

(b) The Company may not elaborate on results obtained in clinical trials without FDA approval unless such trials accurately relate to the language contained in the Indications Section of the OPC.

(c) As a corollary, the Company may elaborate on results obtained in clinical trials if such results accurately relate to the language contained in the Indications Section of the OPC.

We have also considered the possibility that the 3rd and 4th paragraphs of the Indications Section of the OPC were inadvertently omitted from the regulations.

Bristol Laboratories is currently in the process of preparing a request for the convening of an advisory scientific panel to determine the validity and scope of the reserve drug theory. This request will contain the reasons for convening the panel, suggested issues to be decided, the make-up of the panel, suggested ground rules to be followed and reasons why the previous panel did not decide the issue in dispute and other pertinent factors.

In view of the controversies and misunderstandings which have surrounded dicloxacillin and other semi-synthetic penicillins, an early and detailed response in connection with all these matters would be appreciated greatly if we are to be in a position properly to advise our clients with respect to the labeling and advertising for its semi-synthetic penicillins.

Very truly yours,

CORCORAN, FOLEY, YOUNGMAN & ROWE.

MEMORANDUM OF CONFERENCE

Bristol Laboratories, Syracuse, N.Y., AF 15-068.
Dynapen, NDA 50-028.

MAY 27, 1968.

Present (Bristol Laboratories): Mr. Morris S. Weeden, president; Mr. Robert B. Simonton, attorney; Hubert C. Peltier, M.D.; Messrs. Corcoran, Foley, Meers and Lane.

Present (Food and Drug Administration): Commissioner Goddard; H. L. Ley, Jr., M.D.; B. H. Minchew, M.D.; R. S. McCleery, M.D.; J. J. Jennings, M.D.; R. E. Kauffman, M.D.; K. H. Potts, M.D.; Mr. W. W. Goodrich; Mr. H. W. Chadduck.

Subject: Initial Dynapen promotion.

This meeting at 9:00 a.m. this date was requested by the Commissioner in his telephone conversation with Mr. Weeden late Friday, May 24, 1968. Parallel with this action, the Commissioner approved cancellation of certification of Dynapen, including all lots initially certified. Also, action was taken to embargo, at the wholesale level, all shipments of Dynapen. Meanwhile, the Secretary had been notified of the action taken and had been given a copy of the promotional letter in question as well as a copy of the complaint sheet.

Dr. Goddard opened the meeting and, using the DMA comments drafted on May 23, 1968, recounted the principal complaints against the "Dear Doctor" promotional letter headed "new high potency penicillin specific for skin and soft tissue infections." He said that the letter violated every principle discussed regarding the indications for use in the labeling of Dynapen and that was the reason why telegraphic action had been taken to cancel certification.

Mr. Weeden said Bristol had discussed the restricted use of Dynapen, and realizing the competition with penicillin-G decided to tell physicians about the site of infections rather than the cause (organism). Bristol selected skin and soft tissue, which, according to Weeden, were associated with "staph" infections. He went on to say that Bristol had not thought of expanding claims beyond the package insert allowances. On questioning, he and his associates said that the promotional letter had gone to the printer on May 15, was mailed out May 17 and that when the letter was written, Bristol did not have Dynapen available for marketing.

Commenting on the foregoing statement, Dr. Ley pointed out that the Dynapen labeling details had been known to Bristol on March 28. Dr. Goddard emphasized that even if Bristol hadn't been aware of the *Federal Register* monograph details, the promotional labeling was basically wrong due to its lack of fair balance, minimization of side effects, etc. He called attention to the Loridine current ad as a good example of advertising. He said it was hard to understand why Bristol's letter had been the way it was after he and his associates had met with