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## OFFICE OF GOVERNMENT ETHICS

### 5 CFR Part 2638

RIN 3209-AA07

#### Executive Agency Ethics Training Programs; Amendments

AGENCY: Office of Government Ethics (OGE).

ACTION: Final rule; amendments.

**SUMMARY:** The Office of Government Ethics is issuing a final rule amending subpart G of 5 CFR part 2638 on Executive Agency Ethics Training Programs, which was published as a final rule last April. The Office of Government Ethics could not then include references in the training regulation to other rules that were not issued as final or interim at that time. The publication of the Standards of Ethical Conduct for Employees of the Executive Branch as a final rule and of the interim rule on Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture since then allows OGE to include references to these regulations within subpart G of this part. Moreover, in order to allow agencies sufficient time to complete the initial ethics orientation with the new standards, OGE is also extending the deadline for completion of the initial ethics orientation until February 3, 1993.

**EFFECTIVE DATE:** December 10, 1992.

**FOR FURTHER INFORMATION CONTACT:** Stuart C. Gilman or John C. Condray, Office of Government Ethics, telephone (202/FTS) 523-5757, FAX (202/FTS) 523-6325.

**SUPPLEMENTARY INFORMATION:** In accordance with section 301 of Executive Order 12674 of April 12, 1989, as amended by Executive Order 12731 of October 17, 1990, and consistent with its authority under the Ethics in Government Act, as amended,

the Office of Government Ethics published the training regulation, subpart G of 5 CFR part 2638, as a final rule on April 7, 1992 (57 FR 11886-11891, as corrected at 57 FR 15219 (April 27, 1992)). As stated in the preamble to the final rule, procedures of the Office of the Federal Register prevent a final regulation from cross-referencing other regulations until the other regulations have also been published as final or interim rules. Although OGE would have liked to have cross-referenced both the new standards and the financial disclosure regulations in this training regulation when it was published last April, the decision was made to publish this regulation before the standards were finalized in order to allow executive branch agencies as much time as possible to plan their training programs. The April final rule preamble to this subpart G regulation indicated that, once the standards and the financial disclosure regulations were published in final or interim form, OGE would amend this regulation to cross-reference those regulations. As it turned out, in fact, OGE ended up separately publishing the financial disclosure regulation (57 FR 11800-11830) on April 7, 1992, the same day the training regulation was published. The financial disclosure regulation was subsequently corrected at 57 FR 21854-21855 (May 22, 1992). In addition, on August 7, 1992, OGE published the final Standards of Ethical Conduct for Employees of the Executive Branch (57 FR 35006-35067, as corrected at 57 FR 48557 (October 27, 1992) and 57 FR 52583 (November 4, 1992)). The Office of Government Ethics is therefore amending subpart G so that it cross-references both these regulations. As explained last April, because of the central importance of the new standards issued under Executive Order 12674, as amended, to employees' understanding of their ethical obligations, § 2638.703(a) of the training regulation is being revised to specifically include the standards, together with any supplemental regulation thereto of the concerned agency, among the items that must be provided as part of the initial ethics orientation. Section 2638.704(c) is also being revised; it will now include the standards (and any agency supplement regulation) as part of the minimum content of an agency's annual ethics training for covered employees.

As stated in the April final rule preamble to this subpart G, the minimum content requirement does not require rote repetition each year of familiar material; inclusion of the standards is meant to be the starting point for annual training, not its sum total. A cross-reference to the financial disclosure regulation (and any agency supplement) is also being added to the definition of employees who are covered by the annual agency ethics training requirement, at § 2638.704(b)(4).

When OGE published subpart G of part 2638 last April, the deadline for agencies to complete the initial ethics orientation was January 2, 1993. At that time, it was expected that the standards would be published within the next three months, and that the January 2, 1993 timetable would give agencies six months to complete the orientation from the time of the publication of the standards as a final rule. The Office of Government Ethics indicated at that time that OGE would amend this requirement, contained in § 2638.703(a), if the publication date of the standards were delayed. Because the standards were published on August 7, four months after the April publication of the training regulation, OGE is extending the deadline for completion of the initial ethics orientation to February 3, 1993. This date will give agencies 180 days from the publication of the standards to complete the initial ethics orientation for current employees; it will also coincide with the effective date of the new executive branch standards.

#### Administrative Procedure Act

Pursuant to 5 U.S.C. 553 (b) and (d), as Director of the Office of Government Ethics, I find that good cause exists for waiving the general notice of proposed rulemaking and 30-day delay in effectiveness as to these revisions. The notice and delayed effective date are being waived because these amendments to the training regulation concern matters of agency organization, practice and procedure and because it is important to the working of executive branch agency ethics training programs that these revisions to the regulation go into effect as soon as possible. Further, these amendments reflect the changes OGE indicated it would make as previously announced when the final

rule was published in the Federal Register last April.

**Executive Order 12291**

As Director of the Office of Government Ethics, I have determined that this is not a major rule as defined under section 1(b) of Executive Order 12291, Federal Regulation.

**Regulatory Flexibility Act**

As Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this regulation will not have a significant economic impact on a substantial number of small entities because it will affect only Federal executive branch agencies and employees.

**Paperwork Reduction Act**

The Paperwork Reduction Act (5 U.S.C. chapter 35) does not apply to this regulation because it does not contain information collection requirements that require the approval of the Office of Management and Budget.

**List of Subjects in 5 CFR Part 2638**

Administrative practice and procedure, Conflict of interests, Government employees, Reporting and recordkeeping requirements.

Approved, November 18, 1992.

**Stephen D. Potts,**

*Director, Office of Government Ethics.*

Accordingly, for the reasons set forth in the preamble, the Office of Government Ethics is amending part 2638 of subchapter B of chapter XVI of title 5 of the Code of Federal Regulations as follows.

**PART 2638—[AMENDED]**

1. The authority citation for 5 CFR part 2638 continues to read as follows:

**Authority:** 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.

**SUBPART G—EXECUTIVE AGENCY ETHICS TRAINING PROGRAM**

2. Section 2638.703 is amended by revising paragraphs (a) and (b) to read as follows:

**§ 2638.703 Initial agency ethics orientation.**

(a) Each agency employee shall, on or before February 3, 1993, be provided:

(1) A copy of part I of Executive Order 12674, Principles of Ethical Conduct for Government Officers and Employees, dated April 12, 1989, as amended

Executive Order 12731, 3 CFR, 1990 Comp., p. 306;

(2) A copy of part 2635 of this chapter, Standards of Ethical Conduct for Employees of the Executive Branch, and any supplemental regulation of the concerned agency;

(3) The names, titles, office addresses, and telephone numbers of the designated agency ethics official and other agency ethics officials available to answer questions regarding the employee's ethical responsibilities; and

(4) A minimum of one hour of official duty time for the purpose of permitting the employee to review the written materials furnished pursuant to this section. If the agency provides an ethics training course during official duty time, including annual ethics training provided under § 2638.704, or a nominee or other new entrant receives ethics training provided by the Office of Government Ethics or the White House Office, the period of official duty time set aside for individual review may be reduced by the time spent in training.

(b) Each new agency employee who enters on duty after May 7, 1992, shall, within 90 days of the date of his or her entrance on duty, or on or before February 3, 1993, whichever is later, be provided with the materials and time specified in paragraph (a) of this section.

\* \* \* \* \*

3. Section 2638 704 is amended by revising paragraphs (b)(4) and (c)(1) to read as follows:

**§ 2638.704 Annual agency ethics training.**

\* \* \* \* \*

(b) \* \* \*

(4) Employees required to file confidential (nonpublic) financial disclosure reports under subpart I of part 2634 of this chapter and any supplemental regulation or addendum of the concerned agency;

\* \* \* \* \*

(c) \* \* \*

(1) A review of the employees' responsibilities under part I of Executive Order 12674, as amended, and the Standards of Ethical Conduct for Employees of the Executive Branch, part 2635 of this chapter, together with any agency's supplemental regulation. This review shall include examples that relate specifically to agency programs and operations and any ethics-related, agency-specific statute or regulatory restrictions of the particular agency; and

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 16, 807, 814, 860, 861, and 895**

[Docket No. 92N-0007]

**Medical Devices; Procedures for Premarket Notification, Premarket Approval, Classification, Performance Standards Establishment, Banning Devices, and Availability of Regulatory Hearings**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the medical device regulations governing procedures for premarket notification, premarket approval, classification, performance standards development, banning devices, and availability of regulatory hearings to conform these procedures to applicable provisions of the Safe Medical Devices Act of 1990 (the SMDA).

Its publication promotes clarity and certainty to regulated industry and thus fosters economic growth by correcting the provisions in FDA's existing regulations to conform them to the now-governing statutory provisions.

**EFFECTIVE DATE:** January 11, 1993.

**ADDRESSES:** Submit written comments and information to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 12720 Twinbrook Pkwy., Rockville, MD 20857, 301-443-4874.

**SUPPLEMENTARY INFORMATION:**

**I. General**

The SMDA (Pub. L. 101-629) prescribes changes to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301-394), as amended, that improve the regulation of medical devices and strengthen the Medical Device Amendments of 1976 which established a comprehensive framework for the regulation of medical devices. This rule implements certain amendments by the SMDA to sections 510, 513, 514, 515, and 516 of the act (21 U.S.C. 360, 360c, 360d, 360e, and 360f) by amending FDA's existing regulations under these sections. These