

January 11, 1971

Dr. Marion Finkel
Food and Drug Administration
18733 Walker's Choice Rd.
Gaithersburg, Maryland 20760

Dear Dr. Finkel:

An announcement in the "Blue Sheet" that your office at the FDA is reviewing guidelines for new drug evaluation, and the knowledge that Dr. Dorothy Dobbs has left the FDA, prompts me to send to you, a letter sent to Dr. Dobbs on December 1.

"Some weeks ago I received an inquiry which raised my concern. Would I be willing to undertake an EEG study of an anti-obesity agent since the PMA guidelines for evaluating such agents includes the phrase: "Consideration may be given to a small EEG sleep study"? My question is whether the restrictive work "sleep" should be included.

At present, quantitative EEG studies of psychoactive drugs effects have a firm foundation in techniques of EEG analysis, in the classification of drugs, and in the identification of new psychoactive drugs. The literature is most reliable for studies in alert subjects, and it is in such populations that discriminations have been best made. Other data exists for sleep, evoked response and contingent negative variation measures. The literature of the latter twomeasures is sparse.

For sleep, there is much data of a descriptive kind and of generally limited value, since samples are small and studies are few. The principal students, Oswald, Itil and Kales, are not agreed as to drug specificity, or the relations of dose or duration.

In view of the possible value of EEG studies in clinical psychopharmacology, may I urge that any PMA-FDA guidelines which may recommend EEG studies, do so without a "sleep" or "alert" restriction? (Incidentally, such studies may also be useful in bioavailability studies of all psychoactive drug classes, and in classification of anti-psychotic, hallucinogen, stimulant, anti-anxiety and soporific drug doses.)"

Dr. M. Finkel

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I am enclosing a reprint that summarizes the data to 1968, and a more recent report. I would be grateful if you would accept these comments and reports for your deleberations, and I thank you for your consideration.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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