

section (c)(3) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

(3) with respect to such year, the number of times the disclosures required under subsection (c)(3) occurred under subparagraph (B) of such subsection; and

(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

**(f) Periodic review of guidance**

Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.

(June 25, 1938, ch. 675, §712, as added Pub. L. 110-85, title VII, §701(a), Sept. 27, 2007, 121 Stat. 900.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (a)(1), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

The Ethics in Government Act of 1978, referred to in subsecs. (b)(2) and (c)(3), is Pub. L. 95-521, Oct. 26, 1978, 92 Stat. 1824. For complete classification of this Act to the Code, see Short Title note set out under section 101 of Pub. L. 95-521 in the Appendix to Title 5, Government Organization and Employees, and Tables.

The Privacy Act of 1974, referred to in subsec. (c)(3)(A), is Pub. L. 93-579, Dec. 31, 1974, 88 Stat. 1896, which enacted section 552a of Title 5, Government Organization and Employees, and provisions set out as notes under section 552a of Title 5. For complete classification of this Act to the Code, see Short Title of 1974 Amendment note set out under section 552a of Title 5 and Tables.

PRIOR PROVISIONS

A prior section 712 of act June 25, 1938, was renumbered section 711 by Pub. L. 102-571 and is classified to section 379d of this title.

EFFECTIVE DATE

Section effective Oct. 1, 2007, see section 701(c) of Pub. L. 110-85, set out as an Effective Date of 2007 Amendment note under section 355 of this title.

**§ 379d-2. Policy on the review and clearance of scientific articles published by FDA employees**

**(a) Definition**

In this section, the term “article” means a paper, poster, abstract, book, book chapter, or other published writing.

**(b) Policies**

The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

**(c) Timing of submission for review**

If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is directed by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

**(d) Timing for review and clearance**

The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

**(e) Non-timely review**

If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

**(f) Effect**

Nothing in this section shall be construed as affecting any restrictions on such publication or presentation provided by other provisions of law.

(June 25, 1938, ch. 675, §713, as added Pub. L. 110-85, title XI, §1101, Sept. 27, 2007, 121 Stat. 971.)

PART B—COLORS

**§ 379e. Listing and certification of color additives for foods, drugs, devices, and cosmetics**

**(a) Unsafe color additives**

A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 342(c), 351(a)(4), or 361(e) of this title, as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) of this section, for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in