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By direction of the Commission.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2012-23647 Filed 9-25-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2012-N-0447]

Antimicrobial Animal Drug Sales and Distribution Reporting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the advance notice of proposed rulemaking that appeared in the **Federal Register** of July 27, 2012. In the advance notice of proposed rulemaking, FDA requested comments regarding potential changes to its regulations relating to records and reports for approved antimicrobial new animal drugs. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: The comment period for the advance notice of proposed rulemaking that published July 27, 2012 (77 FR 44177) is extended. Submit written or electronic comments by November 26, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0447, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0447 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9062, email: neal.bataller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 27, 2012 (77 FR 44177), FDA published an advance notice of proposed rulemaking with a 60-day comment period to request comments regarding potential changes to its regulations relating to records and reports for approved new animal drugs. FDA is considering revisions to this regulation to incorporate the requirements of section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105). The Agency is also seeking public comment on how best to compile and present the summary information as directed by ADUFA 105, and on alternative methods available to the

Agency for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals.

The Agency has received requests for a 60-day extension of the comment period for the advance notice of proposed rulemaking. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the advance notice of proposed rulemaking.

FDA has considered the requests and is extending the comment period for the advance notice of proposed rulemaking for 60 days, until November 26, 2012. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: September 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-23740 Filed 9-21-12; 4:15 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2010-0154; FRL-9732-8]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; The Washington County 2002 Base Year Inventory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the fine particulate matter (PM_{2.5}) 2002 base year emissions inventory portion of the State of Maryland State Implementation Plan (SIP) revision submitted by the State of Maryland, through the Maryland Department of the

Environment (MDE), on June 6, 2008 for Washington County, Maryland. The emissions inventory is part of Maryland's June 6, 2008 SIP revision that was submitted to meet nonattainment requirements related to the Washington County nonattainment area (hereafter referred to as Washington County Area or Area) for Maryland's 1997 PM_{2.5} National Ambient Air Quality Standard (NAAQS) SIP. EPA is proposing to approve the 2002 base year PM_{2.5} emissions inventory for Washington County submitted by MDE in accordance with the requirements of the Clean Air Act (CAA).

DATES: Written comments must be received on or before October 26, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2010-0154 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. Email: mastro.donna@epa.gov.

C. Mail: EPA-R03-OAR-2010-0154, Donna Mastro, Acting Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2010-0154. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you

include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.*, 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. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT:

Asrah Khadr, (215) 814-2071, or by email at khadr.asrah@epa.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Summary of SIP Revision
- III. Proposed Action
- IV. Statutory and Executive Order Reviews

I. Background

Throughout this document, whenever "we," "us," or "our" is used, we mean EPA. On July 18, 1997 (62 FR 38652), EPA promulgated the 1997 PM_{2.5} NAAQS, including an annual standard of 15.0 micrograms per cubic meter (µg/m³) based on a 3-year average of annual mean PM_{2.5} concentrations, and a 24-hour (or daily) standard of 65 µg/m³ based on a 3-year average of the 98th percentile of 24-hour concentrations. EPA established the standards based on significant evidence and numerous health studies demonstrating that serious health effects are associated with exposures to PM_{2.5}.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the United States as attaining or not attaining the NAAQS; this designation process is described in section 107(d)(1) of the CAA. In 1999, EPA and state air-quality agencies initiated the monitoring

process for the 1997 PM_{2.5} NAAQS and, by January 2001, established a complete set of air-quality data. On January 5, 2005, EPA published initial air-quality designations for the 1997 PM_{2.5} NAAQS (70 FR 944), which became effective on April 5, 2005, based on air-quality monitoring data for calendar years 2001-03.

On April 14, 2005, EPA promulgated a supplemental rule amending the agency's initial designations (70 FR 19844), with the same effective date (April 5, 2005) as that which was promulgated at 70 FR 944. As a result of this supplemental rule, PM_{2.5} nonattainment designations are in effect for 39 areas, comprising 208 counties within 20 states (and the District of Columbia) nationwide, with a combined population of approximately 88 million. The Washington County Area which is the subject of this rulemaking was included in the list of areas not attaining the 1997 PM_{2.5} NAAQS.

On June 6, 2008, the State of Maryland submitted a revision to the Maryland SIP (#08-05) to meet nonattainment requirements for the Washington County Area. On November 20, 2009 (74 FR 60199), EPA determined that Maryland had attained the 1997 PM_{2.5} NAAQS in the Washington County Area. That determination was based upon quality assured, quality controlled and certified ambient air monitoring data that showed the Area had monitored attainment of the 1997 PM_{2.5} NAAQS for the 2004-2006 monitoring period and that continued to show attainment of the 1997 PM_{2.5} NAAQS based on the 2005-2007 data. The November 20, 2009 determination suspended the requirements for Maryland to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIP revisions related to attainment of the standard for so long as the nonattainment area continues to meet the 1997 PM_{2.5} NAAQS. On February 29, 2012, MDE withdrew portions of the June 6, 2008 Washington County, Maryland 1997 PM_{2.5} SIP revisions including the attainment plan, analysis of reasonably available control measures, attainment demonstration, contingency plans and mobile source budgets. To meet the requirements of CAA section 172(c)(3), MDE did not request the withdrawal of the 2002 base year emission inventory portion of the June 6, 2008 1997 PM_{2.5} SIP revision. Section 172(c)(3) of the CAA requires submission and approval of a comprehensive, accurate, and current inventory of actual emissions.

II. Summary of SIP Revision

The 2002 base year emission inventory submitted by MDE on June 6, 2008 for Washington County, Maryland includes emissions estimates that cover the general source categories of stationary point sources, stationary nonpoint sources, nonroad mobile sources and onroad mobile sources. The pollutants that comprise the inventory are nitrogen oxides (NO_x), volatile organic compounds (VOCs), PM_{2.5}, coarse particles (PM₁₀), ammonia (NH₃), and sulfur dioxide (SO₂). EPA has reviewed the results, procedures and methodologies for the 2002 base year emissions inventory submitted by MDE for Washington County, Maryland. The year 2002 was selected by MDE as the base year for the emissions inventory per 40 CFR 51.1008(b). A discussion of the emissions inventory development as well as the emissions inventory can be found in the June 6, 2008 SIP submittal.

The CAA section 172(c)(3) emissions inventory is developed by the incorporation of data from multiple sources. States were required to develop and submit to EPA a triennial emissions inventory according to the Consolidated Emissions Reporting Rule (CERR) for all source categories (*i.e.*, point, area, nonroad mobile and on-road mobile). The 2002 emissions inventory was based on data developed by MDE. The data were developed according to current EPA emissions inventory guidance, "Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter NAAQS and Regional Haze Regulations," August 2005. EPA agrees that the process used to develop this emissions inventory is adequate to meet the requirements of CAA section 172(c)(3), the implementing regulations, and EPA guidance for emission inventories. More information regarding the review of the base year inventory can be found in the technical support document (TSD) that is located in this docket.

III. Proposed Action

EPA is proposing to approve the 2002 base year emissions inventory portion of the SIP revision submitted by Maryland through MDE on June 6, 2008 for Washington County, Maryland. We have made the determination that this action is consistent with section 110 of the CAA. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
 - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
 - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
 - 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);
 - Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
 - Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
 - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
 - Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
 - Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).
- In addition, this proposed rule, pertaining to the PM_{2.5} 2002 base year emissions inventory portion of the Washington County, Maryland June 6, 2008 SIP submittal, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the

state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 30, 2012.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2012-23698 Filed 9-25-12; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Dockets No. FWS-R9-MB-2012-0028 and FWS-R9-MB-2012-0038; FF09M21200-123-FXMB1231099BPP0L2]

RINs 1018-AY61, 1018-AY66

Migratory Bird Hunting; Application for Approval of Copper-Clad Iron Shot and Fluoropolymer Shot Coatings as Nontoxic for Waterfowl Hunting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; availability of draft environmental assessments.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to approve copper-clad iron shot and fluoropolymer coatings for hunting waterfowl and coots. We published a notice of application for nontoxic shot approval for copper-clad iron shot in the **Federal Register** on June 20, 2012 (77 FR 36980), and one for the fluoropolymer shot coatings on July 6, 2012 (77 FR 39983). Having completed our review of the application materials for both, we have concluded that neither the shot nor the coatings are likely to adversely affect fish, wildlife, or their habitats.

DATES: Electronic comments on this proposal via <http://www.regulations.gov> must be submitted by 11:59 p.m. Eastern time on October 26, 2012. Comments submitted by mail must be postmarked no later than October 26, 2012.

ADDRESSES: *Document Availability.* You may view the application and our draft environmental assessments by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Search for Docket No. FWS-R9-MB-2012-0028 for