

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 12055

TITLE 22

HEALTH CARE SERVICES
MEDICAL ASSISTANCE PROGRAM

1300.10.15

(Register 74, No. 16—54-74)

(g) Substantial evidence that a drug product is "equivalent in quality" shall mean evidence consisting of adequate and well controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate equivalence. Provided, however, that when the Director has made every reasonable effort to secure such investigations, but has been unable to obtain them, he may rely upon a recommendation concerning comparative therapeutic effect made by the Medical Therapeutics and Drug Advisory Committee, as provided for in Welfare and Institutions Code Section 14180 et seq., and such recommendation shall be considered to be substantial evidence.

(h) The evidence which the Director intends to rely on at the public hearing for the establishment of the MAIC shall be available to any member of the interested public for copying and inspection at reasonable times and places and the notice of the hearing shall so state and announce. The hearing officer shall grant a continuance of no more than thirty (30) days for further hearing upon request of any interested party for the purpose of rebuttal of any such evidence which was not made so available at least thirty (30) days prior to the hearing.

(i) Proceedings before the Director for the establishment of MAICs shall be undertaken at public hearing and in accordance with the following procedures and all other procedures required by law:

(1) At least thirty (30) days prior notice shall be given to all interested parties of the time and place of the public hearing. Upon request, the Department shall furnish any interested party a copy of the proposed regulation and the name or names of the manufacturers of the drug products used to establish the MAICs.

(2) Oral evidence shall be taken only on oath or affirmation administered by the Director or his duly authorized representative.

(3) The director shall consider all relevant matter presented to him before establishing the MAIC, and his decision shall be based solely on that evidence.

(4) During the course of the public hearing, any interested party shall be given an opportunity to examine any witness and to present relevant evidence.

(5) The hearing need not be conducted according to technical rules relating to evidence and witnesses.

(6) Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule which might make improper the admission of such evidence over objection in civil actions. Irrelevant or unduly repetitious evidence may be excluded.

(7) If the hearing is presided over by a person other than the Director, such person shall be present during consideration of the establishment of the MAICs by the Director, and shall assist and advise the Director.

(8) Where good cause is shown the hearing officer may hold the hearing record open for a period of up to thirty (30) days in order to receive additional relevant evidence.