proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Pemoline in Schedule IV

On August 19, 1974, the Assistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, sent the following letter to the Administrator of the Drug Enforcement Administration:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

AUGUST 19, 1974.

Mr. JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration
1405 I Street, NW.,
Washington, D.C. 20537

DEAR MR. BARTELS: The Food and Drug Administration expects to complete its evaluation of a New Drug Application for Cylert (pemoline, Abbott Laboratories) in the near future.

This letter is to request that Cylert be controlled in Schedule IV of the Controlled Substances Act (PL 91-513) concomitant with its New Drug Application approval.

Cylert is a central nervous system stimulant which will be indicated only for children with certain learning or behavioral disorders. It is not anticipated that proper therapeutic use will lead to problems of abuse of Cylert.

However, the pharmacological profile of pemoline, reports of its abuse, and its recent appearance in the illicit market indicate that the drug should be controlled in the interest of public health.

Control in Schedule IV is recommended pursuant to the following evaluation of Cylert;

1. Cylert has a low potential for abuse relative to the drugs or other substances in Schedule III. Its actual potential for abuse has not been determined in appropriately controlled clinical trials.

2. A New Drug Application for Cylert has been submitted to the FDA. Should this application be approved, Cylert would have a currently accepted medical use in the United States.

3. Abuse of Cylert may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

Attached is a summary of the information on which this report is based. Should members of your staff wish clarification or additional information, please feel free to contact the Food and Drug Administration.

Sincerely yours,

CHARLES C. EDWARDS, M.D.,
Assistant Secretary for Health.

Upon receipt of this letter, the Drug Enforcement Administration undertook a review of the following: (1) Materials submitted to DEA by the Department of Health, Education, and Welfare with the letter of August 19, 1974; (2) materials submitted to the Food and Drug Administration (FDA) in connection with the New Drug Application on this drug; (3) published scientific and medical literature from the United States and other nations regarding this drug; (4) selected investigatory files compiled for law enforcement purposes by the Drug Enforcement Administration; and (5) the legislative history of the Controlled Substances Act.

Based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and 201(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on information now available, pemoline has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

2. Pemoline will, upon the approval of New Drug Application by the FDA, have a currently accepted medical use in treatment in the United States.

3. Abuse of pemoline may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

Therefore, under the authority vested in the Attorney General by section 201 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator proposes that, upon approval of the New Drug Application for Cylert by FDA, § 1308.14 of Title 21 of the Code of Federal Regulations (CFR) be amended to read:

§ 1308.14 Schedule IV.

* * * * *

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

* * * * *

(3) Pemoline (including organometallic complexes and chelates thereof), 1530.

All interested persons are invited to submit their comments or objections in writing regarding this proposal. The comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration, Department of Justice, Room 1130, 1405 Eye Street NW., Washington, D.C. 20537, and must be received no later than December 9, 1974.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail that a hearing on these objections will be held as soon as the matter may be heard at the Drug Enforcement Administration, 1405 Eye Street, NW., Washington, D.C. 20537. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

If no objections presenting reasonable grounds for a hearing on the proposal are received within the time limitations, and all interested parties waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing and, after giving consideration to written comments, issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: November 1, 1974.

JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration.

[FR Doc.74-26073 Filed 11-6-74;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service (Agricultural Adjustment)

[7 CFR Part 725]

FLUE-CURED TOBACCO

Determinations on Marketing Quotas for the 1975-76 Marketing Year

Pursuant to the Agricultural Adjustment Act of 1938, as amended (7 U.S.C. 1281 et seq., hereinafter referred to as the "Act"), the Secretary is preparing to determine and announce the amount of the national marketing quota, the national average yield goal and the national acreage allotment for flue-cured tobacco for the 1975-76 marketing year.