

Food and Drug Administration, HHS

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setting activity is in the public interest and will promote the objectives of the act and the agency, the participation is exempt from the requirements of paragraph (d)(1) (ii) and/or (iii) of this section. This determination will be included in the public file on standard-setting activities established by the Freedom of Information Staff and in any relevant administrative file. The activity may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between FDA and the associations of State and local government officials listed below in this paragraph, and the large number of agency employees who are members of or work with these associations, participation in the activities of these associations is exempt from paragraphs (d)(1) through (7) of this section, except that a list of the committees and other groups of these associations will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI-35):

- (i) American Association of Food Hygiene Veterinarians (AAFHV).
- (ii) American Public Health Association (APHA).
- (iii) Association of American Feed Control Officials, Inc. (AAFCO).
- (iv) Association of Food and Drug Officials (AFDO).
- (v) Association of Official Analytical Chemists (AOAC).
- (vi) Association of State and Territorial Health Officials (ASTHO).
- (vii) Conference for Food Protection (CFP).
- (viii) Conference of State Health and Environmental Managers (COSHEM).
- (ix) Conference of Radiation Control Program Directors (CRCPD).
- (x) International Association of Milk, Food, and Environmental Sanitation, Inc. (IAMFES).
- (xi) Interstate Shellfish Sanitation Conference (ISSC).
- (xii) National Association of Boards of Pharmacy (NABP).

(xiii) National Association of Departments of Agriculture (NADA).

(xiv) National Conference on Interstate Milk Shipments (NCIMS).

(xv) National Conference of Local Environmental Health Administrators (NCLEHA).

(xvi) National Conference on Weights and Measures (NCWW).

(xvii) National Environmental Health Association (NEHA).

(xviii) National Society of Professional Sanitarians (NSPS).

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 52 FR 35064, Sept. 17, 1987; 54 FR 9035, Mar. 3, 1989]

§ 10.100 Public calendar.

(a) *Public calendar.* A public calendar will be prepared and made publicly available by FDA each week showing, to the extent feasible, significant events of the previous week, including significant meetings with persons outside the executive branch, that involve the representatives of FDA designated under paragraph (c) of this section.

(1) Public calendar entries will include:

(i) Significant meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision;

(ii) Significant meetings, conferences, seminars, and speeches; and

(iii) Social events sponsored by the regulated industry.

(2) The public calendar will not include reports of meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment at FDA), meetings with members of the press, or meetings with onsite contractors.

(b) *Calendar entries.* The calendar will specify for each entry the date, person(s), and subject matter involved. If a large number of persons are in attendance, the name of each individual need not be specified. When more than one FDA representative is in attendance, the most senior agency official will report the meeting on the public calendar.

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(c) *Affected persons.* The following FDA representatives are subject to the requirements of this section:

- (1) Commissioner of Food and Drugs.
- (2) Senior Associate Commissioners.
- (3) Deputy Commissioners.
- (4) Associate Commissioner for Regulatory Affairs.
- (5) Center Directors.
- (6) Chief Counsel for the Food and Drug Administration.

(d) *Public display.* The public calendar will be placed on public display at the following locations:

- (1) Division of Dockets Management.
- (2) Office of the Associate Commissioner for Public Affairs.
- (3) The FDA home page, to the extent feasible.

[66 FR 6468, Jan. 22, 2001]

§ 10.105 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in an administrative proceeding subject to this part.

(b) A petition, comment, objection, or other representation by an organization will not abridge the right of a member to take individual action of a similar type, in the member's own name.

(c) It is requested that each organization participating in FDA administrative proceedings file annually with the Division of Dockets Management a current list of all of the members of the organization.

(d) The filing by an organization of an objection or request for hearing under §§ 12.20 through 12.22 does not provide a member a legal right with respect to the objection or request for hearing that the member may individually exercise. A member of an organization wishing to file an objection or request for hearing must do so individually.

(e) In a court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name. Regardless of whether the case is brought or consid-

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ered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and a member of the organization that the issues are precluded from further litigation by the member under the doctrines of collateral estoppel or res judicata.

§ 10.110 Settlement proposals.

At any time in the course of a proceeding subject to this part, a person may propose settlement of the issues involved. A participant in a proceeding will have an opportunity to consider a proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, will not be admissible in evidence in an FDA administrative proceeding. FDA will oppose the admission in evidence of settlement information in a court proceeding or in another administrative proceeding.

§ 10.115 Good guidance practices.

(a) *What are good guidance practices?* Good guidance practices (GGP's) are FDA's policies and procedures for developing, issuing, and using guidance documents.

(b) *What is a guidance document?*

(1) Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.

(2) Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.

(3) Guidance documents do not include: Documents relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms.