





abeling and puckaging injectables





Tablet compression machine making methadone. Computerized security control center,

Raw materials vault/alarm system.

The above photographs were taken at Eli Lilly and Company, Indianapolis, during a DEA Compliance visitation

Substances Act which took effect in May 1971, DEA has accomplished a number of important actions, not the least of which relates to drug scheduling action. These actions, of course, are not our exclusive mandate; in making our recommendations we work very closely with the Food and Drug Administration and the National Institute on Drug Abuse. Examples of these actions would be the moving of Phencyclidine (PCP) from Schedule III to Schedule II and the March 14, 1977 final order placing dextropropoxyphene (Darvon, et al.) under control in Schedule IV. Since May 1971, we have controlled 35 drugs, have moved eleven drugs to another schedule and have decontrolled six drugs. In addition, controls on several hundred commercial preparations which contain controlled substances have been lessened by classifying these products as exempted, excepted or excluded.

Simultaneous to rescheduling certain drugs we also establish production quotas for those substances. Quotas create smaller inventories and a less zealous marketing atmosphere which, when coupled with stringent security and regulatory safeguards on prescribing and dispensing the drugs, substantially reduce the potential for diversion. In setting quotas,

DEA again relies heavily upon the FDA to furnish with estimates of legitimate medical need.

For example, just prior to Schedule II control, in 1971, U.S. amphetamine production was approximately 66,000 pounds per year. The quota for 1977 is 7,700 pounds.

Despite this cutback --- drastic though it may seem --- no one with a legitimate need for these drugs has been deprived. As with amphetamines, substantial production decreases have also been effected on phenmetrazine (Preludin), methaqualone (Quaalude, et al.) and the three fast-acting barbiturates, amobarbital, secobarbital, and pentobarbi-

While success has been obtained in reducing diversion at the manufacturer/distributor level, success at the retail level (e.g., physicians, pharmacies) is much less dramatic. Under the Controlled Substances Act, the primary responsibility at this level is left with the States. DEA is required to register every professional who possesses a valid State license, unless he has a drug felony conviction or materially falsifies his registration application.

However, the number of retail registrants totals more than 50,000, and State police are