middle, 1 square foot; and inboard, 2.5 square feet).
3. Seats do not have to meet the test requirements of Title 14 CFR part 25, Appendix F, parts IV and V, when installed in compartments that are not otherwise required to meet these requirements. Examples include:
   a. Airplanes with passenger capacities of 19 or less,
   b. Airplanes that do not have § 25.853, Amendment 25–61 or later, in their certification basis and do not need to comply with the requirements of 14 CFR 121.312, and
   c. Airplanes exempted from § 25.853, Amendment 25–61 or later.

Issued in Renton, Washington, on December 24, 2008.

Linda Navarro,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–328 Filed 1–9–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520
[Docket No. FDA–2008–N–0039]

Oral Dosage Form New Animal Drugs; Phenylbutazone Tablets and Boluses

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 new animal drug application (NADA) filed by First Priority, Inc. The supplemental application provides for revising the description of a 1-gram oral dosage form of phenylbutazone from tablet to bolus. The supplemental NADA is approved as of December 10, 2008, and 21 CFR 520.1720a is amended to reflect the approval.

Approval of this supplemental NADA 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(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:


2. In § 520.1720a, revise paragraphs (a) and (b)(3); and add paragraph (b)(6) to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

(a) Specifications. Each tablet contains 100, 200, or 400 milligrams (mg), or 1 gram (g) of phenylbutazone. Each bolus contains 1, 2, or 4 gram g of phenylbutazone.

(b) * * *

(3) Nos. 000856 and 061263 for use of 100-mg or 1-g tablets in dogs and horses. * * * * *

(6) No. 058829 for use of 100-mg or 1-g tablets in dogs and horses, or 1-g boluses in horses. * * * * *

Dated: January 5, 2009.

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E9–265 Filed 1–9–09; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

Approval and Promulgation of Air Quality Implementation Plans; the Metropolitan Washington Nonattainment Area; Determination of Attainment of the Fine Particle Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is determining that the Metropolitan Washington, DC–MD–VA nonattainment area for the 1997 fine particle (PM_{2.5}) National Ambient Air Quality Standard (NAAQS) has attained the 1997 PM_{2.5} NAAQS.

DATES: Effective Date: This final rule is effective on January 12, 2009.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2008–0736. All documents in the docket are listed in the www.regulations.gov Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Specifically available docket materials are available either electronically through www.regulations.gov or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

FOR FURTHER INFORMATION CONTACT: Melissa Linden, (215) 814–2096, or by e-mail at linden.melissa@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

1. What Action Is EPA Taking?
2. What Is the Effect of This Action?
3. When Is This Action Effective?
4. Final Action
5. Statutory and Executive Order Reviews
6. Public Comment

I. What Action Is EPA Taking?

EPA is determining that the Metropolitan Washington, DC–MD–VA nonattainment area for the 1997 PM_{2.5} NAAQS has attained the 1997 PM_{2.5} NAAQS.
NAAQS. This determination is based upon quality assured, quality controlled and certified ambient air monitoring data that show the area has monitored attainment of the 1997 PM\textsubscript{2.5} NAAQS since the 2004–2006 monitoring period, and monitoring data that continue to show attainment of the 1997 PM\textsubscript{2.5} NAAQS based on the 2005–2007 data. In addition, quality controlled and quality assured monitoring data submitted during the calendar year 2008, which are available in the EPA Air Quality System (AQS) database, but not yet certified, show this area continues to attain the 1997 PM\textsubscript{2.5} NAAQS.

Other specific requirements of the determination and the rationale for EPA’s proposed action are explained in the notice of proposed rulemaking (NPR) published on October 22, 2008 (73 FR 62945) and will not be restated here. A public comment was received supporting the determination proposed in the NPR.

II. What Is the Effect of This Action?

This final action, in accordance with 40 CFR 51.1004(c), suspends the requirements for this area to submit attainment demonstrations and associated reasonably available control measures, reasonable further progress plans, contingency measures, and other planning state implementation plans (SIPs) related to attainment of the 1997 PM\textsubscript{2.5} NAAQS for so long as the area continues to attain the 1997 PM\textsubscript{2.5} NAAQS.

III. When Is the Action Effective?

EPA finds that there is good cause for this approval to become effective on the date of publication of this action in the Federal Register, because a delayed effective date is unnecessary due to the nature of the approval. The expedited effective date for this action is authorized under both 5 U.S.C. 553(d)(1), which provides that rule actions may become effective less than 30 days after publication if the rule “grants or recognizes an exemption or relieves a restriction” and 5 U.S.C. 553(d)(3), which allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.” As noted above, this determination of attainment suspends the requirements for the Washington Metropolitan nonattainment area to submit an attainment demonstration and associated reasonably available control measures, a reasonable further progress plan, contingency measures, and any other planning SIPs related to attainment of the standard for so long as the area continues to attain the 1997 PM\textsubscript{2.5} NAAQS. The suspension of these requirements is sufficient reason to allow an expedited effective date of this rule under 5 U.S.C. 553(d)(1). In addition, the Metropolitan Washington, DC–MD–VA nonattainment area’s suspension from these requirements provide good cause to make this rule effective on the date of publication of this action in the Federal Register, pursuant to 5 U.S.C. 553(d)(3). The purpose of the 30-day waiting period prescribed in 5 U.S.C. 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Where, as here, the final rule suspends requirements rather than imposing obligations, affected parties, such as the Commonwealth of Virginia, the District of Columbia and the State of Maryland do not need time to adjust and prepare before the rule takes effect.

IV. Final Action

EPA is determining that the Metropolitan Washington, DC–MD–VA nonattainment area for the 1997 PM\textsubscript{2.5} NAAQS has attained the 1997 PM\textsubscript{2.5} NAAQS. This determination is based upon quality assured, quality controlled, and certified ambient air monitoring data that show that the area has monitored attainment of the 1997 PM\textsubscript{2.5} NAAQS since the 2004–2006 monitoring period, and continues to monitor attainment of the standard based on the 2005–2007 data. This final action, in accordance with 40 CFR 51.1004(c), will suspend the requirements for this area to submit attainment demonstrations and associated reasonably available control measures, reasonable further progress plans, contingency measures, and other planning SIPs related to attainment of the 1997 PM\textsubscript{2.5} NAAQS for so long as the area continues to attain the 1997 PM\textsubscript{2.5} NAAQS.

V. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action makes a determination based on air quality data, and would, if finalized, result in the suspension of certain Federal requirements. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). Because this rule makes a determination based on air quality data, and results in the suspension of certain Federal requirements, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely makes a determination based on air quality data and results in the suspension of certain Federal requirements, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 “Protection of Children from Environmental Health Risks” (62 FR 19885, April 23, 1997) because it determines that air quality in the affected area is meeting Federal standards.

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply because it would be inconsistent with applicable law for EPA, when determining the attainment status of an area, to use voluntary or consensus standards in place of promulgated air quality standards and monitoring procedures that otherwise satisfy the provisions of the CAA. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Under Executive Order 12898, EPA finds that this rule involves a determination of attainment based on air quality data and will not have disproportionately high and adverse human health or environmental effects on any communities in the area.
including minority and low-income communities.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 13, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action, pertaining to the Metropolitan Washington, DC–MD–VA nonattainment area for the 1997 PM$_{2.5}$ NAAQS, may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements.


Donald S. Welsh,
Regional Administrator, Region III.

§ 52.477 Control strategy: Particulate matter.

Determination of Attainment. EPA has determined, as of January 12, 2009, the District of Columbia portion of the Metropolitan Washington, DC–MD–VA nonattainment area for the 1997 PM$_{2.5}$ NAAQS has attained the 1997 PM$_{2.5}$ NAAQS. This determination, in accordance with 40 CFR 52.1004(c), suspends the requirements for this area to submit an attainment demonstration and associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as the area continues to attain the 1997 PM$_{2.5}$ NAAQS.

Subpart V—Maryland

3. Section 52.1081 is added to read as follows:

§ 52.1081 Control strategy: Particulate matter.

Determination of Attainment. EPA has determined, as of January 12, 2009, the Maryland portion of the Metropolitan Washington, DC–MD–VA nonattainment area for the 1997 PM$_{2.5}$ NAAQS has attained the 1997 PM$_{2.5}$ NAAQS. This determination, in accordance with 40 CFR 52.1004(c), suspends the requirements for this area to submit an attainment demonstration and associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as the area continues to attain the 1997 PM$_{2.5}$ NAAQS.

Subpart VV—Virginia

4. Section 52.2429 is added to read as follows:

§ 52.2429 Control strategy: Particulate matter.

Determination of Attainment. EPA has determined, as of January 12, 2009, the Virginia portion of the Metropolitan Washington, DC–MD–VA nonattainment area for the 1997 PM$_{2.5}$ NAAQS has attained the 1997 PM$_{2.5}$ NAAQS. This determination, in accordance with 40 CFR 52.1004(c), suspends the requirements for this area to submit an attainment demonstration and associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as the area continues to attain the 1997 PM$_{2.5}$ NAAQS.