

*B. Navane*

1. NDA's need to be more adequately organized and the data better documented.
2. It was suggested that Dr. Mitchell Balter (NIMH) be invited to the next considering efficacy based on the material available to the committee members.
3. All medical officer's reviews should be standardized. A sample is to be presented to the Committee prior to the next meeting.

*C. Class labeling*

1. Committee members were not in total agreement that psychoactive drugs should not be used for stresses of everyday life in non-diagnosis patients. Data at this time, however, is not available. It was the opinion of some of the Committee members that advertising for a psychoactive drug should promote the drug only for symptomatic relief of anxiety in medically or psychiatrically diagnosed disorders. Mr. Jerome Levine (NIMH) is to investigate possibilities for implementing research in the area of psychotropic drugs used for the relief of symptoms produced by everyday stresses.

2. It was suggested that Dr. Mitchell Walter (NIMH) be invited to the next Committee meeting for discussions of his findings concerning the patterns of use of psychoactive drugs.

*D. Hydergine*

1. The Committee did not vote as to whether or not the submission would be considered acceptable since they had not reviewed the actual data.

2. It was suggested that definite benefits could be derived from appointing a Task Force which would consider the development of geriatric scales (standard) and in establishing criteria for the evaluation of studies in the geriatric population.

*E. Anorexic agents*

1. The length of time for testing such agents should be at least 12 weeks.

2. Criteria have been proposed by a previous committee with expertise in the use of such agents. If data show that such agents are effective in obesity, the Neuropharmacology Advisory Committee will become involved in discussions regarding possible abuse potential.

*F. Conflict of interest*

1. The Members of the Committee expressed a concern in this area since most, if not all, have been or are involved in consulting with or conducting trials for various drug firms. They wish to be appraised of the legal responsibilities and implications.

2. This topic is to be placed on the next Agenda and specific standards for procedure will be proposed.

*G. Review of "possibly effective" drugs*

The Committee was generally in favor of Dr. Finkel's discussion of the proposal that Committee members (or Junior Staff) be actively involved in the evaluation of such drugs.

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THE FDA REVIEW OF ANORECTIC DRUGS: BACKGROUND, CURRENT STATUS, AND PROBLEM AREAS

(Presented by Barrett Scoville, M.D., Deputy Director and Elmer A. Gardner, M.D., Director, Division of Neuropharmacological Drug Products, Food and Drug Administration, as part of the symposium: "Drugs and the Control of Overweight: Medical Considerations and Public Policy," June 12, 1972, Washington Hilton Hotel, Washington, D.C.)

The Food and Drug Administration is intensely interested in the discussions of this symposium and appreciates both the efforts that have gone into it and the opportunity to exchange ideas with other discussants. This is a time at which policy in respect to the use of anorectic drugs is being formulated, and we are seeking as much input as possible.

The title of the symposium summarizes the issue, which is one not just of a medical decision but one of public policy. It is a particularly difficult area, in which facts and value judgments are often unwittingly confused. Obesity, almost alone among the pathological conditions, remains a moral issue in many people's eyes, as Jean Mayer regretfully noted. It is regarded with the severity