

§ 10.100

21 CFR Ch. I (4–1–01 Edition)

§ 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.

(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) Dockets Management Branch.

(2) Office of the Associate Commissioner for Public Affairs.

(3) The FDA home page, to the extent feasible.

[66 FR 6468, Jan. 22, 2001]

EFFECTIVE DATE NOTE: At 66 FR 12849, Mar. 1, 2001, § 10.100 was stayed from Jan. 22, 2001, to Apr. 22, 2001.

§ 10.100a Public calendars.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar will be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks, the public meetings, conferences, hearings, advisory committee meetings, seminars, and other public proceedings of FDA, and other significant public events involving FDA, e.g., congressional hearings.

(2) A copy of this public calendar will be placed on public display in the following places:

(i) Dockets Management Branch.

(ii) Office of the Associate Commissioner for Public Affairs.

(iii) A central place in each center.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

(b) *Retrospective public calendar of meetings.* (1) A public calendar will be prepared and made publicly available each week showing for the previous week meetings with persons outside the executive branch and other significant events involving the representatives of FDA designated under paragraph (b)(3) of this section, but telephone conversations will be included on an optional basis and meetings with the working press, except for “house organs” (i.e., publications of firms that manufacture or distribute regulated products, or industry associations), and with on-site contractors will not be included. Meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees will be included when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision and involves more than a brief description of the matter.

(2) The calendar will include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar will specify the date and the person and

subject matter involved. When more than one FDA representative is in attendance, only the presiding or head representative will report the meeting on the public calendar. If a large number of persons is involved, the name of each need not be specified. 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 in FDA) will not be reported.

(3) The following FDA representatives and their deputies are subject to the requirements of paragraphs (b)(1) and (2) of this section:

- (i) Commissioner of Food and Drugs.
- (ii) Deputy Commissioner.
- (iii) Associate Commissioners.
- (iv) Executive and Special Assistants to the Commissioner.
- (v) [Reserved]
- (vi) Director, National Center for Toxicological Research.
- (vii) Center Directors.
- (viii) Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel.

(4) A copy of the public calendar will be placed on public display in the following places:

- (i) Dockets Management Branch.
- (ii) Office of the Associate Commissioner for Public Affairs.
- (iii) A central place in each center.
- (iv) A central place in each field office.
- (v) A central place at the National Center for Toxicological Research.

[66 FR 12849, Mar. 1, 2001]

EFFECTIVE DATE NOTE: At 66 FR 12849, Mar. 1, 2001, §10.100a was added, effective Jan. 22, 2001, to Apr. 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 Dockets Management Branch 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 considered 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.