

Rules and Regulations

Federal Register

Vol. 80, No. 172

Friday, September 4, 2015

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2014–0023]

Gypsy Moth Generally Infested Areas; Additions in Minnesota, Virginia, West Virginia, and Wisconsin

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the gypsy moth regulations by adding areas in Minnesota, Virginia, West Virginia, and Wisconsin to the list of generally infested areas based on the detection of infestations of gypsy moth in those areas. As a result of the interim rule, the interstate movement of regulated articles from those areas was restricted. The interim rule was necessary to prevent the artificial spread of the gypsy moth to noninfested areas of the United States.

DATES: Effective on September 4, 2015, we are adopting as a final rule the interim rule published at 80 FR 12916–12917 on March 12, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Chaloux, National Policy Manager, Emerald Ash Borer Program and Gypsy Moth Program, Plant Protection and Quarantine, APHIS, 4700 River Road Unit 137, Riverdale, MD 20737; (301) 851–2064.

SUPPLEMENTARY INFORMATION: The gypsy moth, *Lymantria dispar* (Linnaeus), is a destructive pest of forest, shade, and commercial trees such as nursery stock and Christmas trees. The gypsy moth regulations (contained in 7 CFR 301.45 through 301.45–12 and referred to

below as the regulations) restrict the interstate movement of regulated articles from generally infested areas to prevent the artificial spread of the gypsy moth.

In an interim rule¹ effective and published in the **Federal Register** on March 12, 2015 (80 FR 12916–12917, Docket No. APHIS–2014–0023), we amended the regulations in § 301.45–3(a) by adding the following areas to the list of generally infested areas: Cook and Lake Counties in Minnesota; Tazewell County in Virginia; McDowell, Mercer, Raleigh, Summers, and Wyoming Counties in West Virginia; and Iowa County in Wisconsin. As a result of the interim rule, the interstate movement of regulated articles from these areas was restricted.

Comments on the interim rule were required to be received on or before May 11, 2015. We received two comments by that date. The comments were from the National Plant Board and an individual. Both commenters supported the interim rule. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule without change.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 80 FR 12916–12917 on March 12, 2015.

¹To view the interim rule and the comments we received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2014-0023>.

Done in Washington, DC, this 31st day of August 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–21998 Filed 9–3–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Housing Service

Rural Utilities Service

Farm Service Agency

7 CFR Part 1980

RIN 0570–AA94

Strategic Economic and Community Development

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, Rural Utilities Service, Farm Service Agency, U.S. Department of Agriculture (USDA).

ACTION: Interim rule with public comment; reopening of public comment period.

SUMMARY: Through this action, the Rural Housing Service, the Rural Business-Cooperative Service, the Rural Utilities Service, and the Farm Service Agency are reopening the comment period for the interim rule, published on May 20, 2015 “Strategic Economic and Community Development”.

DATES: Comments on the interim rule that was published on May 20, 2015 (80 FR 28807) and effective June 19, 2015, must be received by September 18, 2015.

ADDRESSES: Submit your comments on this rule by any of the following methods:

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

- *Mail:* Submit written comments via the U.S. Postal Service to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, STOP 0742, 1400 Independence Avenue SW., Washington, DC 20250–0742.

- *Hand Delivery/Courier:* Submit written comments via Federal Express Mail, or other courier service requiring

a street address, to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, 300 7th Street SW., 7th Floor, Washington, DC 20024.

All written comments will be available for public inspection during regular work hours at the 300 7th Street, SW., 7th Floor address listed above.

FOR FURTHER INFORMATION CONTACT: Farah Ahmad, Rural Business-Cooperative Service, U.S. Department of Agriculture, Stop 3254, 1400 Independence Avenue SW., Washington, DC 20250-0783, Telephone: 202-245-1169. Email: Farah.Ahmad@wdc.usda.gov.

SUPPLEMENTARY INFORMATION: On July 20, 2015, the Rural Housing Service, the Rural Business-Cooperative Service, the Rural Utilities Service, and the Farm Service Agency published an interim rule with comment in the **Federal Register** (80 FR 28807), “Strategic Economic and Community Development.” The interim rule identified that public comments were to be submitted by August 18, 2015. Unfortunately, the Web site Regulations.gov inadvertently closed the comment period on July 20, 2015, which was the closing date for comments on the information collection request. To compensate for closing the comment period early via the Regulations.gov Web site, this action provides commenters additional time to submit comments on the interim rule.

Dated: August 26, 2015.
Lisa Mensah,
Under Secretary, Rural Development.

Dated: August 27, 2015.
Michael Scuse,
Under Secretary, Farm and Foreign Agricultural Services.

[FR Doc. 2015-21898 Filed 9-3-15; 8:45 am]
BILLING CODE 3410-XY-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 524, and 558

[Docket No. FDA-2015-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during May and June 2015. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a nonsubstantive change. This technical amendment is being made to improve the accuracy of the regulations.

DATES: This rule is effective September 4, 2015.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during May and June 2015, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING MAY AND JUNE 2015

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR sections	FOIA summary	NEPA review
141-417	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	CORAXIS (moxidectin) Topical Solution for Dogs.	Original approval for the prevention of heartworm disease, and for the treatment and control of intestinal hookworm, roundworm and whipworm infections in dogs.	524.1450	yes	CE. ^{1,2}
141-188	Merial Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640.	MARQUIS (ponazuril) Oral Paste.	Supplemental approval of a revised dosage that includes a loading dose on the first day of treatment.	520.1855	yes	CE. ^{1,2}
141-262	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	CERENIA (maropitant citrate) Tablets.	Supplemental approval extending duration of daily administration until resolution of acute vomiting.	520.1315	yes	CE. ^{1,2}