

time, other than as a result of the acquisition of the primary residence, the amount of such excess shall be included as a liability); and

(iii) Indebtedness that is secured by the person's primary residence in excess of the estimated fair market value of the primary residence shall be included as a liability.

(2) Paragraph (e)(1) of this section will not apply to any calculation of a person's net worth made in connection with a purchase of securities in accordance with a right to purchase such securities, provided that:

(i) Such right was held by the person on July 20, 2010;

(ii) The person qualified as an accredited investor on the basis of net worth at the time the person acquired such right; and

(iii) The person held securities of the same issuer, other than such right, on July 20, 2010.

* * * * *

■ 5. Amend Part 230 by removing the authority citation after the undesignated center heading "Regulation D—Rules Governing the Limited Offer and Sale of Securities Without Registration Under the Securities Act of 1933" and preliminary notes preceding §§ 230.501 to 230.508.

■ 6. Amend § 230.501 by:

- a. Revising paragraph (a)(5); and
- b. Removing the word "principal" and adding in its place the word "primary" in paragraph (e)(1)(i).

The revision reads as follows:

§ 230.501 Definitions and terms used in Regulation D.

* * * * *

(a) * * *

(5) Any natural person whose individual net worth, or joint net worth with that person's spouse, exceeds \$1,000,000.

(i) Except as provided in paragraph (a)(5)(ii) of this section, for purposes of calculating net worth under this paragraph (a)(5):

(A) The person's primary residence shall not be included as an asset;

(B) Indebtedness that is secured by the person's primary residence, up to the estimated fair market value of the primary residence at the time of the sale of securities, shall not be included as a liability (except that if the amount of such indebtedness outstanding at the time of sale of securities exceeds the amount outstanding 60 days before such time, other than as a result of the acquisition of the primary residence, the amount of such excess shall be included as a liability); and

(C) Indebtedness that is secured by the person's primary residence in excess

of the estimated fair market value of the primary residence at the time of the sale of securities shall be included as a liability;

(ii) Paragraph (a)(5)(i) of this section will not apply to any calculation of a person's net worth made in connection with a purchase of securities in accordance with a right to purchase such securities, provided that:

(A) Such right was held by the person on July 20, 2010;

(B) The person qualified as an accredited investor on the basis of net worth at the time the person acquired such right; and

(C) The person held securities of the same issuer, other than such right, on July 20, 2010.

* * * * *

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 7. The general authority citation for Part 239 is revised to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z-2, 77z-3, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78o-7 note, 78u-5, 78w(a), 78ll, 78mm, 80a-2(a), 80a-3, 80a-8, 80a-9, 80a-10, 80a-13, 80a-24, 80a-26, 80a-29, 80a-30, and 80a-37, unless otherwise noted.

* * * * *

§ 239.500 [Amended]

■ 8. Amend § 239.500 by removing the reference to "4(6)" and adding in its place "4(5)" in the heading and in the first sentence of paragraph (a)(1).

■ 9. Amend Item 6 in Form D (referenced in § 239.500) by:

■ a. Removing the phrase "Securities Act Section 4(6)" and adding in its place "Securities Act Section 4(5)" next to the appropriate check box; and

■ b. Removing the reference to "4(6)" and adding in its place "4(5)" in the first sentence of the first paragraph of the General Instructions.

Note: The text of Form D does not, and the amendments will not, appear in the Code of Federal Regulations.

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 10. The general authority citation for Part 270 continues to read in part as follows:

Authority: 15 U.S.C. 80a-1 *et seq.*, 80a-34(d), 80a-37, and 80a-39, unless otherwise noted.

* * * * *

§ 270.17j-1 [Amended]

■ 11. Amend § 270.17j-1, paragraph (a)(8), by removing the references to

"4(6)" and "77d(6)" and adding in their places "4(5)" and "77d(5)", respectively.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 12. The authority citation for Part 275 continues to read in part as follows:

Authority: 15 U.S.C. 80b-2(a)(11)(G), 80b-2(a)(11)(H), 80b-2(a)(17), 80b-3, 80b-4, 80b-4a, 80b-6(4), 80b-6a, and 80b-11, unless otherwise noted.

* * * * *

§ 275.204a-1 [Amended]

■ 13. Amend § 275.204a-1, paragraph (e)(7) by removing the references to "4(6)" and "77d(6)" and adding in their places "4(5)" and "77d(5)", respectively.

By the Commission.

Dated: December 21, 2011.

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2011-33333 Filed 12-28-11; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA-2011-N-0003]

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Topical Solution

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 Cross Vetpharm Group, Ltd. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites when cattle are treated with a topical solution of ivermectin.

DATES: This rule is effective December 29, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276-8197, email: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to ANADA 200-318 for

BIMECTIN (ivermectin) Pour-On, a topical solution used on cattle to control infestations of certain species of external and internal parasites. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites that were approved for the pioneer product with 3 years of marketing exclusivity (69 FR 501, January 6, 2004). The supplemental ANADA is approved as of September 21, 2011, and 21 CFR 524.1193 is amended to reflect the approval.

Approval of this supplemental ANADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The Agency has determined under 21 CFR 25.33 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 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1193 [Amended]

■ 2. In § 524.1193, in paragraph (b)(1), in numerical sequence add “, and 061623”; and in paragraph (b)(2), remove “061623,”.

Dated: December 22, 2011.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 2011–33382 Filed 12–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 158

[Docket ID DOD–2009–OS–0029]

RIN 0790–AI48

Operational Contract Support

AGENCY: Department of Defense (DoD).

ACTION: Interim final rule.

SUMMARY: This part establishes policy, assigns responsibilities, and provides procedures for operational contract support (OCS), including OCS program management, contract support integration, and integration of defense contractor personnel into contingency operations outside the United States.

An interim final rule is required to procedurally close gaps and ensure the correct planning, oversight and management of DoD contractors supporting contingency operations, by updating the existing outdated policy. The existing policies are causing significant confusion, as they do not reflect current practices and legislative mandates. The inconsistencies between local Geographic Command guidance and the DoD-wide policies and the Defense Federal Acquisition Regulations Supplement are confusing for those in the field—in particular, with regard to policy on accountability and visibility requirements. Given the sustained employment of a large number of contractors in the U.S. Central Command area of responsibility; the importance of contractor oversight in support of the counter-insurgency operation in Afghanistan; and, the requirement to effectively manage contractors during the transition in Iraq, this issue has become so significant that DoD needs to revise the DoD-wide policies as a matter of urgency.

DATES: This rule is effective December 29, 2011. Comments must be received by February 27, 2012.

ADDRESSES: You may submit comments, identified by docket number and or/RIN number and title, by any of the following methods:

- *Federal Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, 2nd floor, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general

policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT:

Shanna Poole, (703) 692–3032.

SUPPLEMENTARY INFORMATION: The revised policies include: (1) Incorporation of lessons learned from current operations; (2) requirements for the development of contractor oversight plans; (3) requirements for adequate military personnel necessary to execute contract oversight; and, (4) standards of medical care for deployed contractors.

Regulatory Procedures

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

It has been certified that 32 CFR part 158 does not:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in these Executive Orders.

Section 202, Pub. L. 104–4, “Unfunded Mandates Reform Act”

It has been certified that 32 CFR part 158 does not contain a Federal mandate that may result in expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96–354, “Regulatory Flexibility Act” (5 U.S.C. 601)

It has been certified that 32 CFR part 158 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.