FDA DRUG COMPLIANCE INFORMATION LETTER

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
FOOD AND DRUG ADMINISTRATION
Bureau of Drugs
Office of Compliance

February 28, 1973

TO: Manufacturers, Repackers, and Relabelers of Drug Products

RE: Drug Surveillance Reports

The Food and Drug Administration, as part of its regulation of the American drug supply, routinely conducts drug quality surveys. FDA now intends to publish the results of its drug quality surveys, and to send copies to all manufacturers, repackers and relabelers of drug products. In this way, the industry will be advised concerning FDA's laboratory findings on batches of different classes of marketed drugs. This is in line with FDA's attempts to provide to the public and the regulated industries as much valuable information as it can within the scope of the Freedom of Information Law. It is hoped that information of this nature will lead to better compliance by regulated industries. Each report will include pertinent information such as scope of survey, sampling information, laboratory tests and summary of results.

The analytical methods used are either those specified by the United States Pharmacopeia (U.S.P.) and National Formulary (N.F.), or automated procedures developed by FDA or adapted from published methods and validated. Many of the methods may be found in the FDA's "Drug Autoanalysis Manual," available from the Division of Industry Liaison. Samples analyzed and found defective by non-official methods are check-analyzed by U.S.P., N.F., or other official methods such as those of the Association of Official Analytical Chemists (AOAC). Defective samples are followed up by FDA Field Offices so as to remove offending batch(es) from the market either by legal action, voluntary recall, or destruction, or cooperative action by State or local authorities.

Test results may or may not be indicative of the quality of other lots of the same product or other products produced by the listed manufacturer.

The first survey report is on central nervous system stimulants.

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