

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10641

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Monitoring Marketed Drugs

A second basic approach to assuring the quality of drugs is a monitoring program involving the sampling and analysis of marketed drugs to determine their adherence to compendial standards, as well as standards established in New Drug Applications (NDA).

Criteria used in selecting drugs for examination are:

- Therapeutic Significance - drugs prescribed for serious conditions or diseases.
- Complexity of Compounding - for instance, drug products in which the active ingredient of a potent drug makes up a small portion of the total weight of a solid dosage form.
- Product History - drugs for which quality failures have occurred, or which have a potential for degradation or decomposition.

The objectives of this program are to:

- Identify defective batches of drug products and remove them from the marketplace.
- Help determine the reasons for batch failures and assure that manufacturing procedures are corrected as necessary to eliminate the problems.