§ 14.172  Utilization of an advisory committee at the request of an interested person.

Any interested person may request, under §10.30, that a specific matter relating to a particular human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. The request must demonstrate the importance of the matter and the reasons why it should be submitted for a hearing at that time. The Commissioner may grant or deny the request.

§ 14.174 Advice and recommendations in writing.

Advice and recommendations given by a committee on a specific drug or a class of drugs are ordinarily in the form of a written report. The report may consist of the approved minutes of the meeting or a separate written report. The report responds to the specific issues or questions which the Commissioner has addressed to the advisory committee, and states the basis of the advice and recommendations of the committee.