

Rules and Regulations

Federal Register

Vol. 72, No. 116

Monday, June 18, 2007

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

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

DEPARTMENT OF THE INTERIOR

Office of the Secretary

2 CFR Part 1400

43 CFR Parts 12, 42, and 43

RIN 1090-AA96

Department of the Interior Implementation of OMB Guidance on Nonprocurement Debarment and Suspension

AGENCY: Office of the Secretary, Interior.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of the Interior (Department) proposes to remove its regulations implementing the government-wide common rule on nonprocurement debarment and suspension, and to adopt in their place the Office of Management and Budget's (OMB) guidance. This regulatory action would implement OMB's initiative to streamline and consolidate all federal regulations on nonprocurement debarment and suspension into one part of the CFR. The Department does not intend to modify any of its current policy.

DATES: This interim rule is effective July 18, 2007. Submit comments on this interim rule by August 17, 2007.

ADDRESSES: You may submit comments on the rulemaking by any of the following methods listed below. Please use the Regulation Identifier Number (RIN) 1090-AA96 in your message:

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

- E-mail: Melodee_Stith@ios.doi.gov. Please submit Internet comments as an ASCII file and avoid the use of special characters and any form of encryption. Also, please include "Attn: RIN 1090-

AA96" and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, call the contact person listed below.

- Regular U.S. Mail: E. Melodee Stith, U.S. Department of the Interior, Office of Acquisition and Property Management, 1849 C Street, NW., Mail Stop 2607-MIB, Washington, DC 20240.

- Overnight mail, courier, or hand-delivery: E. Melodee Stith, U.S. Department of the Interior, Office of Acquisition and Property Management, 1849 C Street, NW., Mail Stop 2607-MIB, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Melodee Stith at (202) 208-5830 or by e-mail at Melodee_Stith@ios.doi.gov.

SUPPLEMENTARY INFORMATION:

Background

On August 31, 2005, the Office of Management and Budget (OMB) issued an interim final guidance that implemented its Guidance for Governmentwide Debarment and Suspension (Nonprocurement), codified in Part 180 of Title 2 of the Code of Federal Regulations (70 FR 51862, August 31, 2005). In addition to restating and updating its guidance on nonprocurement debarment and suspension, the interim final guidance requires all Federal agencies to adopt a new approach to Federal agency implementation of the guidance. OMB requires each agency to issue a brief rule that: (1) Adopts the guidance, giving it regulatory effect for that agency's activities; and (2) states any agency-specific additions, clarifications, and exceptions to the government-wide policies and procedures contained in the guidance. That guidance also requires agencies to implement the OMB guidance by February 28, 2007.

Pursuant to the requirements in OMB's interim final guidance, the Department of the Interior (Department) proposes to: (1) Remove 43 CFR Part 42; (2) replace the Department's part containing the full text of the debarment and suspension common rule with a brief part implementing OMB's guidance and any provisions specific to the Department; (3) co-locate the Department's part with OMB's guidance in 2 CFR along with other agencies' regulations in that title; and (4) revise references in 43 CFR Part 12 with the citation to the Department's regulations

located in Title 2, CFR Subtitle B section 1400.

This interim final regulatory action would implement the OMB's initiative to streamline and consolidate all Federal regulations on nonprocurement debarment and suspension into one part of the CFR, and does not make any change to current policy and procedures. Under 5 U.S.C. 553(b)(3)(A) agencies are not required to undergo notice and comment procedure for "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice."

Invitation to Comment

We intend the new part in 2 CFR to adopt the OMB guidelines with the same additions and clarifications made to the common rule on nonprocurement debarment and suspension in the **Federal Register** publication of November 26, 2003 (68 FR 66628).

Administrative Procedure Act

The Department has determined that the public notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. 553(b), do not apply because of the good cause exception under 5 U.S.C. 553(b)(3)(B), which allows the agency to suspend the notice and public procedure when the agency finds for good cause that those requirements are impractical, unnecessary, and contrary to the public interest. This action would merely remove the Department's current policy and provisions related to the debarment and suspension common rule and replace it with a brief part adopting OMB's guidance and implementing any provisions specific to the Department. In addition, it would co-locate the Department's regulations with OMB's guidance in 2 CFR along with other agencies' rules in that title. These revisions are purely administrative in nature and do not modify the Department's current policy.

Executive Order 12866

This proposed regulatory action has been determined to be not significant for purposes of E.O. 12866.

Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b))

This rule, if adopted, would not have a significant economic impact on a substantial number of small entities. This action would merely remove the

Department's current policy and provisions related to the debarment and suspension common rule and replace it with a brief part adopting OMB's guidance and implementing any provisions specific to the Department. In addition, it would co-locate the Department's regulations with OMB's guidance in 2 CFR along with other agencies' rules in that title. These revisions are purely administrative in nature and do not modify the Department's current policy. Because these changes are not substantive, we believe that this action would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This action adopts the common rule established by OMB regarding persons who have been debarred or suspended. This rule:

- a. Does not have an annual effect on the economy of \$100 million or more.
- b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Takings (E.O. 12630)

Under the criteria in Executive Order 12630, this rule does not have significant takings implications. A takings implication assessment is not required.

Unfunded Mandates Act of 1995 (Sec. 202, Pub. L. 104-4)

This regulatory action does not contain a Federal mandate that will result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector of \$100 million or more in any one year.

Paperwork Reduction Act of 1995 (44 U.S.C., Chapter 35)

This regulatory action will not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the Paperwork Reduction Act unless that

collection displays a currently valid OMB Control Number.

Federalism (Executive Order 13132)

This regulatory action does not have Federalism implications, as set forth in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in Executive Order 13175, we have evaluated this rule and determined that it has no potential effects on federally recognized Indian tribes. This rule makes non-substantive changes to the Department's nonprocurement debarment and suspension procedures.

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required.

Data Quality Act

In developing this rule we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106-554).

List of Subjects

2 CFR Subtitle B, Part 1400

Administrative practice and procedure, Debarment and suspension, Grant programs, Reporting and recordkeeping requirements.

43 CFR Part 12

Administrative practice and procedure, Administrative and audit requirements and cost principles for assistance programs.

43 CFR Part 42

Administrative practice and procedure, Governmentwide Debarment and Suspension (nonprocurement).

43 CFR Part 43

Administrative practice and procedure, Governmentwide Requirements for Drug-Free Workplace (Financial Assistance).

Dated: May 11, 2007.

James E. Cason,

Associate Deputy Secretary.

■ Accordingly, under the authority of 5 U.S.C. 301, the Department of the Interior makes the following amendments to the Code of Federal Regulations, Title 2, Subtitle B, Part 1400 and Title 43 CFR Parts 12, 42, and 43:

TITLE 2—GRANTS AND AGREEMENTS

■ 1. Add Chapter 14, consisting of Part 1400, to Subtitle B to read as follows:

CHAPTER 14—DEPARTMENT OF THE INTERIOR

PART 1400—NONPROCUREMENT DEBARMENT AND SUSPENSION

Sec.

1400.10 What does this part do?

1400.20 When does this part apply to me?

1400.30 What policies and procedures must I follow?

Subpart A—General

1400.137 Who in the Department of the Interior may grant an exception to let an excluded person participate in a covered transaction?

Subpart B—Covered Transactions

1400.215 Which nonprocurement transactions, in addition to those listed in 2 CFR 180.215, are not covered transactions?

1400.220 What contracts and subcontracts, in addition to those listed in 2 CFR 180.220, are covered transactions?

Subpart C—Responsibilities of Participants Regarding Transactions

1400.332 What methods must I use to pass requirements down to participants at lower tiers with whom I intend to do business?

Subpart D—Responsibilities of Federal Agency Officials Regarding Transactions

1400.437 What method do I use to communicate to a participant the requirements described in the OMB guidance at 2 CFR 180.435?

Subpart E—H—[Reserved]

Subpart I—Definitions

1400.930 Debarring official (Department of the Interior supplement to the definition at 2 CFR 180.930).

- 1400.970 Nonprocurement transaction (Department of the Interior supplement to the definition at 2 CFR 180.930).
- 1400.1010 Suspending official (Department of the Interior supplement to the definition at 2 CFR 180.930).

Authority: E.O. 12549 (3 CFR, 1986 Comp., p. 189); E.O. 12689 (3 CFR, 1989 Comp., p. 235); sec. 2455 Pub. L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note); 5 U.S.C. 301.

§ 1400.10 What does this part do?

This part adopts the Office of Management and Budget (OMB) guidance in subparts A through I of 2 CFR part 180, as supplemented by this part, as the Department of the Interior policies and procedures for nonprocurement debarment and suspension. It thereby gives regulatory effect to the OMB guidance as supplemented by this part. This part satisfies the requirements in section 3 of Executive Order 12549, "Debarment and Suspension" (3 CFR 1986 Comp., p. 189), Executive Order 12689, "Debarment and Suspension" (3 CFR 1989 Comp., p. 235) and 31 U.S.C. 6101 note (Section 2455, Pub. L. 103-355, 108 Stat. 3327).

§ 1400.20 When does this part apply to me?

This part and, through this part, pertinent portions of the OMB guidance in subparts A through I of 2 CFR part 180 (see table at 2 CFR 180.100(b)) apply to you if you are—

(a) Participant or principal in a "covered transaction" (see subpart B of 2 CFR part 180 and the definition of "nonprocurement transaction" at 2 CFR 180.970, as supplemented by subpart B and § 1400.970);

(b) Respondent in a Department of the Interior suspension or debarment action;

(c) Department of the Interior debarment or suspension official, i.e., the Director, Office of Acquisition and Property Management; or

(d) Department of the Interior grants officer, agreements officer, or other official authorized to enter into any type of nonprocurement transaction that is a covered transaction.

§ 1400.30 What policies and procedures must I follow?

(a) The Department of the Interior policies and procedures that you must follow are specified in:

(1) Each applicable section of the OMB guidance in subparts A through I of 2 CFR part 180; and

(2) The supplement to each section of the OMB guidance that is found in this part under the same section number. (The contracts that are covered transactions, for example, are specified by section 220 of the OMB guidance

(i.e., 2 CFR 180.220) as supplemented by section 220 in this part (i.e., Sec. 1400.220)).

(b) For any section of OMB guidance in subparts A through I of 2 CFR part 180 that has no corresponding section in this part, Department of the Interior policies and procedures are those in the OMB guidance.

Subpart A—General

§ 1400.137 Who in the Department of the Interior may grant an exception to let an excluded person participate in a covered transaction?

Within the Department of the Interior, the Director, Office of Acquisition and Property Management has the authority to grant an exception to let an excluded person participate in a covered transaction, as provided in the OMB guidance at 2 CFR 180.135.

Subpart B—Covered Transactions

§ 1400.215 Which nonprocurement transactions, in addition to those listed in 2 CFR 180.215, are not covered transactions?

(a) Transactions entered into pursuant to Public Law 93-638, 88 Stat. 2203.

(b) Under natural resource management programs, permits, licenses, exchanges, and other acquisitions of real property, rights-of-way, and easements.

(c) Transactions concerning mineral patent claims entered into pursuant to 30 U.S.C. 22 *et seq.*; and

(d) Water service contracts and repayments entered into pursuant to 43 U.S.C. 485.

§ 1400.220 What contracts and subcontracts, in addition to those listed in 2 CFR 180.220, are covered transactions?

Although the OMB guidance at 2 CFR 180.220(c) allows a Federal agency to do so (also see optional lower tier coverage in the figure in the appendix to 2 CFR part 180), the Department of the Interior does not extend coverage of nonprocurement suspension and debarment requirements beyond first-tier procurement contracts under a covered nonprocurement transaction.

Subpart C—Responsibilities of Participants Regarding Transactions

§ 1400.332 What methods must I use to pass requirements down to participants at lower tiers with whom I intend to do business?

You as a participant must include a term or condition in lower-tier transactions requiring lower-tier participants to comply with subpart C of the OMB guidance in 2 CFR part 180.

Subpart D—Responsibilities of Federal Agency Officials Regarding Transactions

§ 1400.437 What method do I use to communicate to a participant the requirements described in the OMB guidance at 2 CFR 180.435?

To communicate to a participant the requirements described in 2 CFR 180.435 of the OMB guidance, you must include a term or condition in the transaction that requires the participant's compliance with subpart C of 2 CFR part 180, as supplemented by subpart C of this part, and requires the participant to include a similar term or condition in lower-tier covered transactions.

Subpart E—H—[Reserved]

Subpart I—Definitions

§ 1400.930 Debarring official (Department of the Interior supplement to the definition at 2 CFR 180.930).

The Debarring Official for the Department of the Interior is the Director, Office of Acquisition and Property Management.

§ 1400.970 Nonprocurement transaction (Department of the Interior supplement to the definition at 2 CFR 180.970).

In addition to those listed in 2 CFR 180.970, the Department of the Interior includes the following as nonprocurement transactions:

(a) Federal acquisition of a leasehold interest or any other interest in real property;

(b) Concession contracts;

(c) Disposition of Federal real and personal property and natural resources; and

(d) Any other nonprocurement transactions between the Department and a person.

§ 1400.1010 Suspending official (Department of the Interior supplement to the definition at 2 CFR 180.930).

The Suspending Official for the Department of the Interior is the Director, Office of Acquisition and Property Management.

Subpart J—[Reserved]

TITLE 43, PUBLIC LANDS: INTERIOR

PART 12—ADMINISTRATIVE AND AUDIT REQUIREMENTS AND COST PRINCIPLES FOR ASSISTANCE PROGRAMS

■ 2. The authority citation for part 12 continues to read as follows:

Authority: E.O. 12549 (3 CFR, 1986 Comp., p. 189); E.O. 12689 (3 CFR, 1989 Comp., p.

235); Sec. 2455, Pub. L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note); 5 U.S.C. 301; U.S.C. 6101 note.

§ 12.75 [Removed]

- 3. Remove § 12.75.

§ 12.913 [Removed]

- 4. Remove § 12.913.

PART 42—GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT) [REMOVED]

- 5. Remove part 42.

PART 43—GOVERNMENTWIDE REQUIREMENTS FOR DRUG-FREE WORKPLACE (FINANCIAL ASSISTANCE)

- 6. The authority for part 43 continues to read as follows:

Authority: E.O. 12549 (3 CFR, 1986 Comp., p. 189); E.O. 12689 (3 CFR, 1989 Comp., p. 235); Sec. 2455, Pub. L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note); 5 U.S.C. 301; 31 U.S.C.

§ 43.510 [Amended]

- 7. Amend § 43.510(c) by removing the citation “43 CFR Part 42” and adding “2 CFR Part 180” in its place.

§ 43.630 [Amended]

- 8. Amend § 43.630 by removing the phrase “the common rule, Government-wide Debarment and Suspension (Nonprocurement), that implements Executive Order 12549 and Executive Order 12689” and adding the citation “2 CFR part 180” in its place.

§ 43.670 [Amended]

- 9. Amend § 43.670 by removing the phrase “the common rule, Government-wide Debarment and Suspension (Nonprocurement), that implements Executive Order 12549 and Executive Order 12689” and adding the citation “2 CFR part 180” in its place.

[FR Doc. 07-2949 Filed 6-15-07; 8:45 am]

BILLING CODE 4310-RF-M

NUCLEAR REGULATORY COMMISSION

10 CFR Chapter I

RIN 3150-A118

Administrative Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its

regulations to update a telephone number for the Office of Information Services and an NRC Web site location. This document is necessary to inform the public of these changes to the NRC's regulations.

EFFECTIVE DATE: June 18, 2007.

FOR FURTHER INFORMATION CONTACT:

Thomas Smith, Office of Information Services, Nuclear Regulatory Commission, Washington, DC 20555-0001, 301-415-7043, e-mail TES@nrc.gov.

SUPPLEMENTARY INFORMATION: The NRC is revising its regulations to update a telephone number for the Office of Information Services and an NRC Web site location. The Web site contains detailed guidance on making electronic submissions to the agency. This guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1) and (2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

A regulatory analysis has not been prepared for this final rule. This final rule makes only minor administrative changes to the regulations that reference a telephone number and an NRC Web site, and imposes no burden on licensees. Therefore, a regulatory analysis is not necessary.

Backfit Analysis

The NRC has determined that these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1); therefore a backfit analysis is not necessary.

Congressional Review Act

In accordance with the Congressional Review Act, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Because these amendments deal solely with agency organization and procedure, and represent minor administrative matters which do not raise any significant policy or regulatory issue, the NRC has determined that notice and comment is not necessary under the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(A), and that in any event there is good cause for dispensing with such notice and comment under 5 U.S.C. 553(d)(3)(B). In addition, the NRC has determined that good cause exists for making the rule immediately effective upon publication, as provided for under 5 U.S.C. 553(d)(3), because the amendments represent minor administrative matters which do not raise any significant policy or regulatory issue and do not impose any significant regulatory requirement upon any regulated entity or person.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, 42 U.S.C. 2201, as amended, and 42 U.S.C. 5841, the NRC is adopting the following amendments to 10 CFR Chapter I to read as follows:

10 CFR Chapter I [Amended]

- 1. In Chapter I revise all references to “(301) 415-6030” to read “(301) 415-0439”.
- 2. In Chapter I revise all references to “<http://www.nrc.gov/site-help/eie.html>” to read “<http://www.nrc.gov/site-help/e-submittals.html>”.

Dated at Rockville, Maryland, this 4th day of June, 2007.

For the Nuclear Regulatory Commission.

Luis A. Reyes,

Executive Director for Operations.

[FR Doc. E7-11708 Filed 6-15-07; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lincomycin

AGENCY: Food and Drug Administration, HHS.