

EXHIBIT 1

PART 12—FORMAL  
EVIDENTIARY PUBLIC  
HEARING

12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

12.22 Filing objections and requests for a hearing on a regulation or order.

12.23 Notice of filing of objections.

12.24 Ruling on objections and requests for hearing.

12.26 Modification or revocation of regulation or order.

12.28 Denial of hearing in whole or in part.

12.30 Judicial review after waiver of hearing on a regulation.

12.32 Request for alternative form of hearing.

12.35 Notice of hearing; stay of action.

12.38 Effective date of an order.

12.40 Appearance.

PART 16—REGULATORY  
HEARING BEFORE THE FDA

16.22 Initiation of regulatory hearing.

16.24 Regulatory hearing required by the act or a regulation.

16.26 Denial of hearing and summary decision.

PART 13—PUBLIC HEARING  
BEFORE A PUBLIC BOARD OF  
INQUIRY

13.5 Notice of a hearing before a Board.

PART 15—PUBLIC HEARING  
BEFORE THE  
COMMISSIONER

15.20 Notice of a public hearing before the Commissioner.

12.45 Notice of participation.

12.50 Advice on public participation in hearings.

12.60 Presiding officer.

12.62 Commencement of functions.

12.70 Authority of presiding officer.

12.75 Disqualification of presiding officer.

12.78 Unavailability of presiding officer.

12.80 Filing and service of submissions.

12.83 Advisory opinions.

12.85 Disclosure of data and information by the participants.

12.87 Purpose; oral and written testimony; burden of proof.

12.89 Participation of nonparties.

12.90 Conduct at oral hearings or conferences.

12.91 Time and place of prehearing conference.

12.92 Prehearing conference procedure.

16.40 Commissioner.

16.42 Presiding officer.

16.44 Communication to presiding officer and Commissioner.

16.60 Hearing procedure.

16.62 Right to counsel.

13.10 Members of a Board.

13.15 Separation of functions; ex parte communications; administrative support.

13.20 Submissions to a Board.

13.25 Disclosure of data and information by the participants.

13.30 Proceedings of a Board.

15.21 Notice of participation; schedule for hearing.

15.25 Written submissions.

15.30 Conduct of a public hearing before the Commissioner.

12.93 Summary decisions.

12.94 Receipt of evidence.

12.95 Official notice.

12.96 Briefs and argument.

12.97 Interlocutory appeal from ruling of presiding officer.

12.98 Official transcript.

12.99 Motions.

12.100 Administrative record of a hearing.

12.105 Examination of record.

12.120 Initial decision.

12.125 Appeal from or review of initial decision.

12.130 Decision by Commissioner on appeal or review of initial decision.

12.139 Reconsideration and stay of action.

12.140 Review by the courts.

12.159 Copies of petitions for judicial review.

16.80 Administrative record of a regulatory hearing.

16.85 Examination of administrative record.

16.95 Administrative decision and record for decision.

16.119 Reconsideration and stay of action.

16.120 Judicial review.

13.40 Administrative record of a Board.

13.45 Examination of administrative record.

13.50 Record for administrative decision.

15.40 Administrative record.

15.45 Examination of administrative record.