

§ 5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration.

(a) *Applicability.* This section does not apply to special Government employees.

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

(1) *Confidential filer* means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.

(2) *Prohibited financial interest* means a financial interest prohibited by § 5501.104(a), including those financial interests that are excepted under § 5501.104(b) of this chapter.

(3) *Public filer* means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.

(4) *Remainder of HHS* has the meaning set forth in § 5501.102(b)(2) of this chapter.

(5) *Separate agency component* has the meaning set forth in § 5501.102(a) of this chapter.

(c) *Report of prohibited financial interests*—(1) *New entrant employees.* A new entrant employee shall report in writing within 30 days after entering on duty with the FDA any prohibited financial interest and the value thereof held upon commencement of employment with the agency.

(2) *Reassigned employees.* An employee of a separate agency component other than the FDA or of the remainder of HHS who is reassigned to a position at the FDA shall report in writing within 30 days of entering on duty with the FDA any prohibited financial interest and the value thereof held on the effective date of the reassignment to the agency.

(3) *Incumbent employees.* An incumbent employee of the FDA who acquires any prohibited financial interest shall report such interest and the value thereof in writing within 30 days after acquiring the financial interest.

[70 FR 5564, Feb. 3, 2005, as amended at 70 FR 51573, Aug. 31, 2005; 70 FR 61713, Oct. 26, 2005]

§ 5502.107 Supplemental disclosure of financial interests in substantially affected organizations applicable to employees of the National Institutes of Health.

(a) *Applicability.* This section does not apply to special Government employees.

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

(1) *Clinical investigator* means an employee identified as a principal investigator, accountable investigator, lead associate investigator, medical advisory investigator, associate investigator, or other subinvestigator in an NIH clinical study involving human subjects under a clinical research protocol approved by an institutional review board.

(2) *Clinical research* has the meaning set forth in 42 U.S.C. 284d(b).

(3) *Institutional review board (IRB)* means any board, committee, or other group formally designated by an institution to review a clinical research protocol and approve the initiation of biomedical research involving human subjects and to assess periodically the progress of the investigation to protect the rights and welfare of the trial participants.

(4) *Confidential filer* means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.

(5) *Public filer* means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.

(6) *Remainder of HHS* has the meaning set forth in § 5501.102(b)(2) of this chapter.

(7) *Separate agency component* has the meaning set forth in § 5501.102(a) of this chapter.

(8) *Substantially affected organization* has the meaning set forth in § 5501.109(b)(10) of this chapter.

(c) *Report of financial interests in substantially affected organizations*—(1) *New entrant employees.* A new entrant employee who is a public filer or a confidential filer or who is designated to

serve as a clinical investigator shall report in writing within 30 days after entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held upon commencement of employment with the agency.

(2) *Reassigned employees.* An employee of a separate agency component, other than the NIH, or of the remainder of HHS who is either a public filer, a confidential filer, or a clinical investigator who is reassigned to a position at the NIH shall report in writing within 30 days of entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held on the effective date of the reassignment to the agency.

(3) *Incumbent employees.* An incumbent employee of the NIH who is either a public filer, a confidential filer, or a clinical investigator who acquires any financial interest in a substantially affected organization shall report such

interest and the value thereof in writing within 30 days after acquiring the financial interest. Any incumbent employee, irrespective of financial disclosure filing status, who is designated a clinical investigator shall report in writing within 30 days of the approval of the clinical research protocol by the relevant institutional review board any financial interest in a substantially affected organization and the value thereof held on the date of the IRB approval.

(4) *Initial report by on duty employees.* An employee on duty at the NIH on August 31, 2005, who is either a public filer, a confidential filer, or a clinical investigator shall report in writing on or before October 31, 2005, any financial interest in a substantially affected organization and the value thereof held on the date the report is filed.

[70 FR 51573, Aug. 31, 2005, as amended at 70 FR 61713, Oct. 26, 2005]