ii. For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

3. What to report. You must report the information about each obligating action that the submission instructions posted at http://www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives

1. Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if—
   i. the total Federal funding authorized to date under this award is $25,000 or more; and
   ii. in the preceding fiscal year, you received—
      (A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
      (B) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
   iii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm.)

2. Where and when to report. You must report subrecipient executive total compensation described in paragraph c.1. of this award term:
   i. To the recipient.
   ii. By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.
   d. Exemptions
      If, in the previous tax year, you had gross income, from all sources, under $300,000, you are exempt from the requirements to report:
      i. Subawards, and
      ii. The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions. For purposes of this award term:
   1. Entity means all of the following, as defined in 2 CFR part 25:
      i. A Governmental organization, which is a State, local government, or Indian tribe;
      ii. A foreign public entity;
      iii. A domestic or foreign nonprofit organization;
      iv. A domestic or foreign for-profit organization;
      v. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.
   2. Executive means officers, managing partners, or any other employees in management positions.
   3. Subaward:
      i. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
      ii. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. 210 of the attachment to OMB Circular A–133, “Audits of States, Local Governments, and Non-Profit Organizations”).
      iii. A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.
   4. Subrecipient means an entity that:
      i. Receives a subaward from you (the recipient) under this award; and
      ii. Is accountable to you for the use of the Federal funds provided by the subaward.
   5. Total compensation means the cash and noncash dollar value earned by the executive during the preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):
      i. Salary and bonus.
      ii. Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
   iii. Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
      iv. Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
   v. Above-market earnings on deferred compensation which is not tax-qualified.
   vi. Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds $10,000.

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include in its financial assistance awards to require recipients to maintain current CCR registrations, which requires that they also have DUNS numbers. The guidance also specifies that each recipient may make subawards only to entities that have DUNS numbers.

DATES: Effective September 14, 2010.


SUPPLEMENTARY INFORMATION:

I. Summary of Changes

On February 18, 2010 (75 FR 7316), OMB proposed a number of changes to title 2 of the Code of Federal Regulations (2 CFR). Some of the proposed changes were to provide new guidance to agencies that was needed to implement section 872 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110–417, hereafter referred to as “section 872”), as that statute applies to grants. Some of the other proposed changes were to update guidance that existed elsewhere and relocate it in 2 CFR to provide needed context for the new guidance implementing section 872. The remaining changes were administrative in nature, to create seven subchapters in 2 CFR, Chapter I, as a better organizational framework for existing and future content in that chapter.

OMB now is finalizing some of those proposed changes, with the rest to follow separately. The substantive changes being finalized relate to the use of DUNS numbers and registration in the CCR. These changes are being finalized separately and expedited because they will enhance the quality of information available to the public when recipients begin on October 1, 2010 to report information on subawards, as required by the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282, as amended, hereafter referred to as “the Transparency Act”). OMB also is finalizing the administrative changes proposed in February 2010, by creating the new subchapters in 2 CFR, Chapter I.

II. Relationship to Existing Requirements

The requirement for applicants to have DUNS numbers is not new. OMB established the DUNS requirement for applicants for grants or cooperative agreements in 2003. The policy was published in the Federal Register [68 FR 38402] and communicated to Federal agencies in OMB Memorandum M–03–16. The requirement was broadened to include applicants for other types of Federal financial assistance subject to the Transparency Act in 2008, in OMB Memorandum 08–19. Therefore, the sole effect of the guidance following this preamble is to relocate the requirement in the Code of Federal Regulations, in 2 CFR part 25.

There are several existing requirements concerning applicants’ registration in the CCR. For example, an applicant must be registered in CCR if it wants to submit its applications electronically through Grants.gov. In another example, several providers of payment management services require that recipients be registered in CCR before receiving payments. As yet another example, OMB Memorandum M–09–10 required applicants for funding under the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, hereafter referred to as “the Recovery Act”) to register in CCR. The guidance following this preamble broadens the existing requirements to all other applicants for Federal financial assistance awards subject to the Transparency Act.

Similarly, the requirement for recipients to maintain their registration in the CCR throughout the period of performance under their awards is not entirely new. The final OMB guidance on reporting under the Recovery Act, OMB Memorandum M–09–21, requires recipients to register in CCR in order to access the FederalReporting.gov site at which they must report. That memorandum also allows a recipient to delegate some reporting responsibilities to its first-tier subrecipients, in which case those subrecipients must register in the CCR in order to report (a first-tier subrecipient is one that receives a subaward directly from the prime recipient, as distinct from a lower-tier subrecipient that receives a subaward from another subrecipient). For prime recipients, the guidance following this preamble broadens the existing Recovery Act requirement to recipients of other awards subject to the Transparency Act. Although the guidance proposed in February 2010 would have broadened the CCR requirement to first-tier subrecipients, the final guidance being adopted at this time does not require CCR registration for any subrecipients.

The standard award term that agencies must use to communicate the CCR requirement to recipients is new. It will help ensure Government-wide uniformity, a benefit for recipients that receive awards from multiple agencies.

Applicants and recipients of grants and cooperative agreements must comply with the policy by October 1, 2010. Applicants and recipients of all other financial assistance types must comply by a date to be provided by the agency.

III. Comments and Responses

We received comments on the proposed guidance in 2 CFR part 25 from three State agencies and three Federal agencies. We considered the comments in developing the final guidance, which closely parallels the proposed guidance. We made some changes based on the recommendations and others for clarity. The following paragraphs summarize the comments and our responses:

Comment: Three State agencies commented on the requirements for first-tier subrecipients in the award term in Appendix A to the proposed 2 CFR part 25. Two agencies cited burdens on subrecipients and the Transparency Act’s definition of “Federal award” as reasons to exempt a subrecipient from the requirement to register in the CCR if the amount of the subaward is $25,000 or less. The third agency asked whether the prime recipient would be required to submit verification of subrecipients’ compliance with the CCR requirement to the Federal agency and, if so, how frequently it would be required to do so. One of the agencies also recommended exempting subrecipients with awards of $25,000 or less from the requirement to obtain a DUNS number.

Response: Agree in part. We revised the final guidance so that there is no requirement at this time for any subrecipient to register in the CCR. Concerning the requirement for first-tier subrecipients to obtain a DUNS number, we did not adopt a $25,000 threshold. The DUNS number still is the only identifier with the advantages that led us to establish it in 2003 as the universal identifier for recipients of grants and cooperative agreements (see the preamble to 68 FR 38403, June 27, 2003). We do not agree that the one-time requirement to obtain a DUNS number is an undue hardship. We appreciate that first-tier subrecipients who are not also prime recipients of other Federal awards may need to adjust their procedures and systems initially to accommodate the DUNS number requirement, but we believe that the long-term benefits to transparency justify those changes.

Comment: Two Federal agencies commented on the definition of “award”
in section 25.305 of the proposed 2 CFR part 25. One agency questioned whether excluding technical assistance and transfers of Federally owned property from the definition could have the inadvertent effect of exempting them from the effects of suspension and debarment actions taken under 2 CFR part 180, in which the term “nonprocurement transaction” is defined in a way that would include them. The second agency suggested adding the words “for the purposes of this part” to the definition.

Response: Agree to add “for the purposes of this part” for added clarity, as the term “award” must be defined in each part of 2 CFR in a way that conforms to the purpose of that part. For example, the definitions of “award” in 2 CFR parts 182 and 225 differ significantly. Part 182 implements the Drug-Free Workplace Act of 1988 (41 U.S.C. 701–707, as amended) and defines “award” to include grants and cooperative agreements. The definition of “award” in 2 CFR part 225, “Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A–87),” includes not only grants and other financial assistance awards but also cost reimbursement contracts, because that part specifies principles and standards for determining costs for that wider range of Federal funding instruments.

Comment: A Federal agency suggested that we delete paragraph 25.200(a)(2) in the proposed 2 CFR part 25 because it would be burdensome for an agency to modify every program announcement it already had issued under which it anticipated making awards after October 1, 2010. It further noted that the wording included some announcements under which applications already had been submitted.

Response: We disagree. We did not delete paragraph 25.200(a)(2), as suggested. We revised it to require agencies to notify potential applicants only in previously issued announcements that have due dates for applications or plans after October 1, 2010, and not all announcements under which awards would be made after that date. This does not change the fact that all new awards, as defined in the policy, after October 1, 2010 must reflect this reporting requirement. Providing potential applicants with more complete information about the requirements with which they will have to comply if their applications are successful is important, in order to enable them to make better informed decisions on whether to invest the time and expense in preparing applications. That benefit for potential applicants justifies the burdens on agencies associated with issuing amendments to the previously issued announcements.

List of Subjects in 2 CFR Part 25
Administrative practice and procedures, Grants administration, Grant programs, Loan programs.

Danny Werfel, Controller.

Authority and Issuance
For the reasons set forth above, the Office of Management and Budget amends 2 CFR, subtitle A, as follows:

SUBTITLE A
PARTS 2–99—[TRANSFERRED TO
CHAPTER I]

1. In subtitle A to title 2, parts 2 through 99, which are currently reserved, are transferred to chapter I.

2. Subchapter A to chapter I, consisting of parts 2 through 19, is established and reserved to read as follows:

Subchapter A—General Matters [Reserved]

PARTS 2–19—[RESERVED]

3. Subchapter B to chapter I, consisting of parts 20 through 39, is established and added to read as follows:

Subchapter B—Pre-Award Responsibilities

PARTS 20–24—[RESERVED]

PART 25—UNIVERSAL IDENTIFIER
AND CENTRAL CONTRACTOR
REGISTRATION

Sec.

Subpart A—General

25.100 Purposes of this part.

25.105 Types of awards to which this part applies.

25.110 Types of recipient and subrecipient entities to which this part applies.

25.115 Deviations.

Subpart B—Policy

25.200 Requirements for program announcements, regulations, and application instructions.

25.205 Effect of noncompliance with a requirement to obtain a DUNS number or register in the CCR.

25.210 Authority to modify agency application forms or formats.

25.215 Requirements for agency information systems.

25.220 Use of award term.

Subpart C—Definitions

25.300 Agency.

25.305 Award.

25.310 Central Contractor Registration (CCR).

25.315 Data Universal Numbering System (DUNS) Number.

25.320 Entity.

25.325 For-profit organization.

25.330 Foreign public entity.

25.335 Indian Tribe (or “Federally recognized Indian Tribe”).

25.340 Local government.

25.345 Nonprofit organization.

25.350 State.

25.355 Subaward.

25.360 Subrecipient.

Appendix A to Part 25—Award Term


Subpart A—General

§ 25.100 Purposes of this part.

This part provides guidance to agencies to establish:

(a) The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as a universal identifier for Federal financial assistance applicants, as well as recipients and their direct subrecipients.

(b) The Central Contractor Registration (CCR) as the repository for standard information about applicants and recipients.

§ 25.105 Types of awards to which this part applies.

This part applies to an agency’s grants, cooperative agreements, loans, and other types of Federal financial assistance included in the definition of “award” in § 25.305. The requirements in this part must be implemented for grants and cooperative agreements by October 1, 2010. The requirements in this part must be implemented for all other award forms listed in § 25.200 requirement at a date to be specified in the future.

§ 25.110 Types of recipient and subrecipient entities to which this part applies.

(a) General. Through an agency’s implementation of the guidance in this part, this part applies to all entities, other than those exempted in paragraphs (b), (c), and (d) of this section, that—

(1) Apply for or receive agency awards; or

(2) Receive subawards directly from recipients of those agency awards.

(b) Exemptions for individuals. None of the requirements in this part apply to an individual who applies for or receives Federal financial assistance as a natural person (i.e., unrelated to any business or non-profit organization he or she may own or operate in his or her name).

(c) Exemptions for Federal agencies. The requirement in this part to maintain a current registration in the CCR does not apply to an agency of the Federal...
Government that receives an award from another agency.

(d) Other exemptions. (1) Under a condition identified in paragraph (d)(2) of this section, an agency may exempt an entity from an applicable requirement to obtain a DUNS number, register in the CCR, or both.

(1) The program announcement, regulation, or other issuance must require each entity that applies and does not have an exemption under §25.110 to:

(a) Be registered in the CCR prior to submitting an application or plan;

(b) Maintain an active CCR registration with current information at all times during which it has an active Federal award or an application or plan under consideration by an agency; and

(c) Provide its DUNS number in each application or plan it submits to the agency.

(2) For purposes of this policy:

(a) The applicant is the entity that meets the agency’s or program’s eligibility criteria and has the legal authority to apply and to receive the award. For example, if a consortium applies for an award to be made to the consortium as the recipient, the consortium must have a DUNS number. If a consortium is eligible to receive funding under an agency program but the agency’s policy is to make the award to a lead entity for the consortium, the DUNS number of the lead entity will be used.

(3) To remain registered in the CCR database after the initial registration, the applicant must be reviewed and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate, and complete.

§25.205 Effect of noncompliance with a requirement to obtain a DUNS number or register in the CCR.

(a) An agency may not make an award to an entity until the entity has complied with the requirements described in §25.200 to provide a valid DUNS number and maintain an active CCR registration with current information (other than any requirement that is not applicable because the entity is exempted under §25.110).

(b) At the time an agency is ready to make an award, the intended recipient has not complied with an applicable requirement to provide a DUNS number or maintain an active CCR registration with current information, the agency: (1) May determine that the applicant is not qualified to receive an award; and

(2) May use that determination as a basis for making an award to another applicant.

§25.210 Authority to modify agency application forms or formats.

To implement the policies in §§25.200 and 25.205, an agency may add a DUNS number field to application forms or formats previously approved by OMB, without having to obtain further approval to add the field.

§25.215 Requirements for agency information systems.

Each agency that makes awards (as defined in §25.325) must ensure that systems processing information related to the awards, and other systems as appropriate, are able to accept and use the DUNS number as the universal identifier for financial assistance applicants and recipients.

§25.220 Use of award term.

(a) To accomplish the purposes described in §25.100, an agency must include in each award (as defined in §25.305) the award term in Appendix A to this part.

(b) An agency may use different letters and numbers than those in Appendix A to this part to designate the paragraphs of the award term, if necessary, to conform the system of paragraph designations with the one used in other terms and conditions in the agency’s awards.

Subpart C—Definitions

§25.300 Agency.

Agency means a Federal agency as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).

§25.305 Award.

(a) Award, for the purposes of this part, means an award of Federal financial assistance that a non-Federal entity described in §25.110(a) receives or administers in the form of—

(1) A grant;

(2) A cooperative agreement (which does not include a cooperative research and development agreement pursuant to the Federal Technology Transfer Act of 1986, as amended (15 U.S.C. 3710a));

(3) A loan;

(4) A loan guarantee;

(5) A subsidy;

(6) Insurance;

(7) Food commodities;

(8) A direct appropriation;

(9) Assessed or voluntary contributions; or

(10) Any other financial assistance transaction that authorizes the non-Federal entity’s expenditure of Federal funds.
(b) An Award does not include:
(1) Technical assistance, which provides services in lieu of money; and
(2) A transfer of title to Federally owned property provided in lieu of money, even if the award is called a grant.

§ 25.310 Central Contractor Registration (CCR).
Central Contractor Registration (CCR) has the meaning given in paragraph C.1 of the award term in Appendix A to this part.

§ 25.315 Data Universal Numbering System (DUNS) Number.
Data Universal Numbering System (DUNS) Number has the meaning given in paragraph C.2 of the award term in Appendix A to this part.

§ 25.320 Entity.
Entity, as it is used in this part, has the meaning given in paragraph C.3 of the award term in Appendix A to this part.

§ 25.325 For-profit organization.
For-profit organization means a non-Federal entity organized for profit. It includes, but is not limited to:
(a) An “S corporation” incorporated under Subchapter S of the Internal Revenue Code;
(b) A corporation incorporated under another authority;
(c) A partnership;
(d) A limited liability corporation or partnership; and
(e) A sole proprietorship.

§ 25.330 Foreign public entity.
Foreign public entity means:
(a) A foreign government or foreign governmental entity;
(b) A public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288–288f);
(c) An entity owned (in whole or in part) or controlled by a foreign government; and
(d) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.

§ 25.335 Indian Tribe (or “Federally recognized Indian Tribe”).
Indian Tribe (or “Federally recognized Indian Tribe”) means any Indian Tribe, band, nation, or other organized group or community, including any Alaskan Native village or regional or village corporation (as defined in, or established under, the Alaskan Native Claims Settlement Act (43 U.S.C. 1601, et seq.) that is recognized by the United States as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

§ 25.340 Local government.
Local government means a:
(a) County;
(b) Borough;
(c) Municipality;
(d) City;
(e) Town;
(f) Township;
(g) Parish;
(h) Local public authority, including any public housing agency under the United States Housing Act of 1937;
(i) Special district;
(j) School district;
(k) Intrastate district;
(l) Council of governments, whether or not incorporated as a nonprofit corporation under State law; and
(m) Any other instrumentality of a local government.

§ 25.345 Nonprofit organization.
Nonprofit organization—
(a) Means any corporation, trust, association, cooperative, or other organization that—
(1) Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest;
(2) Is not organized primarily for profit; and
(3) Uses net proceeds to maintain, improve, or expand the operations of the organization.
(b) Includes nonprofit—
(1) Institutions of higher education;
(2) Hospitals; and
(3) Tribal organizations other than those included in the definition of “Indian Tribe.”

§ 25.350 State.
State means—
(a) Any State of the United States;
(b) The District of Columbia;
(c) Any agency or instrumentality of a State other than a local government or State-controlled institution of higher education;
(d) The Commonwealths of Puerto Rico and the Northern Mariana Islands; and
(e) The United States Virgin Islands, Guam, American Samoa, and a territory or possession of the United States.

§ 25.355 Subaward.
Subaward has the meaning given in paragraph C.4 of the award term in Appendix A to this part.

§ 25.360 Subrecipient.
Subrecipient has the meaning given in paragraph C.5 of the award term in Appendix A to this part.

Appendix A to Part 25—Award Term
I. Central Contractor Registration and Universal Identifier Requirements

A. Requirement for Central Contractor Registration (CCR)

Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain the currency of your information in the CCR until you submit the final financial report required under this award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term.

B. Requirement for Data Universal Numbering System (DUNS) Numbers

If you are authorized to make subawards under this award, you:
1. Must notify potential subrecipients that no entity (see definition in paragraph C of this award term) may receive a subaward from you unless the entity has provided its DUNS number to you.
2. May not make a subaward to an entity unless the entity has provided its DUNS number to you.

C. Definitions

For purposes of this award term:
1. Central Contractor Registration (CCR) means the Federal repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR Internet site (currently at http://www.ccr.gov).
2. Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (currently 866–705–5711) or the Internet (currently at http://fedgov.dnb.com/webform).
3. Entity, as it is used in this award term, means all of the following, as defined at 2 CFR part 25, subpart C:
   a. A Governmental organization, which is a State, local government, or Indian Tribe;
   b. A foreign public entity;
   c. A domestic or foreign nonprofit organization;
   d. A domestic or foreign for-profit organization; and
   e. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.
4. Subaward:
   a. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
   b. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. .310 of the attachment to OMB Circular A–133, “Audits of States, Local Governments, and Non-Profit Organizations”).
c. A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

5. Subrecipient means an entity that:
   a. Receives a subaward from you under this award; and
   b. Is accountable to you for the use of the Federal funds provided by the subaward.

PART 26–39—[RESERVED]

4. Subchapter C to chapter I, consisting of parts 40 through 59, is established and reserved to read as follows:

Subchapter C—Award Content and Format [Reserved]

PARTS 40–59—[RESERVED]

5. Subchapter D to chapter I, consisting of parts 60 through 79, is established and added to read as follows:

Subchapter D—Post-Award Responsibilities

PARTS 60–79—[RESERVED]

6. Subchapter E to chapter I, consisting of parts 80 through 99, is established and reserved to read as follows:

Subchapter E—Cost Principles [Reserved]

PARTS 80–99—[RESERVED]

7. Subchapter F to chapter I, consisting of parts 100 through 119, is established and reserved to read as follows:

Subchapter F—Audit Requirements [Reserved]

PARTS 100–119—[RESERVED]

8. Subchapter G to chapter I, consisting of parts 120 through 199, is established, and a new subchapter heading is added to read as follows:

Subchapter G—National Policy Requirements

[FR Doc. 2010–22706 Filed 9–13–10; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

[Docket No. FDA–2010–N–0002]

Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of New Animal Drug Applications; Chloramphenicol; Lincomycin; Pyrantel Tartrate; and Tylosin Phosphate and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of four new animal drug applications (NADAs). In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of these NADAs.

DATES: This rule is effective September 24, 2010.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine, 21 Plaza, OMG, MD 20855, 240–276–09799; email: john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611; International Nutrition, Inc., 7706 F Plaza, Omaha, NE 68127; and Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001 have requested that FDA withdraw approval of the four NADAs listed in the following paragraph because they are no longer manufactured or marketed:

In a notice published elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 65–137, 121–337, 132–923, and 138–342, and all supplements and amendments thereto, is withdrawn, effective September 24, 2010. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these withdrawals of approval.

Following these changes of sponsorship, Feed Service Co., Inc., and John J. Ferrante are no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

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 Part 520

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, 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:


510.600 [Amended]

2. In §510.600, in the table in paragraph (c)(1), remove the entries for “Feed Service Co., Inc.” and “John J. Ferrante”; and in the table in paragraph (c)(2), remove the entries for “030841” and “058034”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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


4. In §520.390b, revise paragraph (b) to read as follows:

§520.390b Chloramphenicol capsules.

* * * * * *(b) Sponsors. See Nos. 000069 and 050057 in §510.600(c) of this chapter for use as in paragraph (d) of this section.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:


6. In §558.325, revise paragraphs (a) and (c)(3)(ii); and in the table in paragraphs (d)(2)(ii) and (d)(2)(iii), in the “Sponsor” column, remove “043733” to read as follows: