

the matter in the office of the Dockets Management Branch. The Dockets Management Branch shall maintain a separate chronological index of all advisory opinions filed. The index will specify the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

(h) Action undertaken or completed in conformity with an advisory opinion which has subsequently been amended or revoked is acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. Whenever possible, an amended or revoked advisory opinion will state when action previously undertaken or completed does not remain acceptable, and any transition period that may be applicable.

(i) An interested person may submit written comments on an advisory opinion or modified advisory opinion. Four copies of any comments are to be sent to the Dockets Management Branch for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Comments will be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or §10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994]

**§10.90 Food and Drug Administration regulations, guidelines, recommendations, and agreements.**

(a) *Regulations.* FDA regulations are promulgated in the FEDERAL REGISTER under §10.40 or §10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidelines and recommendations, or both. The dissemination of draft notices and regulations is subject to §10.80.

(b) *Guidelines.* FDA guidelines are included in the public file of guidelines established by the Dockets Management Branch, under this paragraph, unless they have been published as regulations under paragraph (a) of this section.

(1) Guidelines establish principles or practices of general applicability and do not include decisions or advice on particular situations. Guidelines relate to performance characteristics, pre-clinical and clinical test procedures, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. Guidelines state procedures or standards of general applicability that are not legal requirements but are acceptable to FDA for a subject matter which falls within the laws administered by the Commissioner.

(i) A person may rely upon a guideline with assurance that it is acceptable to FDA, or may follow different procedures or standards. When different procedures or standards are chosen, a person may, but is not required to, discuss the matter in advance with FDA to prevent the expenditure of money and effort on activity that may later be determined to be unacceptable.

(ii) Use of testing guidelines established by FDA assures acceptance of a test as scientifically valid, if properly conducted, but does not assure approval of any ingredient or product so tested. Test results or other available information may require disapproval or additional testing.

(2) A guideline represents the formal position of FDA on a matter and, except as provided in paragraph (b)(3) of this section, obligates the agency to

follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with a guideline issued under this section that has not been amended or revoked.

(3) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to a guideline before amending or revoking the guideline as provided in paragraph (b)(5) of this section. This action may be taken only with the approval of the Commissioner, who may not delegate that function. Amendment or revocation of the guideline involved will be expedited.

(4) A guideline will be included in the public file upon approval of the guideline by the Commissioner or relevant center director and publication of a notice of its availability. The notice will state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline.

(5) A guideline may be amended or revoked by the Commissioner or relevant center director and publication of a notice of the amendment or revocation. The notice will state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline. All original guidelines and subsequent amendments will be retained in the public file permanently so that a complete record of the development of each guideline is available.

(6) Action undertaken or completed in conformity with a guideline which has subsequently been amended or revoked will remain acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. This determination may be made at the time of or after amendment or revocation of the guideline. Whenever possible, notice of an amended or revoked guideline will state when it has been determined that action previously undertaken or completed in conformity with a prior guideline does not remain acceptable, and any transition period that may be applicable.

(7) The notice of a guideline or of an amended or revoked guideline will state that an interested person may submit written comments on the guideline. Four copies of comments are to be sent to the Dockets Management Branch for inclusion in the public file on the guideline. The comments will be considered in determining whether further amendments to or reinstatement of a guideline are warranted.

(8) A guideline may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(9) A statement relating to acceptable procedures or standards given by an FDA employee orally, or in writing but not under § 10.85 of this section, is an informal communication that represents the best judgment of that employee at that time but does not constitute a guideline, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate the agency to the views expressed.

(10) Because of the large number of analytical methods involved in FDA activities, their length and complexity and the volume and frequency of amendment, paragraph (b)(4) of this section does not apply to analytical methods except to the extent that the Commissioner concludes that particular analytical methods should be included in the public file for a particular purpose. FDA analytical methods are available for public disclosure under part 20.

(11) The dissemination of draft guidelines is subject to the same provisions as the dissemination of draft notices and regulations under § 10.80.

(c) *Recommendations.* In addition to the guidelines subject to paragraph (b) of this section, FDA often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C. 243 and 263d(b). These recommendations may, in the discretion of the Commissioner,

be handled under the procedures established in paragraph (b) of this section, except that the recommendations will be included in a separate public file of recommendations established by the Dockets Management Branch and will be separated from the guidelines in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations under paragraph (a) of this section.

(d) *Agreements.* Formal agreements, memoranda of understanding, or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Freedom of Information Staff (HFI-35) under §20.108. A document not included in the public file is deemed to be rescinded and has no force or effect whatever.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

**§10.95 Participation in outside standard-setting activities.**

(a) *General.* This section applies to participation by FDA employees in standard-setting activities outside the agency. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal Government agencies.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Freedom of Information Staff.

(3) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitations will be extended to a representative sampling of the public, including consumer groups,

industry associations, professional societies, and academic institutions.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI-35).

(3) The availability for public disclosure of records relating to the activity will be governed by part 20.

(4) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitation will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(d) *Standard-setting activities by private groups and organizations.* (1) An FDA employee may engage in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide. A request for official participation must be made by the group or organization in writing, must describe the scope of the activity, and must demonstrate that the minimum standards set out in paragraph (d)(5) of this section are met. Except as provided in paragraph (d)(7) of this section, a request that is granted will be the subject of a letter from the Commissioner or the center director to the organization stating—