

§ 17.15 Parties to the hearing.

(a) The parties to the hearing shall be the respondent and the Center(s) with jurisdiction over the matter at issue. No other person may participate.

(b) The parties may at any time prior to a final decision by the entity deciding any appeal agree to a settlement of all or a part of the matter. The settlement agreement shall be filed in the docket and shall constitute complete or partial resolution of the administrative case as so designated by the settlement agreement. The settlement document shall be effective upon filing in the docket and need not be ratified by the presiding officer or the Commissioner of Food and Drugs.

(c) The parties may be represented by counsel, who may be present at the hearing.

§ 17.17 Summary decisions.

(a) At any time after the filing of a complaint, a party may move, with or without supporting affidavits (which, for purposes of this part, shall include declarations under penalty of perjury), for a summary decision on any issue in the hearing. The other party may, within 30 days after service of the motion, which may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision.

The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law.

(c) Affidavits shall set forth only such facts as would be admissible in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated. When a motion for summary decision is made and supported as provided in this regulation, a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts

showing that there is a genuine issue of material fact for the hearing.

(d) If, on motion under this section, a summary decision is not rendered on all issues or for all the relief asked, and if additional facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings on facts still at issue. The facts specified not to be at issue shall be deemed established.

(e) Except as provided in § 17.18, a party may not obtain interlocutory review by the entity deciding the appeal (currently the DAB) of a partial summary decision of the presiding officer. A review of final summary decisions on all issues may be had through the procedure set forth in § 17.47.

§ 17.18 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section, rulings of the presiding officer may not be appealed before consideration on appeal of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the entity deciding the appeal (currently the DAB) if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made, a participant may file a brief on the appeal only if specifically authorized by the presiding officer or the entity deciding the appeal (currently the DAB), and if such authorization is granted, only within the period allowed by the presiding officer or the entity deciding the appeal. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period allowed by the entity deciding the appeal (currently the DAB). The deadline for filing an interlocutory appeal is subject to the discretion of the presiding officer.

§ 17.19 Authority of the presiding officer.

(a) The presiding officer shall conduct a fair and impartial hearing, avoid