proposed rules

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Mebutamate in Schedule IV

On September 12, 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, WASHINGTON, D.C. 20201

SEPTEMBER 12, 1974.

Mr. JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration,
1405 I St. NW.,
Washington, D.C. 20005.

DEAR MR. BARTELS: The Food and Drug Administration expects to complete its review of a New Drug Application (NDA) for mebutamate in the near future.

The scientific and medical aspects of the potential for abuse of mebutamate have been completed by the appropriate agencies within the Department of Health, Education, and Welfare.

Should the NDA for mebutamate be approved, we recommend that it be controlled in Schedule IV of the Controlled Substances Act (PL 91-513). The FDA will withhold final approval of mebutamate until such time as the Drug Enforcement Administration has evaluated this recommendation and has completed the administrative processing of the request.

The enclosed document delineates the basis for the Schedule IV control recommendation for mebutamate.

If there are questions regarding this matter, members of the FDA Drug Abuse Staff will provide assistance to your staff.

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 September 12, 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; and (4) 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, mebutamate has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

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

3. Abuse of mebutamate 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 Mebutamate by FDA, § 1308.14(b), of Title 21 of the Code of Federal Regulations (CFR) be revised to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(b) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1)	Barbital	2,145
(2)	Chloral betaine	2,460
(3)	Chloral hydrate	2,465
(4)	Ethchlorvynol	2,540
(5)	Ethinamate	2,545
(6)	Mebutamate	2,800
(7)	Meprobamate	2,820
(8)	Methohexital	2,264
(9)	Methylphenobarbital	2,250
(10)	Paraldehyde	2,585
(11)	Petrichloral	2,591
(12)	Phenobarbital	2,285

* * * * *

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, N.W., Washington, D.C. 20537, and must be received no later than January 13, 1975.

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, N.W., 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: December 9, 1974.

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

[FR Doc.74-29093 Filed 12-12-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

ACRYLONITRILE COPOLYMERS INTENDED FOR USE IN CONTACT WITH FOOD

Notice of Proposed Rule Making

Correction

In FR Doc. 74-25590 appearing at page 38907 in the Monday November 4, 1974 issue make the following changes:

1. On page 38908 the first word of the fifth line of the first complete paragraph in column two should read "permit."

2. On page 38909 the eighteenth line of § 121.4010(c) should read "a non-rodent mammal, and (5) tests to."