R–2203A Eagle River, AK [Amended]

By removing the existing Using Agency information and substituting the following:

Using agency. U.S. Army, AK (USARAK), Commanding General, Fort Richardson, AK.

R–2203B Eagle River, AK [Amended]

By removing the existing Using Agency information and substituting the following:

Using agency. U.S. Army, AK (USARAK), Commanding General, Fort Richardson, AK.

R–2203C Eagle River, AK [Amended]

By removing the existing Using Agency information and substituting the following:

Using agency. U.S. Army, AK (USARAK), Commanding General, Fort Richardson, AK.

* * * * *

R–2205 Stuart Creek, AK [Amended]

By removing the existing Using Agency information and substituting the following:

Using agency. U.S. Army, AK (USARAK), Commanding General, Fort Richardson, AK.

Issued in Washington, DC, on March 2, 2011.

Rodger A. Dean,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2011–5246 Filed 3–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No.: FAA–2002–11301; Amendment No. 121–315A]

RIN 2120–AH14

Antidrug and Alcohol Misuse Prevention Programs for Personnel Engaged in Specified Aviation Activities; Supplemental Regulatory Flexibility Determination

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; supplemental regulatory flexibility determination.

SUMMARY: This document announces the completion and availability of a supplemental regulatory flexibility determination for a previously published final rule. That final rule amended the FAA regulations governing drug and alcohol testing to clarify that each person who performs a safety-sensitive function for a regulated employer by contract, including bysubcontract at any tier, is subject to testing.

DATES: Submit comments on or before May 9, 2011.

ADDRESSES: Send comments identified by docket number 2002–11301 using any of the following methods:

- *Federal eRulemaking Portal*: Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue, SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov*, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, *etc.*). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nicole Nance, Office of Aviation Policy and Plans, APO–300, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3311; e-mail *nicole.nance@faa.gov.* For legal questions concerning this document, contact Anne Bechdolt, Regulations Division, AGC–220, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7230; e-mail *anne.bechdolt@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On February 28, 2002, the FAA issued a notice of proposed rulemaking seeking to revise the drug and alcohol testing regulations by amending the definition of employee (67 FR. 9366, 9377, Feb. 28, 2002). The FAA action addressed those individuals performing safety-sensitive functions under contract who may not have been subject to testing under the drug and alcohol testing regulations established in 1988 and 1994, respectively. Upon review of comments, the FAA, in 2004, issued a supplemental notice of proposed rulemaking to seek comment regarding how small entities would be impacted by this rule (69 FR 27980, May 17, 2004). From the comments received the FAA believed that the rule would not have a significant impact on a substantial number of small entities.

On January 10, 2006, the FAA issued the final rule (71 FR 1666). This rule requires that each person who performs a safety-sensitive aviation function directly for an employer is subject to testing and that each person who performs a safety-sensitive function at any tier of a contract for that employer is also subject to testing. This requirement includes contractors and subcontractors. Contracting companies have two testing options: Option one is for the contracting company to obtain and implement its own FAA drug and alcohol (D&A) testing programs. Under this option, the company would subject the individuals to testing. The other option is for the regulated employer to maintain its own testing programs and subject the individual to testing under these programs. To establish a D&A program a company would need to develop and maintain testing, training, and annual reporting requirements.

To comply with the Regulatory Flexibility Analysis (RFA), and to evaluate the impact on small businesses, the FAA described and estimated the number of affected businesses and estimated the economic impact. In the final regulatory flexibility analysis the FAA estimated that the costs were minimal, and that contractors would absorb some of these costs. In order to estimate the maximum impact of this regulation on regulated entities the FAA assumed that all of the additional cost would be passed along to regulated employers. Since costs were minimal, the FAA again certified that the rule would not have a significant economic impact on a substantial number of small entities. 71 FR 1666, 1674 (Jan. 10, 2006)

The Aeronautical Repair Station Association, Inc., (ARSA) and other affected businesses challenged the final rule on several grounds, including the FAA's compliance with the Regulatory Flexibility Act. The entities argued that contractors and subcontractors were directly affected by the final rule, and in failing to consider them in the final

regulatory flexibility analysis, the FAA failed to comply with the RFA. Upon review, the U.S. Court of Appeals for the District of Columbia upheld "the substance of the 2006 final rule" and remanded "for the limited purpose of conducting the analysis required under the RFA, treating the contractors and subcontractors as regulated entities." The Court found that contractors and subcontractors were directly affected by the final rule and that the FAA failed to comply with the RFA by not considering them in the analysis. To comply with the Court's ruling, the FAA has extended the regulatory flexibility analysis to include contractors and subcontractors as discussed below.

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation." To achieve this principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration." The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

Discussion

The Small Business Administration (SBA) has established small business size standards pursuant to the Small Business Act (Act) (Pub. L. 85–236, as amended) and related legislative guidelines. Using the NAICS (North American Industrial Classification System) classifications, the SBA classifies "small" businesses based on their employment or annual revenue. For this rule, part 145 certificated repair stations and their subcontractors are considered small businesses as defined by this definition. Repair stations are classified as "Other Support Activities for Air Transport" (488190) with small businesses defined as businesses with annual revenues of $7 million or less. Subcontractors, conversely, overlap several industries and have multiple NAICS codes. The SBA and ARSA provided a list of 21 NAICS codes for suppliers, parts fabricators and metal finishers, among others that may perform safety sensitive repairs and therefore would be considered a subcontractor under the rule. For these NAICS codes the definition of a small business ranges from 500 to 1,000 employees or annual revenues of $7 million or less.

Based upon data compiled by the Transportation Security Administration (TSA) for an aircraft repair station security rule, in the RFA the FAA estimated the number of small business repair stations. TSA used revenue and employment records from Dun & Bradstreet for approximately 2,276 domestic repair stations.[1] From this total they identified 2,123 that reflect small businesses as defined by the SBA. Their analysis indicates that most repair stations are small businesses. Accepting the TSA percentage of small entities for domestic repair stations and our internal data, the FAA has estimated that out of 4,105 domestic U.S. certificated repair stations 3,829 are small businesses with revenues of $7 million or less.

After estimating the number of small entity repair stations, we now focus on describing subcontractors impacted by this rule. In order to provide a description of subcontractors, the FAA examined the submitted list of 21 NAICS codes provided by the SBA and ARSA. There was some duplication in the codes, reducing the actual number of codes to be examined.

During the comment period ARSA not only provided a list of NAICS codes, but they also conducted and provided information on a Non-Certificated Maintenance Subcontractor (NCMS) Survey. Some of the information from the survey proved to be useful in determining the small business impact on subcontractors, particularly the responses to questions 1 (number of employees), 2 (annual revenue), 3 (an existing contract with a U.S. air carrier to perform maintenance), 4 (type of work). These responses are used, in this analysis, to determine the characteristics of these companies.

The FAA finds it appropriate to start with the responses to question 4, which deals with the work-related functions of the respondents, as a snapshot of some of the types of companies that need to be included in this analysis. The FAA grouped the responses to question 4 into the NAICS codes that both ARSA and the SBA provided and the FAA was able to correlate 98 of the 134 survey respondents with these codes; these 98 are shown in Table 1 below. While there are discrepancies with regard to the count, we can validate 98 of the 134 responses. This shows the wide spectrum of businesses providing contracting support.

TABLE 1—SURVEY RESULTS—NAICS CODES AND WORK FUNCTIONS

Number of NCMS	NAICS Code	Work functions	Require D&A program?
1	313311	Fireproofing of fabrics	Y
14	313320	Metallizing (including plating)	S
9	332322	Manufacturing airframe parts (mostly sheet metal)	N
		Manufacturing per approved drawing or data	N
		Manufacturing small parts; some of which are used by part 121 operators	N
23	332710	Chemical milling (reduction of weight)	S
		Machining	S
		Machining and welding of ground support parts for planes	N
		Machining of turbine engine components	S
		Machining; chrome plating; anodize; metal finishing; shot peening	S
3	332722	Manufacturer of miniature turned parts. Screws and like	N

[1] Aircraft Repair Station Security (49 CFR part 1520 and 1554). Regulatory and Economic Analysis: Transportation Security Administration Department of Homeland Security, October 15, 2009.

TABLE 1—SURVEY RESULTS—NAICS CODES AND WORK FUNCTIONS—Continued

Number of NCMS	NAICS Code	Work functions	Require D&A program?
2	332811	Heat treating	Y
1	332812	Painting	Y
8	332813	Chrome plating; nickel plating (metal finishing)	S
		Machining; chrome plating; anodize; metal finishing; shot peening	S
		Metal finishing (grinding) (zinc plating)	S
		Plating; precision grinding; non-destructive testing	S
3	332999	Die-cut parts—shims; washers; gaskets; *etc.*	N
1	334511	Rebuild electro-mechanical switches for aviation use	N
1	336412	Overhauling of engine blocker doors	Y
22	488190	Minor maintenance	Y
		Maintenance on 135 charter aircraft line	Y
		Overhauling of engine blocker doors	Y
5	541380	Calibration and repair of test and measuring equipment	N
		Hydrostatic testing	N
		Inspection	N
		Machining & fabrication of test fixtures & equipment used in repair processes	N
		Non-destructive testing	N
1	561740	Cleaning seat covers	N
4	811310	Machining and welding of ground support parts for planes	N
		Manufacturing & precision grinding and testing of various fuel & hydraulic/pneumatic valve assemblies.	N

Table 1 also indicates whether a specific function would require a D&A program. The last column is either marked with "Y" meaning yes, "N" meaning no, and "S" meaning some in this grouping might need such a program, as this work function conceivably could mandate such a program. Companies that have work that is strictly manufacturing will not be required to comply with the D&A testing rules. Several companies mentioned in their survey responses that they do not perform maintenance, and would not be included among companies required to set up and implement D&A testing. For example, the 14 companies characterized as 313320, which involves metal finishing including plating, may need to conduct D&A testing if some of the work they perform is considered maintenance under 14 CFR part 43.

The responses to questions 1 and 2 address the number of employees and the annual revenue reported by the surveyed companies. These responses are helpful in establishing the type of impact that this program will have on these companies. Question 1 asked "How many employees does your company have?" Table 2 summarizes the responses provided by the ARSA survey. All but two of the responses are in the category of 750 or below. The two responses for "1501+" are outliers and, for computational purposes, can be ignored. Approximately 75% of the respondents stated that they employed between 1 and 50 employees, indicating that the majority of subcontracting companies are small entities.

TABLE 2—SURVEY RESULTS—EMPLOYEES BY COMPANY

Response	Count	Percent
1 to 10	43	32.09
11 to 50	58	43.28
51 to 100	10	7.46
101 to 500	18	13.43
501 to 750	3	2.24
751 to 1000	0	0.00
1001 to 1500	0	0.00
1501+	2	1.49
Total	134	100.00

Question 2 of the survey asked about the company's annual revenues; Table 3 summarizes the survey responses:

TABLE 3—SURVEY RESULTS—ANNUAL REVENUE BY COMPANY

Response	Count	Percent
Under $750,000	43	32.09
$750,000 to $1 million	14	10.45
$1 million to $2 million	20	14.93
$2 million to $6 million	24	17.91
$6 million to $10.5 million	8	5.97
$10.5 million to $21.5 million	7	5.22
$21.5 million to $25 million	1	0.75
$25 million to $30 million	4	2.99
More than $30 million	13	9.70
Total	134	100.00

Most of these companies reported average annual revenue of $7 million or less.

As noted above, ARSA did a survey and 134 members responded; the FAA believes that this is only a fraction of the total number of NCMS. As mentioned above, a small business is defined as having either 1,000 employees or less, or having revenue of $7 million or less, depending on the NAICS code. The majority of the companies in the ARSA survey are small entities which leads the FAA to believe that a substantial number of subcontractors will be small entities impacted by this rule.

The next step is to estimate the economic impact. The FAA rule requires small businesses to administer random drug tests to those employees who perform safety-sensitive functions. For a high cost estimate, the FAA based costs on subcontractors initiating and then implementing their own programs. It is important to note that these costs are much higher than when repair stations or contractors at higher tiers absorb some of the cost of D&A testing for the smaller firms. Moreover, most repair stations have drug and alcohol programs and therefore would not experience a cost burden based on the amendments to this rule. However, to estimate the maximum impact of this regulation on regulated employers, the FAA assumes that all of the additional cost for D&A testing is absorbed by each NCMS. The costs include: (1) Testing, (2) training and education, (3) program development and maintenance, and (4) annual documentation. The assumptions and calculations are described below:

General Cost and Salary Assumptions

Maintenance supervisor salary—$39.68/hour
Maintenance employee salary—$33.07/hour
Blended Wage [2]—$33.84
Instructor salary—$36.37/hour
1 Supervisor for every 8 employees
1 Instructor for every 20 employees

Testing Cost

Drug and alcohol tests are required periodically for all employees performing safety sensitive functions. The test costs approximately $45 or $35, respectively. The test includes specimen collection, laboratory processing, and MRO (medical review officer) verification. Testing takes place during an employee's shift. This is time not worked but still paid by the company and is included as part of the testing cost. Previously, the FAA estimated that the testing process would take 45 minutes, but because of industry comments the FAA has adopted a 2 hour testing window for this analysis. The total cost of testing is calculated by adding the 2 hour blended wage paid to the employee to the cost of the test. The total cost of testing sums to $113 per employee for a drug test and $102 per employee for an alcohol test.

Training and Education

Training costs are a combination of supervisor and employee training costs, plus the cost to establish and maintain a training program. For both the antidrug and alcohol misuse prevention programs, the employer will train supervisors to make reasonable cause/suspicion determinations. In addition, supervisors and employees will receive training on the effects and consequences of drug use on personal health, safety, and work environment, as well as the manifestations and behavioral cues that may indicate drug use and abuse. For supervisors, this training is initially estimated to take an hour and a half, followed by a recommended annual hourly refresher course. Employee training will also be given annually for approximately an hour. Training costs include the cost of the instructor at $84 per supervisor and $70 per employee.

Companies must also establish an education program that includes informational material, videos, *etc.* Per employee, these costs average $65 per person. Summing all of these together gives an estimated total education and training cost of either $149 per supervisor or $135 per employee per year.

Program Development and Maintenance

Each subcontractor will have to devote resources to developing an antidrug and alcohol misuse prevention testing program. In addition, each of these subcontractors will have to spend time to produce information required for their registration and submit it to the FAA. At the FAA, this information will have to be processed, and entered into the appropriate database. The FAA estimates that development and maintenance of a drug and alcohol program would each require a minimum of 16 administrative hours per program at $21 per hour for a total of $336 per company per year.

Annual Documentation

Each subcontractor has to periodically submit documentation. They will be required to report or submit the following documents; Training records, reasonable suspicion cases of drug and alcohol misuse, a positive drug or alcohol test, an employee's refusal to submit to a drug or alcohol test, post-accident alcohol tests, and, if a post-accident alcohol test is not promptly administered, documentation stating the reasoning behind the delay. The FAA estimates that it will cost $1.29 to report each training record, to document each reasonable suspicious case, or to submit every rationale behind tests not being promptly administered. Notification of a positive drug or alcohol test or an employee's refusal to be tested is estimated to take .25 administrative hours at an hourly rate of $21 at roughly $5 per notification. The FAA projects that these documents will be submitted annually, but each company on average only submits a certain number of reports. Using this average, documentation cost is estimated at $50 per company for the first year and $4.50 per company for subsequent years.

We estimate that the typical subcontracting company has 25 employees. This number comes from Table 2 above, where 75% of the respondents have fewer than 50 employees. Several of the costs are variable costs and are dependent on the number of employees; testing costs, supervisor training, and employee training. For testing and training costs, the FAA multiplied the cost per employee by the average number of employees. For a small subcontracting company with 25 employees we estimate $2,825 for drug tests, $2,550 for alcohol tests, and $3,417 for training. Adding these numbers to per company cost of program development and maintenance and annual documentation costs gives the average cost per-company of $6,628 or $6,353 for drug testing and alcohol testing, respectively. Detailed calculations are done below. This value can be compared to annual revenues to determine the impact on companies with 25 employees. Using the survey results from Table 2 and 3 above, we believe that a subcontracting company with 25 employees will have annual revenues of $750,000 to $2 million. For a company with $750,000 to $2 million in annual revenue estimated costs of $12,981 is less than 2% of their annual revenue. From this example we conclude that even for firms with revenues less than $750,000 per year, if we underestimated the compliance cost by more than 10%, the compliance cost is still less than 2% of their annual revenue. Since most of the costs are employee driven the compliance cost will be less than 2% of annual revenue for all companies.

From this the FAA asserts that although there are a substantial number of small businesses the economic impact is minimal.

Cost for Firms With 25 Employees and Annual Revenue of $750,000 to $2 Million

Cost of Drug Testing Program

$113 Testing Cost × 25 Employees = $2,825
$149 Supervisor Training × 3 Supervisors = $447
$135 Employee Training × 22 Employees = $2,970
$336 Program Development per Company
+$50 for Annual Documentation per Company

Total Cost = $6,628 per Company

Cost of Alcohol Testing Program

$102 Testing Cost × 25 Employees = $2,550
$149 Supervisor Training × 3 Supervisors = $447
$135 Employee Training × 22 Employees = $2970
$336 Program Development per Company = $336
+$50 for Annual Documentation per Company

Total Cost = $6,353 per Company

The FAA is aware that a substantial number of small entities must comply with this rule; however, the percentage of cost to revenue is less that 1 percent, therefore we believe that this rule does

[2] Two of the costs described below, testing costs and employee training costs, involve all employees, both supervisors and non-supervisors. For these two sets of calculations, the FAA uses a weighted wage rate from the maintenance supervisor and maintenance employee salary that is applicable to all employees.

not have a significant economic impact. Therefore the FAA preliminarily certifies that this rule will not have a significant economic impact on a substantial number of small entities.

The FAA solicits comments regarding this determination on this supplemental regulatory flexibility analysis. Please provide detailed economic analysis to support the position of higher cost. The FAA also invites comments regarding other small entity concerns with respect to the final rule.

Nan Shellabarger,

Director, Office of Aviation Policy and Plans.

[FR Doc. 2011–5257 Filed 3–7–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 14, and 17

[Docket No. FDA–2010–N–0560]

RIN 0910–AG55

Amendments to General Regulations of the Food and Drug Administration; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of April 14, 2011, for the final rule that appeared in the **Federal Register** of November 30, 2010 (75 FR 73951). The direct final rule amends certain general regulations of FDA to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act, by revising the Agency's regulations to require tobacco products to be subject to the same general requirements that apply to other FDA-regulated products. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: April 14, 2011.

FOR FURTHER INFORMATION CONTACT: Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., rm. 204G, Rockville, MD 20850, 1–877–CTP–1373.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 30, 2010 (75 FR 73951), FDA solicited comments concerning the direct final rule for a 75-day period ending February 14, 2011. FDA stated that the effective date of the direct final rule would be on April 14, 2011, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 14, and 17 are amended. Accordingly, the amendments issued thereby are effective.

Dated: March 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5147 Filed 3–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2011–N–0003]

Oral Dosage Form New Animal Drugs; Spinosad and Milbemycin Oxime

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 new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for veterinary prescription use of chewable tablets containing spinosad and milbemycin oxime in dogs for the treatment and prevention of flea infestations and for the prevention and control of various internal parasites.

DATES: This rule is effective March 8, 2011.

FOR FURTHER INFORMATION CONTACT: Angela Clarke, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8318, e-mail: *angela.clarke@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–321 that provides for veterinary prescription use of TRIFEXIS (spinosad and milbemycin oxime) Chewable Tablets in dogs for the treatment and prevention of flea infestations and for the prevention and control of various internal parasites. The NADA is approved as of January 4, 2011, and the regulations in part 520 (21 CFR part 520) are amended by adding § 520.2134 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

FDA 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 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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:

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

■ 2. Add § 520.2134 to read as follows:

§ 520.2134 Spinosad and milbemycin.

(a) *Specifications.* Each chewable tablet contains 140 milligrams (mg) spinosad and 2.3 mg milbemycin oxime, 270 mg spinosad and 4.5 mg milbemycin oxime, 560 mg spinosad and 9.3 mg milbemycin oxime, 810 mg spinosad and 13.5 mg milbemycin oxime, or 1,620 mg spinosad and 27 mg milbemycin oxime.

(b) *Sponsor.* See No. 000986 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer once a month at a