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:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1193 is amended by revising paragraphs (c)(2) and (c)(3) to read as follows:

§ 520.1193 Ivermectin tablets and chewable cubes.

* * * * *

(c) * * *

(2) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(3) *Limitations.* Use once-a-month. Recommended for dogs 6 weeks of age and older. Initial use within 1 month after first exposure to mosquitoes. Final use within 1 month after last exposure to mosquitoes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 9, 1996.

Robert C. Livingston,

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

[FR Doc. 96–19410 Filed 7–30–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 803

RIN 0910–AA09

Docket No. [91N–0295]

Medical Devices; Medical Device Reporting; Baseline Reports; Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: In response to numerous requests for the Food and Drug Administration (FDA) to further consider comments concerning manufacturer medical device reporting (MDR) baseline reporting requirements, FDA is staying the effective date of certain portions of the baseline reporting requirements. The stay of these requirements will allow FDA to further evaluate the issues raised by the comments and to determine whether the requirements should be revised.

EFFECTIVE DATE: July 31, 1996.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 11, 1995 (60 FR 63578) FDA published a final rule amending part 803 (21 CFR part 803) requiring medical device manufacturers to submit certain reports relating to adverse events (hereinafter referred to as the December 1995 final rule). The effective date of this rule was initially to be April 11, 1996. However, on April 11, 1996 (61 FR 16043), FDA extended the effective date to July 31, 1996.

Under the December 1995 final rule, manufacturers were required to submit individual reports of adverse events on a monthly basis, as well as annual baseline reports. Section 803.55 requires that the baseline reports include information specifically identifying a device for which an adverse event has been submitted, the number of devices manufactured and distributed in the last 12 months, an estimate of the number of devices in current use, and a brief description of any methods used to estimate the number of devices distributed and in current use. Among the primary purposes of these baseline data requirements is to provide information on population exposure to a particular device which together with the number of adverse event reports would provide relevant information about the rate of reported events for a particular device to aid the agency in evaluating an adverse event's significance. For example, information concerning the number of devices manufactured, distributed or in current use (hereinafter referred to as denominator data) is intended to enable the agency to determine how many people are exposed to potential risk from a device and whether 100 malfunction reports for a particular device represents a .001 percent (100 of 10,000,000) reported failure or a 10 (100 of 1,000) percent reported failure.

After issuing the December 11, 1995, final rule, FDA received numerous requests for reconsideration of the baseline reporting requirements. Specifically, industry objected that the requirements for denominator data were burdensome. These comments led FDA to meet with the Health Industry Manufacturers Association (HIMA) and several other industry representatives on April 19, May 23, June 13, and July 1, 1996. During these meetings and FDA internal meetings, issues concerning industry burdens and FDA evaluation of data were put forth that had previously not been considered.

Specifically, issues were raised about the ability to derive accurate information about adverse event rates of devices by the denominator data. The agency needs additional time to consider and better understand methods used to derive denominator estimates. FDA believes that a pilot program to analyze how certain variables affect the denominator data and how that data is used would allow the agency to implement denominator data requirements to evaluate the rate of and relative impact of adverse events more accurately. FDA intends to evaluate these issues further, and with the cooperation of industry in the near future, to implement such a pilot program, and subsequently to analyze these factors. Assuming that there is sufficient participation in the program, FDA anticipates that the completion of a successful pilot program would take from 12 to 18 months.

Because of the need for further analysis of variables affecting denominator data, FDA believes that baseline denominator data requirements should be stayed. The agency believes a pilot program may allow FDA to analyze the best possible means to obtain denominator data. At the completion of the pilot program, or a determination that because of inadequate participation, the pilot program is not feasible, FDA will either lift the stay of the December 1995 final rule baseline denominator reporting requirements, retain the stay, or proceed to revise these requirements.

The Administrative Procedure Act (Pub. L. 79–404) and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds (and incorporates the finding and a brief statement of reasons thereof in the rules issued) that notice and public comment procedures thereon are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(8); § 10.40(e)(1)).) FDA finds that there is good cause for dispensing with notice and comment procedures to stay the effective date of the manufacturer baseline reporting requirements for denominator data (§ 803.55((b)(9) and (10)) (corresponding with data elements 15 and 16 on FDA Form 3417) because such notice and comment procedures are impracticable and contrary to the public interest.

Notice and comment rulemaking on the postponement of baseline reporting denominator data is impracticable. FDA was not aware of significant issues relating to these requirements until after publication of the December 1995 final rule. Since that time, FDA has had numerous meetings with industry representatives and internal meetings to decide the best approach to resolve issues concerning the rule. The last such meeting occurred on July 1, 1996. Without the issuance of a stay under good cause procedures, the baseline denominator information reporting requirements would become effective on July 31, 1996.

In addition, notice and comment rulemaking on the stay of the baseline denominator reporting data would be contrary to the public interest. Because there is not enough time to allow notice and comment on the issue of staying the effective date before it occurs, the baseline denominator data requirements would go into effect on July 31, 1996. Consequently, industry would be required to implement additional procedures that may, after further evaluation, soon be replaced with different procedures leading to more accurate information. This may lead to unnecessary confusion and expense.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 803 is amended as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 371, 374).

2. In the revision of part 803 which was published at 60 FR 63578 (December 11, 1995), the effective date of which was extended until July 31, 1996, at 61 FR 16043 (April 11, 1996), the provisions of § 803.55(b)(9) and (10) are stayed until further notice.

Dated: July 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–19411 Filed 7–30–96; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

5 CFR Chapter LXXIV

29 CFR Part 2703

RIN 3209–AA15

Supplemental Standards of Ethical Conduct for Employees of the Federal Mine Safety and Health Review Commission

AGENCY: Federal Mine Safety and Health Review Commission (Commission).

ACTION: Final rule.

SUMMARY: The Federal Mine Safety and Health Review Commission, with the concurrence of the Office of Government Ethics (OGE), is issuing a final rule for Commission employees that supplements the Standards of Ethical Conduct for Employees of the Executive Branch issued by OGE. This final rule is a necessary supplement to the Standards because it addresses ethical issues unique to the Commission. The final rule prohibits the acquisition or holding of certain financial interests and requires certain employees to obtain prior approval for outside employment. The Commission also is repealing, except for a regulatory waiver provision, its old standards of conduct regulations that are superseded by the Standards, OGE's executive branch-wide financial disclosure regulations, and this final rule. In their place, the Commission is adding a cross-reference section to the current ethics provisions and a section specifying the Chairman's authority to appoint the Commission's ethics officials.

EFFECTIVE DATE: These regulations are effective July 31, 1996.

FOR FURTHER INFORMATION CONTACT: Norman Gleichman, Designated Agency Ethics Official, Federal Mine Safety and Health Review Commission, 1730 K Street, NW., 6th Floor, Washington, DC 20006; telephone: (202) 653–5610 (202–566–2673 for TDD Relay). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Background

On August 7, 1992, the Office of Government Ethics (OGE) published a final rule entitled Standards of Ethical Conduct for Employees of the Executive Branch (Standards). *See* 57 FR 35006–35067, as corrected at 57 FR 48557, 57 FR 52583, and 60 FR 51667, with additional grace period extensions at 59 FR 4779–4780, 60 FR 6390–6391, and 60 FR 66857–66858. The Standards, codified at 5 CFR part 2635 and made effective February 3, 1993, establish uniform standards of ethical conduct that are applicable to all executive branch employees.

With the concurrence of OGE, 5 CFR 2635.105 authorizes executive branch agencies to publish agency-specific regulations supplementing 5 CFR part 2635 that are necessary to implement their respective ethics programs. With OGE's concurrence, the Commission has determined that the following supplemental regulations, being codified in new 5 CFR chapter LXXIV, consisting of part 8401, are necessary for successful implementation of the Commission's ethics program, in light of the Commission's unique programs and operations.

II. Analysis of the Regulations

Section 8401.101 General

Section 8401.101 explains that the supplemental regulations apply to Commission employees and supplement the Standards at 5 CFR part 2635. This section also cross-references the executive branch-wide financial disclosure regulations at 5 CFR part 2634.

Section 8401.102 Prohibited Financial Interests

The Standards, at 5 CFR 2635.403(a), authorize an agency to issue a supplemental regulation prohibiting or restricting the acquisition or holding of a financial interest or a class of financial interests by the agency's employees or any category of its employees, based on a determination that the acquisition or holding of such interests would cause a reasonable person to question the imparti ality and objectivity with which agency programs are administered. Where it is necessary for the agency to carry out its mission, such prohibitions or restrictions may be extended to employees' spouses and minor children, since such family members' financial interests are imputed to employees for conflict of interest purposes.

Section 8401.102(a) expressly prohibits Commission employees (other than special Government employees), as well as the spouses and minor children of such employees, from having any financial interest, including indebtedness or compensated employment, in any company or other person who operates, controls, or supervises a mine subject to the provisions of the Federal Mine Safety and Health Act of 1977, 30 U.S.C. 801 et seq., or any independent contractor performing services or construction at such a mine. The prohibition has been made applicable to employees' spouses