

(b) By designating on a regular prescription blank his desire that the drug dispensed be that approved by the Formulary Board. He could do this by a number of methodologies such as circling the drug, writing "Formulary" on the prescription blank or by any other means so indicated by the Board.

3. Additions to and deletions from the Formulary will be disseminated to all members of the associations represented by periodic mailings.

4. An up-to-date formulary reflecting all additions and deletions will be maintained and provided to all physicians, dentists and pharmacists.

PROTOCOL TO BE FOLLOWED BY DELAWARE FORMULARY IN CONSIDERING A PRODUCT FOR LISTING IN THE FORMULARY

1. All communication between the Board and applicants for listing will be coordinated and centralized through the Formulary Board secretary, or alternatively through the chairman.

2. Applications for listing of a product may be received either unsolicited, or may be solicited by the secretary at the request of the Formulary Board.

3. Upon receipt, applications will generally be reviewed for completeness by the secretary, and he may request any missing or incomplete information from the applicant.

4. In brief summary form, the secretary will proceed to notify the Board members on a weekly basis of applications received. (This will enable any Board member having pertinent information regarding the applicant or his product to bring such information to the attention of the secretary without undue delay.)

5. The secretary will assemble appropriate and sufficient background information regarding the applicant to enable a reasonable judgment to be made as to the qualifications, integrity, and reputation of the applicant. (The amount of information needed here will vary considerably depending upon the circumstances; applicants who have been previously considered or who enjoy well established reputations will require much less information than initial applicants or applicants whose reputations are less well known.)

Towards this end, the secretary may:

(a) review the weekly listings of "Drug Recalls" as released by the FDA, noting any past reference to the applicant or the drug product, and the reasons for any recall or recalls (to indicate nature and severity of any past problems);

(b) consult with the FDA local or District office in which the applicant is geographically located to ascertain applicant's general performance record and compliance with FDA's regulations for Good Manufacturing Practices;

(c) consult with the Defense Personnel Support Center of the Defense Supply Agency (in Philadelphia) to ascertain whether the applicant is on the list of approved bidders of the DPSC;

(d) consult with other government or private (e.g., hospitals) procurement groups or other qualified consultants having knowledge of the applicant or the drug product;

(e) request general—as well as any specific—background information from the applicant as to history of the firm, identification of its offices, nature of its corporate structure, etc.

6. The secretary will complete for review and evaluation by the Formulary Board all information which he assembles and which the applicant supplies.

7. Upon review the Formulary Board may decide to:

(a) approve the product for listing in the Formulary; or

(b) disapprove the product for listing in the Formulary; or

(c) recommend that further information or data be obtained, and defer action pending receipt and evaluation of such additional information. (Such information might include such things as a site visit to the applicant's plant, laboratory testing of the samples supplied, etc.)