15250 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

KEMESCHED AND KAPEAN

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chemical structure and physical, blockcaical and pharmacological characteristics between amphatamine solute and amphetamine for exchange resin complexes, it is factually and scientifically incorrect, inappropriate, and misleading to classify amphetamical resin complexes as amphabatine sults or at any of the other substances included within the terms used in proposed Section 308.12(d)(1) of the regulations.

2. There is not sufficient reliable, probative, and substantial evaluation to support the processant of Bibbetasthe and Fallacarene-T in Senatale II.

a blanket assertion that emphetamines and methemphetamine and their salts, optical isomers and salts of their optical isomers, all meet the criteria for Schedule II control. Pennwalt decies the truth of this assertion as it may be sought to be applied to the preparations Biphetamine and Diphetamine-T. Pennwalt is prepared to rebut by adequate factual and scientific evidence and testimony that the Director may offer which might seek to establish that Biphetamine and Biphetamine-T are salts of amphetamine or, even if they are such salts, that they meet the Schedule II criteria (1) of having a "high potential for abuse" and (2) that their abuse may lead to severe psychological dependence. The Pennwalt rebuttal evidence includes scientific data which demonstrate that the abuse potential of amphetamine resin completes is substantially less than that of amphetamines, amphetamine solar.