materials filed in connection with these reports, except for reports of compliance, and supplemental materials filed in connection with Commission orders requiring divestitures or establishment of business enterprises of facilities, which are confidential until the last divestiture or establishment of a business enterprise or facility, as required by a particular order, has been finally approved by the Commission, and staff letters to respondents advising them that their compliance reports do not warrant any further action. At the time each such report is submitted the filing party may request confidential treatment in accordance with paragraph (c) of this section and the General Counsel or the General Counsel's designee will pass upon such request in accordance with that paragraph;

* * * * *

(c) Confidentiality and in camera material. (1) Persons submitting material to the Commission described in this section may designate that material or portions of it confidential and request that it be withheld from the public record. All requests for confidential treatment shall be supported by a showing of justification in light of applicable statutes, rules, orders of the Commission or its administrative law judges, orders of the courts, or other relevant authority. The General Counsel or the General Counsel's designee will act upon such request with due regard for legal constraints and the public interest. No such material or portions of material (including documents generated by the Commission or its staff containing or reflecting such material or portions of material) will be placed on the public record until the General Counsel or the General Counsel's designee has ruled on the request for confidential treatment and provided any prior notice to the submitter required by law.

* * * * *

(3) To the extent that any material or portions of material otherwise falling within paragraph (b) of this section contain information that is not required to be made public under § 4.10 of this part, the General Counsel or the General Counsel's designee may determine, with due regard for legal constraints and the public interest, to withhold such materials from the public record.

6. Section 4.11 is amended by revising paragraphs (c), (d), (f) and (g) to read as follows:

§ 4.11 Disclosure requests.

* * * * *

(c) *Requests from Federal and State law enforcement agencies.* Requests from law enforcement agencies of the Federal government for nonpublic records shall be addressed to the liaison officer for the requesting agency, or if there is none, to the General Counsel. Requests from State agencies for nonpublic records shall be addressed to the General Counsel. With respect to requests under this paragraph, the General Counsel, the General Counsel's designee, or the appropriate liaison officer is delegated the authority to dispose of them. Alternatively, the General Counsel may refer such requests to the Commission for determination, except that requests must be referred to the Commission for determination where the Bureau having the material sought and the General Counsel do not agree on the disposition. Prior to granting access under this section to any material submitted to the Commission, the General Counsel, the General Counsel's designee, or the liaison officer will obtain from the requester a certification that such information will be maintained in confidence and will be used only for official law enforcement purposes. The certificate will also describe the nature of the law enforcement activity and the anticipated relevance of the information to that activity. A copy of the certificate will be forwarded to the submitter of the information at the time the request is granted unless the agency requests that the submitter not be notified.

(d) *Requests from Federal and State agencies for purposes other than law enforcement.* Requests from Federal and State agencies for access to nonpublic records for purposes not related to law enforcement should be addressed to the General Counsel. The General Counsel or the General Counsel's designee is delegated the authority to dispose of requests under this paragraph. Disclosure of nonpublic information will be made consistent with sections 6(f) and 21 of the FTC Act. Requests under this section shall be subject to the fee and fee waiver provisions of § 4.8.

* * * * *

(f) Requests by current or former employees to use nonpublic memoranda as writing samples shall be addressed to the General Counsel. The General Counsel or the General Counsel's designee is delegated the authority to dispose of such requests consistent with applicable nondisclosure provisions, including sections 6(f) and 21 of the FTC Act.

(g) Employees are encouraged to engage in teaching, lecturing, and writing that is not prohibited by law, Executive order, or regulation. However, an employee shall not use information obtained as a result of his Government employment, except to the extent that such information has been made available to the general public or will be made available on request, or when the General Counsel or the General Counsel's designee gives written authorization for the use of nonpublic information on the basis that the use is in the public interest.

7. Section 4.15 is amended by revising paragraph (c)(3) to read as follows:

§ 4.15 Commission meetings.

* * * * *

(c) * * *

(3) Closed meeting transcripts or minutes required by 5 U.S.C. 552b(f)(1) will be released to the public insofar as they contain information that either is not exempt from disclosure under 5 U.S.C. 552b(c), or, although exempt, should be disclosed in the public interest. The Commission will determine whether to release, in whole or in part, the minutes of its executive sessions to consider oral arguments. With regard to all other closed meetings, the General Counsel or the General Counsel's designee shall determine, in accordance with § 4.9(c), which portions of the transcripts or minutes may be released.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–16030 Filed 6–16–98; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. 96N–0007]

Labeling of Drugs for Use in Milk-Producing Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the new animal drug regulations to remove the existing 96-hour withdrawal time limitation, eliminate the requirement to calculate and label on the basis of the number of 12-hour milking periods that have elapsed since treatment, and permit a milk-discard or withdrawal time to be calculated by elapsed hours since treatment. The agency is taking these actions to allow greater flexibility

in the labeling of new animal drugs for use in milk-producing animals. The increased flexibility will make it easier and more economical for sponsors to comply with the regulations. These actions are part of FDA's continuing effort to achieve the objectives set forth in the President's ''National Performance Review'' initiative, which is intended to provide a comprehensive review of all rules to identify those that are obsolete and burdensome and to delete or revise them.

DATES: July 17, 1998.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1642.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 4, 1996 (61 FR 15003), FDA published a proposed rule to amend the new animal drug regulations to: (1) Remove the existing regulatory limitation regarding a milk-discard or withdrawal time of not more than 96 hours, (2) eliminate the requirement to calculate and label on the basis of the number of 12-hour milking periods that have elapsed since the last treatment, and (3) permit a milk-discard or withdrawal time to be calculated on the basis of hours that have elapsed from the most recent treatment.

The requirements for labeling of new animal drugs intended for use in milk-producing animals at §§ 510.105 and 510.106 (21 CFR 510.105 and 510.106) of the new animal drug regulations provide for specific labeling for antibiotics, antibiotic-containing drugs, and other drugs intended for use in milk-producing animals.

The maximum 96-hour limitation in § 510.105 was based on FDA's perception that 96 hours constituted a maximum practical withdrawal time for the dairy industry. However, FDA now recognizes that a withdrawal time longer than 96 hours may be desirable and practical in certain circumstances. Accordingly, in the proposed rule, FDA proposed to remove the 96-hour limitation to allow the possibility of longer withdrawal times to be considered for milk-producing animals on a case-by-case basis depending on the use and safety of the drug.

Similarly, the 12-hour milking schedule in § 510.106 was established to calculate the number of milkings that occur during the withdrawal period. The 12-hour milking interval was considered to be generally reflective of dairy practice when this regulation was published; however, alternative milking schedules are in common use in the dairy industry today. Accordingly, in the proposed rule, FDA proposed to revise the regulation so that the length of the milking cycle is not specified, eliminating the reference to the milking interval as long as milk is discarded for the assigned number of hours after the latest drug treatment.

No comments were received on the proposed rule.

Because the agency has determined that the underlying rationale in support of the proposed amendment remains sound and because no comments were received, the revisions set forth in the proposed rule are reflected in the final rule. In addition, in the final rule, the agency has deleted the phrase ''(in _____ milkings)'' in § 510.105 to make it consistent with § 510.106 as amended. Also, in the final rule, the agency has added the word ''violative'' before the word ''residues'' in the first sentence of § 510.105(c)(2) and the second sentence of § 510.106 to clarify that labeling statements do not refer to any residues at or below permitted tolerance levels that might be present.

Accordingly, the final rule: (1) Removes the existing regulatory limitation regarding a milk-discard or withdrawal time of not more than 96 hours, (2) eliminates the requirement to calculate and label on the basis of the number of 12-hour milking periods that have elapsed since the last treatment, (3) permits a milk-discard or withdrawal time to be calculated on the basis of hours that have elapsed from the most recent treatment, and makes minor corrections for purposes of consistency and clarification.

These amendments will apply only to future approvals and will not affect currently approved new animal drugs unless a sponsor submits a supplement providing for revised labeling.

As stated in the proposal, these revisions are consistent with the goals of the President's National Performance Review. The agency's actions are part of its continuing effort to achieve the objectives set forth in that initiative, which is intended to provide a comprehensive review of all rules to identify those that are obsolete and burdensome and to delete or revise them.

II. Environmental Impact

FDA has carefully considered the potential environmental effects of this action and has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. This action revises the labeling requirements for drugs, antibiotics, and antibiotic-containing drugs intended for use in milk-producing animals, but will not cause an increase in the existing level of use or cause a change in the intended uses of the product or its substitutes. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, and distributive impacts and equity). The Regulatory Flexibility Act requires agencies to examine the economic impact of a rule on small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation).

This amendment to the new animal drug regulations will remove the existing regulatory requirement that mandates a withdrawal time not exceed 96 hours, and will permit withdrawal times to be calculated from the most recent treatment rather than requiring a 12-hour milking schedule. These actions will permit greater flexibility in the labeling of new animal drugs for use in milk-producing animals. These amendments will apply only to future approvals and will not affect currently approved new animal drugs unless a sponsor submits a supplement providing for revised labeling. The only compliance cost estimated for this rule would be for those drugs that are currently being reviewed for approval and are still unapproved on the date the final rule becomes effective. To the extent that any of these drugs exist, their sponsoring companies would incur a very small administrative expense of preparing a supplement to the application to change the warning language.

FDA concludes that this final rule is consistent with the principles set forth in the Executive Order and in the two statutes. In addition, the agency has

determined that this rule is not a significant regulatory action as defined by the Executive Order, so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the rule would clarify FDA policy, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million (adjusted annually for inflation) in any one year. The final rule allowing greater flexibility in the labeling of new animal drugs for use in milk-producing animals is estimated to result in insignificant expenditures of funds by the private sector, and none by State, local, and tribal governments. Because the expenditures are estimated to be insignificant, FDA is not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

IV. Paperwork Reduction Act of 1995

FDA has determined that this rule contains no collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA concludes that the labeling requirements described in this document are not subject to review by the Office of Management and Budget (OMB) because they do not constitute a ''collection of information'' but rather constitute warning statements that are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)). For that portion of the labeling statement required by § 510.105(c)(2) that is not supplied to the manufacturer (the number of hours necessary to avoid residue in milk used for food), the necessary information is already required under a separate regulation (§ 514.1(b)(7)(i)). This information has already been cleared by OMB (OMB Control number 0910–0032).

V. Federalism

FDA has analyzed the final rule in accordance with the principles set forth in Executive Order 12612 and has determined that this final rule does not warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, 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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.105 is amended by revising paragraph (c)(2) to read as follows:

§ 510.105 Labeling of drugs for use in milk-producing animals.

* * * * *

(c) * * *

(2) The label should bear the following statement: ''Warning: Milk that has been taken from animals during treatment and for _____ hours after the latest treatment must not be used for food'', the blank being filled in with the figure that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry violative residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

3. Section 510.106 is revised to read as follows:

§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement ''Warning: Not for use in animals producing milk, since this use will result in contamination of the milk'' or the statement ''Warning: Milk that has been taken from animals during treatment and for _____ hours after the latest treatment must not be used for food'', the blank being filled in with the figure that the Commissioner has authorized the manufacturer of the drug to use. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no violative residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, the Commissioner may exempt the drug from bearing either of the above warning statements.

Dated: June 9, 1998.

William K. Hubbard

Associate Commissioner for Policy Coordination.

[FR Doc. 98–16063 Filed 6–16–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AR–2–1–7393; FRL–6111–3]

Approval and Promulgation of State Implementation Plans; Arkansas; Recodification of Air Quality Control Regulations and Correction of Sulfur Dioxide Enforceability Deficiencies

AGENCY: Environmental Protection Agency (EPA).

ACTION: Removal of direct final rule amendments.

SUMMARY: On April 10, 1998 (63 FR 17680), EPA published a direct final approval and a proposed approval (63 FR 17793), of a revision to the Arkansas State Implementation Plan (SIP) which added Arkansas Department of Pollution Control and Ecology Regulation #19, ''Compilation of Regulations of the Arkansas State Implementation Plan for Air Pollution Control,'' as adopted by the Arkansas Commission on Pollution Control and Ecology on July 24, 1992, and submitted to EPA on September 14, 1992. The direct final action was published without prior proposal because the Agency anticipated no adverse comments. The EPA received adverse comments on the two April 10, 1998, actions. The commenters asked EPA not to consider the regulation as a revision to the Arkansas SIP. In addition, EPA also received a letter from the Governor of Arkansas dated May 8, 1998, requesting that the **Federal Register** approval of the 1992 Regulation #19 be withdrawn and that the 1992 submittal be returned to the State. Therefore, Region 6 is withdrawing its direct final approval action by removing the amendments made by the direct final rule and restoring the regulatory text