§ 14.22 Meetings of an advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or alternate. No meeting may be held in the absence of the designated Federal employee.

Food and Drug Administration, HHS

the meeting. The time for oral presentations and the extent to which the committee meets in open session other than for such oral presentations is in the discretion of the committee.

(2) Minutes of open sessions are to be maintained, with all written submissions attached which were made to the committee in open session. After approval, the minutes are to be forwarded to the Division of Dockets Management and placed on public display. The extent to which the committee maintains minutes of closed sessions is in the discretion of the committee.

(3) In selecting the members of the committee, the organization involved is to apply the principles relating to conflicts of interest that FDA uses in establishing a public advisory committee. Those principles are set out or cross-referenced in this part and in part 19. Upon request, FDA will assist or provide guidance to any organization in meeting this requirement.

Subpart B—Meeting Procedures

§ 14.20 Notice of hearing before an advisory committee.

(a) Before the first of each month, and at least 15 days in advance of a meeting, the Commissioner will publish a notice in the Federal Register of all advisory committee meetings to be held during the month. Any advisory committee meetings for that month called after the publication of the general monthly notice are to be announced in the Federal Register on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to these notice requirements in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice will be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the Federal Register.

(b) The Federal Register notice will include—

(1) The name of the committee;
(2) The date, time, and place of the meeting;
(3) The general function of the committee;
(4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting;
(5) If any portion of the meeting is closed, a statement of the time of the open and closed portions;
(6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting;
(7) The time set aside for oral statements and other public participation;
(8) The name, address, and telephone number of the advisory committee Designated Federal Officer and any other agency employee designated as responsible for the administrative support for the advisory committee;
(9) A statement that written submissions may be made to the advisory committee through the Designated Federal Officer at any time, unless a cutoff date has been established under §14.35(d)(2);
(10) When a notice is published in the Federal Register less than 15 days before a meeting, an explanation for the lateness of the notice; and

(c) If a public hearing before an advisory committee is used in lieu of a formal evidentiary public hearing under §14.1(a)(3), an initial notice of hearing is to be published separately in the Federal Register containing all the information described in §12.32(e). This procedure may be used for any other hearing before an advisory committee when the Commissioner concludes, as a matter of discretion, that it would be informative to the public.

(d) A list of advisory committee meetings will be distributed to the press by the Associate Commissioner for Public Affairs.