

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 520 is 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 520.1498 is added to read as follows:

§ 520.1498 Nitazoxanide paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.32 mg nitazoxanide.

(b) *Sponsor.* See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* On days 1 through 5, administer 11.36 mg per pound (/lb) body weight; on days 6 through 28, administer 22.72 mg/lb body weight.

(2) *Indications for use—*For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.

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

Dated: December 23, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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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 an abbreviated new animal drug application (ANADA) filed by Fort Dodge Animal Health, Division of Wyeth. The ANADA provides for use of three different strength trenbolone acetate and estradiol implants in cattle. **DATES:** This rule is effective January 6, 2004.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 500 Fifth St. NW., Fort Dodge, IA 50501, filed ANADA 200-367 for the use of three different strength trenbolone acetate and estradiol implants in cattle. SYNOVEX T120 and SYNOVEX T80 are for use in steers fed in confinement for slaughter for

increased rate of weight gain and improved feed efficiency. SYNOVEX T40 is for use in pasture cattle (slaughter, stocker, and feeder steers and heifers) for increased rate of weight gain. Fort Dodge Animal Health's SYNOVEX T120, SYNOVEX T80, and SYNOVEX T40 are approved as generic copies of Intervet, Inc.'s REVALOR-S, REVALOR-IS, and REVALOR-G, approved under NADA 140-897. The application is approved as of November 18, 2003, 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.

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.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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 522.2477 is amended by adding paragraph (b)(3) and by revising the heading of paragraph (d)(3) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

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(b) * * *