FOOD AND DRUG ADMINISTRATION
BUREAU OF DRUGS

Attachment I

GUIDE | BD 4820.3

DRUG EVALUATION - DRUG APPLICATIONS

DRUG CLASSIFICATION

1. Purpose
2. Background
3. IND/NDA Classification System
4. Responsibilities and Procedures

1. PURPOSE. This Guide provides for the classification, by chemical type and therapeutic potential, of commercially sponsored IND's and NDA's.

2. BACKGROUND. The IND/NDA classification system which appears in this section was devised to provide a convenient way of describing drug applications upon initial receipt and throughout the review process.

Although the classification of any given new drug may change during the investigational phases (IND), once that new drug is the subject of an approvable NDA, its chemical and therapeutic classification will thereafter remain static.

This system also provides a basis for reporting the types of new drug products which are being approved or which are under review. The system will, in future years, permit searches of the files in retrospect to identify national trends in the new drug development and approval process. The classification system also identifies drugs which will be submitted to advisory committee review and "end of Phase II" conferences.

3. IND/NDA CLASSIFICATION SYSTEM.

a. Chemical Types:

Type 1 - New molecular entity - i.e., the active moiety is not yet marketed in the United States by any drug manufacturer either as single entity or as part of a combination product.

Type 2 - New salt - i.e., the active moiety is marketed in the United States by the same or another manufacturer but the particular salt, ester, or derivative is not yet marketed in the United States by any drug manufacturer either as a single entity or as part of a combination product.

Type 3 - New formulation - i.e., the compound is marketed in the United States by the same or another manufacturer, but the particular dosage form or formulation is not.

Type 4 - New combination - i.e., contains two or more compounds which have not previously been marketed together in a drug product by any manufacturer in the United States.

Type 5 - Already marketed drug product - i.e., the product duplicates a drug product (the same active moiety, same salt, same formulation, or same combination) already marketed in the United States by another firm.

Type 6 - Already marketed drug product by the same firm - used primarily for new indications for marketed drugs.

N.B. These types are not mutually exclusive, since a new formulation (Type 3) or a new combination (Type 4) may also contain a new molecular entity (Type 1) or a new salt (Type 2). In such cases, both numbers should be included in the overall classification number for the drug. For example, a new molecular entity representing an important therapeutic gain would be classified 1A; if the new entity were also in a new controlled-release formulation, it would be classified 13A. (Data processing forms shall reserve at least three blocks for these numbers).

b. Therapeutic Potential:

Type A - Important therapeutic gain - i.e., drug may provide effective therapy or diagnosis (by virtue of greatly increased effectiveness or safety) for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential).

Type B - Modest therapeutic gain - i.e., drug has a modest, but real, potential advantage over other available marketed drugs - e.g., greater patient convenience, elimination of an annoying but not dangerous adverse reaction, potential for large cost reduction, less frequent dosage schedule, useful in specific subpopulation of those with disease (e.g., those allergic to other available drugs), etc.

Type C - Little or no therapeutic gain - i.e., drug essentially duplicates in medical importance and therapeutic usage one or more already marketed drugs.

Type D - Special situation - i.e., drug has decreased safety or effectiveness compared with alternative marketed drugs, but also has some compensating virtue (e.g., [illegible] patients who do not respond to or are intolerant [illegible] other drugs.

Type E - DESI/OTC Claim - i.e., IND or NDA is intended to support a "less than effective" claim under DESI or OTC review.

N. B. These types are mutally exclusive. Only one of these letters may be included in the overall classification number. (Data processing forms shall reserve at least two blocks for these numbers).

c. Other Information:

Type M - Drug already marketed in a foreign country.

Type P - A very important feature of application is the packaging or container, not the drug itself.

Type R - Drug is subject to specific unique conditions of approval (e.g., additional studies) outlined in approvable or approval letter for NDA.

Type S - Application is sensitive by virtue of wide publicity, congressional interest, unusual request from firm, etc.

Type T - Important problem in toxicity - e.g., carcinogenic in animals.

Type U - Drug is likely to be used in children.

N. B. These types are not mutually exclusive. All appropriate letters shall be included in the overall classification number. (Data processing forms shall reserve at least eight blocks for these letters.)

4. RESPONSIBILITIES AND PROCEDURES.

a. Original IND's and NDA's. The Drug Group Leader is responsible for determining the classification of each original commercially sponsored application. The Division Director is responsible for approving the classification. The procedures for classification are:

(1) Upon receipt and processing of the original IND or NDA by the Division Document Comrol personnel, the original copy is forwarded to the appropriate Group Leader by Form FD 2773, "IND Assignment and Safety Review Transmittal" or Form FD 2617, "NDA Assignment and Review Transmittal."

(2) The Group Leader determines, after consulting with the supervisory chemist [illegible] that when necessary, [illegible] classification, obtains concurrence of the Division Director,

and completes the appropriate box on the transmittal form. (Reviewer assignments are made and posted at this time.)

(3) The transmittal form is then routed to the Division Document Control Room where the classification is entered on Form FD 2772, "IND/NDA History Record" in the box marked "Classification" and then into the Management Information System.

b. IND Amendments. The reviewing Medical Officer is responsible for recommending to the Group Leader changes in classification when justified on the basis of new information in amendments, the medical literature, advisory committee opinions, etc. The Group Leader approves or modifies the recommendation and the Division Director is responsible for approving the classification. The procedures for classification are:

(1) Upon receipt of an IND amendment, the Division Document Control personnel check the classification of the original IND or NDA on the "IND/NDA History Record" and post this classification on the Form FD 2774, "IND/NDA Subsequent Submissions Review Transmittal" (SSRT). The SSRT is attached to the amendment and forwarded to the appropriate reviewer(s).

(2) The reviewing Medical Officer checks the classification as part of his review and either positively reaffirms the classification or recommends a change. If the information in the IND amendment, or from any other source, indicates a change is necessary the reviewer recommends such to the Group Leader in his review.

(3) The Group Leader determines, after consulting with the supervisory chemist and pharmacologist when necessary, whether the classification will be changed. If a change is unnecessary, the Group Leader will so note in his review and no further action is taken. To change a classification the Group Leader obtains the concurrence of the Divison Director and then notifies the Document Control personnel of the change by Form FDH 2034, "Memo Record".

(4) The Division Document Control personnel enter the classification on the "IND/NDA History Record" in the box marked "Classification" if the submission is an IND amendment.

c. As part of the "Summary of Basis of Approval" submitted with an NDA approvable letter to the Bureau Director or Associate Director, the proposed final classification shall be included. This shall be subject to review by the Bureau Director, and once adopted may not be changed.