

Following lunch Dr. Arthur Wentz discussed the Conference on Experimental Design which was held on August 24 and 25, at the FDA. The drug category considered was anti-convulsive drugs. Five workshops were held on the first day and each included representatives from industry, FDA and from the academic world. The purpose of the conference was to exchange ideas on the problems of good experimental designs.

Each workshop had been given a series of questions for their consideration and on the second day there was open discussion of the workshop findings. Dr. Wentz read some of the conclusions of the workshops and agreed to send the summary of the conference proceedings to the Board members.

Dr. Ley discussed the labeling of fatty foods. A few months ago the AMA Committee on Nutrition recommended; 1) In foods containing over 10% fat the manufacturer will be allowed to label the fat content by quantity. (example: 50% polyunsaturated fat) 2) This labeling would be voluntary. The FDA is having to review these recommendations carefully and revise its agency position. The Bureau of Medicine has recommended to the Commissioner that no medical claims be permitted on the labeling or in the advertising. The new proposal would however, enable the physician to identify foods with certain fat contents, for the guidance of his patients.

(Dr. Morrison returned to the meeting)

Dr. Ley described the recruiting program planned by FDA to replace the Public Health Service officers who will be leaving in July of '68 and of '69. He noted that Dr. Goddard is interested in developing an active training program here.

After a coffee break Dr. Ley commented on several problems facing the Bureau including the backlog of supplements, the labeling guidelines, the Modell criticisms, the creation of many new Bureau of Medicine Advisory Committees, and the continuous problem of how to communicate with the practicing physicians.

Dr. Kretchmer invited the Board to meet at Stanford in December and the dates of December 14 and 15 were chosen before the meeting adjourned.

I certify that I attended the twelfth meeting of the Food and Drug Administration Medical Advisory Board on August 31 and September 1, 1967 and that these minutes accurately reflect what transpired.

JEAN D. LOCKHART, M.D.,
Executive Secretary.

MARCH 26, 1968.

Director, Bureau of Medicine

Acting Director, Division of Medical Advertising/OMS

Labeling for Dicloxacillin products

Bristol Labs, Syracuse, N.Y. (AF 15-068) "Dynapen," NDA 50-028

Wyeth Labs, Philadelphia, Pa. (AF 13-548), "Pathocil," NDA 50-011 NDA 50-092

Ayerst Labs, New York, N.Y. (AF 19-003), "Veracillin," NDA 50-046

The proposed package inserts, as revised, for the subject products have been reviewed as requested. The major differences between the 3 labels appear to have been resolved. However, several differences still exist which may deserve consideration before final approval.

I. Dr. Minchew, in his addendum at the end of our memo of December 5, 1967, expressed concern over the open-ended dosage recommendations in the "Veracillin" labeling. In reviewing this, it became apparent that now *all three* package inserts have open ended dosage instructions. Also, the "Veracillin" dosage instructions, in addition to being open ended, recommend a dosage for both adults and children with severe infections twice that of the other two products, i.e. 500 mg v.s. 250 mg and 50 mg/Kg/day v.s. 25 mg/Kg/day respectively.

II. Wyeth's labeling for "Pathocil"

A. The disclaimer statement leading into the "Adverse Reactions" section has not been omitted. Not only is this type of language absent from the other two package inserts, but it is the type of statement which lends itself to misuse and abuse in promotional material, and in our opinion, has no rightful place in official labeling.

B. "Indications section—In reference to page 1:

1. Present paragraph 4 should be moved to follow present paragraph 1.
2. Present paragraph 3 should be moved to follow present paragraph 5 so that it will immediately precede the paragraph beginning "Indicated surgical procedures..."