

which related to recovery and retention of fees for freedom of information requests, was renumbered section 731 of act June 25, 1938, by Pub. L. 102-571, title I, §106(6), Oct. 29, 1992, 106 Stat. 4499, and transferred to section 379f of this title.

§ 379d. Automation of Food and Drug Administration

(a) In general

The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this chapter.

(b) Authorization of appropriations

There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, §711, formerly §712, as added Pub. L. 101-635, title IV, §401, Nov. 28, 1990, 104 Stat. 4585; renumbered §711, Pub. L. 102-571, title I, §106(3), Oct. 29, 1992, 106 Stat. 4498.)

PRIOR PROVISIONS

A prior section 711 of act June 25, 1938, was renumbered section 731 by Pub. L. 102-571 and is classified to section 379f of this title.

§ 379d-1. Conflicts of interest

(a) Definitions

For purposes of this section:

(1) Advisory committee

The term “advisory committee” means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

(2) Financial interest

The term “financial interest” means a financial interest under section 208(a) of title 18.

(b) Appointments to advisory committees

(1) Recruitment

(A) In general

The Secretary shall—

(i) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

(ii) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities; and

(iii) take into account the advisory committees with the greatest number of vacancies.

(B) Recruitment activities

The recruitment activities under subparagraph (A) may include—

(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

(ii) making widely available, including by using existing electronic communica-

tions channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

(iii) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

(2) Evaluation and criteria

When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, a written certification as referred to in section 208(b)(3) of title 18, or a waiver as referred to in subsection (c)(2) of this section for service on the committee at a meeting of the committee.

(c) Disclosures; prohibitions on participation; waivers

(1) Disclosure of financial interest

Prior to a meeting of an advisory committee regarding a “particular matter” (as that term is used in section 208 of title 18), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

(2) Prohibitions and waivers on participation

(A) In general

Except as provided under subparagraph (B), a member of an advisory committee may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

(B) Waiver

If the Secretary determines it necessary to afford the advisory committee essential expertise, the Secretary may grant a waiver of the prohibition in subparagraph (A) to permit a member described in such subparagraph to—

(i) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

(ii) participate as a voting member with respect to a particular matter considered in a committee meeting.