Therefore, pursuant to foregoing findings, approval of the above new drug applications (except for those for which a request for hearing was received), and all amendments and supplements applying thereto is withdrawn effective on March 30, 1973. Shipment in interstate commerce of any combination drug product other than those few listed above that may continue to be marketed pending a ruling on the request for a hearing, or of any parenteral amphetamine product (e.g., amphetamine, dextroamphetamine, levamphetamine, or methamphetamine) is henceforth unlawful.

Dated: March 28, 1973

WILLIAM F. RANDOLF,
Acting Associate Commissioner
for Compliance.

[FR Doc. 73-6230 Filed 3-29-73; 8:45 am]

[From the Federal Register, vol. 38, No. 185, Sept. 25, 1973]

NOTICES

[DESI 5378; Docket No. FDC-D-582; NDA 11-522]

CERTAIN COMBINATION ANORECTIC DRUGS

FINAL ORDER ON OBJECTIONS AND REQUEST FOR A HEARING REGARDING WITHDRAWAL OF APPROVAL OF NEW DRUG APPLICATIONS

In the Federal Register of August 8, 1970 (35 FR 12652) the Commissioner of Food and Drugs published a statement of policy (21 CFR 130.46) concerning amphetamines for human use. The statement contained the findings of the Food and Drug Administration based upon reports received from the National Academy of Sciences-National Research Council (NAS-NRC) Drug Efficacy Study Group. Also published in the Federal Register of August 8, 1970 (35 FR 12678) was a notice (DESI 5378) on drugs containing amphetamines and their salts, stating that the drugs were regarded as possibly effective for their claimed anorectic effect and lacked substantial evidence of effectiveness for their other labeled indications. The statement of policy also contained the findings of the Commissioner that because of the extensive use of the drugs in the treatment of obesity, and their stimulant effect on the nervous system, they have a potential for misure and actual abuse, and production data indicated that amphetamines are produced and prescribed in quantities greatly in excess of demonstrated medical needs. As a condition for continued marketing of amphetamines, the statement of policy required relabeling as specified and the submission of a new drug application (NDA) within one year for all such drugs not then the subject of NDA approval. Holders of approved NDAs were required to submit additional evidence of safety and substantial evidence of efficacy in the form of adequate and well-controlled clinical investigations.

On February 12, 1973, the Commissioner published in the Federal Register (38 FR 4249) a final order stating that there was a lack of substantial evidence of effectiveness for, and a recognized potential for the abuse of, fixed combination drugs for anorectic use which contained, among other ingredients, amphetamine, methamphetamine, or dextroamphetamine. In addition, the Commissioner found that alternative therapeutic measures which are safe and effective are available for use. The Commissioner also stated in the final order that a mixture of dextroamphetamine and amphetamine is ordinarily regarded as a single drug entity. A similar conclusion as to a mixture of dextroamphetamine and methamphetamine, and/or amphetamine and methamphetamine, was not made. In § 3.86 (21 CFR 3.86) the Food and Drug Administration set forth a policy on fixed-combination drugs for prescription use requiring that each drug in a fixed-combination drug contribute to the claimed effect of the drug; section IV, infra. Therefore, drugs containing combinations of amphetamine and methamphetamine and/or dextroamphetamine and methamphetamine, are fixed combination drugs. The final order also stated that a proposal to withdraw approval of such combination drugs for anorectic use was published elsewhere in the same issue of the Federal Register.

In a notice in the Federal Register of February 12, 1973 (38 FR 4279), the Commissioner announced an opportunity for hearing on his proposal to withdraw approval of new drug applications for the combination amphetamine or other