

15226. COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

KLEINFELDER AND KAPLAN

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The liquid injectable methamphetamines are classified as Schedule II controlled drugs. However, it is important to note that John Ingersoll, who is Director of DEED, in a letter addressed to Congressman Pepper, indicated that the Bureau will initiate procedures pursuant to Section 201 of the Act to transfer certain of the amphetamines from Schedule III to Schedule II classification. The effect that such a transfer would have on the manufacturing and distribution of the transferred amphetamines will be discussed later in this letter.

Except as otherwise provided in regulations promulgated by the Attorney General, every person who manufactures, distributes or dispenses any controlled substance (§302), or who imports into the United States any controlled substance, or exports from the United States any controlled substance in Schedules I, II, III, or IV (§1007), is required to obtain annually a registration issued by the Attorney General. A separate registration is required for each principal place of business. Unlike Section 510 of the FDCA, registration under the Act is not automatic, rather, Section 303 and Section 1003 set forth the requirements or criteria for the issuance or denial of a registration. Provisions are made for provisional registration pending registration or denial under the Act. Finally, a procedure, including the right to an administrative hearing and judicial review, is provided for the denial, revocation or suspension of registration (§304).

Registrants, with certain exceptions, are required by Section 307 to keep and make available for inspection the following records or reports: 1) On the effective date of Section 307 and every second year thereafter, a complete and accurate record of all stocks of controlled substances on hand, 2) a current, complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of by him. In addition, registered manufacturers are required, upon request of the Attorney General, to "make periodic reports to the Attorney General of every sale, delivery or other disposal" of any controlled substance and distributors are required to make such reports with respect to narcotic controlled substances.

The label and labeling of controlled substances must contain an identifying symbol in accordance with regulations of the Attorney General. The label of drugs listed in Schedules II, III or IV must bear warnings as to the consequences of illegal distribution which are prescribed by the Secretary of H&M pursuant to Section 503(b) of the FDCA. Also, controlled