

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.

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#### **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 impartiality 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

and minor children based on a determination that such application of the prohibition is necessary to the ability of Commission employees to fulfill their official duties and the ability of the Commission to carry out its mission. Furthermore, the prohibition in this section, including its applicability to employees' spouses and minor children, is necessary to maintain public confidence in the impartiality and objectivity with which the Commission conducts its adjudicatory functions. The Commission believes it important to the success of its mission that those affected by agency decisions have this additional degree of assurance that agency decisions are not influenced by considerations of personal gain on the part of Commission personnel.

A "financial interest" is defined in the Standards at 5 CFR 2635.403(c). In accordance with 5 CFR 2635.403(a), § 8401.102(a) generally prohibits such interests in mining enterprises subject to the Commission's jurisdiction. This section is essentially a re-adoption of 29 CFR 2703.09(b), in which the Commission has prohibited employees from having a financial interest in mining enterprises subject to the Commission's jurisdiction. The Commission interpreted the provision to also apply to spouses and minor children of Commission employees.

Section 8401.102(b) sets forth exceptions to the general financial interest prohibition in § 8401.102(a). The exceptions are intended to permit the acquisition or holding of financial interests that are unlikely to raise questions regarding the objective and impartial performance of Commission employees' official duties or the possible misuse of their positions.

Under § 8401.102(b)(1), the prohibition in § 8401.102(a) does not apply to investments in a publicly traded or publicly available investment fund which, in its prospectus, does not indicate the objective or practice of concentrating its investments in the securities of 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, if the employee neither exercises control over the financial interests held in the fund nor has the ability to exercise such control. Under § 8401.102(b)(2), unless there is a "substantial conflict" within the meaning of 5 CFR 2635.403(b), an employee may own or control a financial interest obtained prior to the employee's commencement of

employment, through a change in marital status, or through circumstances beyond the employee's control, such as acquisition by inheritance, gift, or merger. However, the employee must make full written disclosure to the Designated Agency Ethics Official (DAEO) and the employee will be disqualified from participating in any decision or other particular matter having a direct and predictable effect on the financial interest in question.

Under § 8401.102(c), the DAEO may require divestiture of a financial interest that would otherwise be allowed to be retained under § 8401.102(b)(2), using the standard of "substantial conflict" set forth in 5 CFR 2635.403(b).

Under § 8401.102(d), the DAEO may grant a waiver from the financial interest prohibition in this section based on a determination that the waiver is not inconsistent with 5 CFR part 2635 or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality and objectivity with which Commission programs are administered. An employee may be required under the waiver to disqualify himself from a particular matter or take other appropriate action.

#### *Section 8401.103 Prior Approval for Outside Employment*

Under 5 CFR 2635.803 an agency that determines it is necessary or desirable for the purpose of administering its ethics program may, by supplemental regulation, require employees to obtain prior written approval before engaging in outside employment. The Commission's old standards of conduct regulation at 29 CFR 2703.12 (which is now being repealed) is a grace period (grandfathered) provision which has long required Commission employees classified at GS-13 or above and Commission attorneys at any grade level to obtain approval before engaging in outside employment. The Commission has found this requirement useful in ensuring that its employees avoid violations of the standards of conduct and conflict of interest statutes.

In accordance with 5 CFR 2635.803, the Commission has determined that it is necessary to the administration of its ethics program to continue to require such prior approval. Accordingly, § 8401.103(a) provides that a Commission employee, other than a special Government employee, must obtain the advance written approval from the employee's immediate supervisor and the DAEO before engaging in any outside employment.

This section also sets forth the minimum information required to be included in the request for prior approval.

Section 8401.103(b) provides that approval shall be granted only upon a determination that the outside employment is not expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635 and the Commission's supplemental standards of ethical conduct at this new part 8401 of 5 CFR.

"Employment" is broadly defined in § 8401.103(c)(1) to cover services as an agent, contractor, general partner, teacher, trustee, or writing when done under an arrangement with another person for production or publication of the written product. It does not, however, include participation in the activities of a nonprofit charitable, religious, professional, or public service organization, unless such activities involve providing professional services as defined in 5 CFR 2636.305(b)(1) or are for compensation other than reimbursement of expenses.

#### **III. Repeal and Revision of Commission Employee Responsibilities and Conduct Regulations**

The Commission is repealing its old employee responsibilities and conduct regulations codified at 29 CFR part 2703 which have been superseded by the new executive branch standards of ethical conduct and financial disclosure regulations, 5 CFR parts 2634 and 2635, and the Commission's supplemental standards of ethical conduct established by this rulemaking. In place of its old standards, the Commission is issuing a residual cross-reference provision at new 29 CFR 2703.1 to refer to the executive branch-wide Standards and financial disclosure regulations and to the Commission's new supplemental standards of ethical conduct.

In addition, in accordance with the ethics program responsibility of an agency head, at 5 CFR 2638.202(b), to select a DAEO and alternate DAEO, the Commission is including in 29 CFR part 2703 a new § 2703.2, which provides that the Chairman of the Commission shall appoint such officials to coordinate and manage the Commission's ethics program. Finally, the Commission is retaining in 29 CFR part 2703 the regulatory waiver at § 2703.09(c) (now being redesignated as § 2703.3) which was issued under the prior version of 18 U.S.C. 208(b)(2) (1988) and which has remained in effect pending OGE's issuance of superseding executive branch-wide regulatory waivers.

## IV. Matters of Regulatory Procedure

*Administrative Procedure Act*

The Commission has determined that these rules relate solely to agency organization, procedure, and practice. Therefore, the provisions of the Administrative Procedure Act, as codified at 5 U.S.C. 553, generally requiring notice of proposed rulemaking and other opportunity for public participation, are not applicable. The Commission further finds that there is good cause to make these rules, which are necessary to the successful implementation of the Commission's ethics program, effective upon publication in the Federal Register.

*E.O. 12866, Regulatory Planning and Review*

The Commission has determined that these rules are not subject to Office of Management and Budget review under Executive Order 12866.

*Regulatory Flexibility Act*

The Commission has determined under the Regulatory Flexibility Act (5 U.S.C. 601-611) that these rules will not have significant economic impact on a substantial number of small entities because they affect only Commission employees. Therefore, a Regulatory Flexibility Statement and Analysis has not been prepared.

*Paperwork Reduction Act*

The Commission has determined that the Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because these rules do not contain any information collection requirements that require the approval of the Office of Management and Budget.

## List of Subjects in 5 CFR Part 8401 and 29 CFR Part 2703

Conflict of interests, Executive branch standards of conduct, Government employees.

Dated: July 18, 1996.

Mary Lu Jordan,

*Chairman, Federal Mine Safety and Health Review Commission.*

Approved: July 19, 1996.

Stephen D. Potts,

*Director, Office of Government Ethics.*

For the reasons set forth in the preamble, the Federal Mine Safety and Health Review Commission, with the concurrence of the Office of Government Ethics, is amending title 5 and title 29 of the Code of Federal Regulations as follows:

## TITLE 5—[AMENDED]

1. A new chapter LXXIV, consisting of part 8401, is added to title 5 of the Code of Federal Regulations to read as follows:

## CHAPTER LXXIV—FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

**PART 8401—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION**

## Sec.

8401.101 General.

8401.102 Prohibited financial interests.

8401.103 Prior approval for outside employment.

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp. p. 306; 5 CFR 2635.105, 2635.403(a), 2635.802(a), 2635.803.

**§ 8401.101 General.**

In accordance with 5 CFR 2635.105, the regulations in this part apply to the employees of the Federal Mine Safety and Health Review Commission (Commission) and supplement the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635. Commission employees also are subject to the executive branch financial disclosure regulations at 5 CFR part 2634.

**§ 8401.102 Prohibited financial interests.**

(a) *Prohibition.* Except as provided in this section, no employee (other than a special Government employee), or spouse or minor child of such an employee, shall have a financial interest, including compensated employment or indebtedness, in any company or other person engaged in mining activities subject to the Federal Mine Safety and Health Act of 1977 (Federal Mine Safety and Health Act), 30 U.S.C. 801 et seq.

(b) *Exceptions.* (1) This section does not prohibit an employee, or the spouse or minor child of an employee, from investing in a publicly traded or publicly available investment fund which, in its prospectus, does not indicate the objective or practice of concentrating its investments in the securities of any company or other person engaged in mining activities subject to the Federal Mine Safety and Health Act, provided that the employee neither:

(i) Exercises control over the financial interests held in the fund; nor

(ii) Has the ability to exercise control over the financial interests held in the fund.

(2)(i) Unless divestiture is required by paragraph (c) of this section, this section does not prohibit an employee, or the spouse or minor child of an employee, from owning or controlling securities of any company or other person engaged in mining activities subject to the Federal Mine Safety and Health Act, whenever:

(A) Ownership or control was acquired prior to the employee's commencement of employment, through a change in marital status, or through circumstances beyond the employee's control and without the appearance of attempting to circumvent the prohibitions in this section, such as acquisition by inheritance, gift, or merger, acquisition or other change in corporate ownership, provided that: (1) The employee makes full, written disclosure to the designated agency ethics official within 30 days after the security is acquired or the employment is commenced; and

(2) The employee is disqualified from participating in any decision, examination, audit, or other particular matter having a direct and predictable effect on such company or other person, in which the employee holds a direct or indirect interest.

(B) The securities result from a stock split, stock dividend or the exercise of preemptive rights arising out of securities permitted by paragraph (b)(2)(i)(A) of this section. This paragraph does not permit the holding of stocks purchased through voluntary reinvestment of cash dividends.

(i) For purposes of this section, the term "securities" includes all interests in debt or equity instruments. The term includes, without limitation, secured and unsecured bonds, debentures, notes, securitized assets and commercial paper, as well as all types of preferred and common stock. The term encompasses both current and contingent ownership interests, including any beneficial or legal interest derived from a trust. It extends to any right to acquire or dispose of any long or short position in such securities and includes, without limitation, interests convertible into such securities, as well as options, rights, warrants, puts, calls, and straddles with respect thereto.

(c) *Divestiture.* The designated agency ethics official may require an employee to divest a security the employee is otherwise authorized to retain under paragraph (b)(2) of this section, based on a determination of substantial conflict under § 2635.403(b) of this title.

(d) *Waivers.* The designated agency ethics official may grant a written

waiver from the prohibition contained in this section based on a determination that the waiver is not inconsistent with 5 CFR part 2635 or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality, or otherwise to ensure confidence in the impartiality and objectivity with which Commission programs are administered. A waiver under this paragraph may be accompanied by appropriate conditions, such as requiring execution of a written statement of disqualification. Notwithstanding the grant of any waiver, an employee remains subject to the disqualification requirements of 5 CFR 2635.402 and 2635.502.

**§ 8401.103 Prior approval for outside employment.**

(a) *Prior approval requirement.* (1) Before engaging in any outside employment, whether or not for compensation, a Commission employee who is classified at GS-13 or above, as well as a Commission attorney at any grade level, must obtain the written approval of the employee's immediate supervisor and the designated agency ethics official. This requirement does not apply to a special Government employee of the Commission.

(2) Requests for approval shall be forwarded through the employee's immediate supervisor to the designated agency ethics official and shall include at a minimum the name of the person, group, or organization for whom the work is to be performed; the type of work to be performed; and the proposed hours of work and approximate dates of employment.

(b) *Standard for approval.* Approval shall be granted only upon a determination that outside employment is not expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR 2635 and this part.

(c) *Definitions.* For purposes of this section:

(1) *Employment* means any form of non-Federal employment or business relationship involving the provision of personal services by the employee. It includes but is not limited to personal services as an officer, director, employee, agent, attorney, consultant, contractor, general partner, trustee or teacher. It also includes writing when done under an arrangement with another person for production or publication of the written product. It does not, however, include participation in the activities of a nonprofit charitable, religious, professional,

social, fraternal, educational, recreational, public service or civic organization, unless such activities involve the provision of professional services or advice or are for compensation other than reimbursement expenses.

(2) *Professional services* means the provision of personal services by an employee, including the rendering of advice or consultation, which involves application of the skills of a profession as defined in 5 CFR 2636.305(b)(1).

**TITLE 29—[AMENDED]**

**CHAPTER XXVII—FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION**

2. Part 2703 of 29 CFR chapter XXVII is revised to read as follows:

**PART 2703—EMPLOYEE RESPONSIBILITIES AND CONDUCT**

**Sec.**

2703.1 Cross-reference to employee ethical conduct standards and financial disclosure regulations.

2703.2 Designated Agency Ethics Official and Alternate Designated Agency Ethics Official.

2703.3 Conflict of interest exemption.

Authority: 5 U.S.C. 7301; 18 U.S.C. 208; 5 CFR 2638.202.

**§ 2703.1 Cross-reference to employee ethical conduct standards and financial disclosure regulations.**

Members and employees of the Federal Mine Safety and Review Commission are subject to the executive branch-wide Standards of Ethical Conduct at 5 CFR part 2635; the Commission's regulations at 5 CFR part 8401, which supplement the executive branch-wide standards; and the executive branch-wide financial disclosure regulations at 5 CFR part 2634.

**§ 2703.2 Designated Agency Ethics Official and Alternate Designated Agency Ethics Official.**

The Chairman shall appoint an individual to serve as the designated agency ethics official, and an individual to serve in an acting capacity in the absence of the primary designated agency ethics official (alternate designated agency ethics official), to coordinate and manage the Commission's ethics program.

**§ 2703.3 Conflict of interest exemption.**

The financial interests hereinafter described are, to the extent indicated, exempted from application of the financial conflict of interest prohibition at 18 U.S.C. 208(a) because they have been determined to be too remote or inconsequential to affect the integrity of a Commission employee's services in

any matter in which he may act in an official capacity:

Ownership of shares of stock, bonds, other corporate securities, or shares in a mutual fund or regulated fund or regulated investment company, so long as the current aggregate fair market value of such holdings in a single enterprise does not exceed \$5,000.

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**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 117**

[CGD08-96-025]

RIN 2115-AE47

**Drawbridge Operation Regulations; Red River, LA**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** This rule removes the regulation for the Kansas City Southern Railroad Bridge across the Red River, mile 88.0 at Alexandria, Rapides Parish, Louisiana because the swing span bridge has been removed.

**EFFECTIVE DATE:** This regulation is effective on July 31, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mr. Phil Johnson, Bridge Administration Branch, (504) 589-2965.

**SUPPLEMENTARY INFORMATION:**

**Background and Purpose**

The Kansas City Railroad Bridge was removed from service and demolished on May 3, 1996. Since there is no longer a drawbridge at this location, there is no longer a need for the drawbridge operation regulation.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making the regulation effective less than 30 days after Federal Register publication. Publishing a notice of proposed rulemaking and delaying the effective date are impracticable and unnecessary because the swing span of the bridge is no longer in existence.

**Regulatory Evaluation**

This rule is not a significant regulatory action under Executive Order 12866 and is not significant under the DOT Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that