

Food and Drug Administration

21 CFR Part 876

[Docket Nos. 78N-1979, 78N-1981, and 78N-2062]

Medical Devices; Classification of Certain Gastroenterology-Urology Devices; Correction; Reopening of Comment Period and Meeting Announcement

Correction

In FR Doc. 81-10509 appearing at page 20687 in the issue for Tuesday, April 7, 1981, make the following correction:

On page 20688, in the second column, in the second full paragraph, in the eleventh line, "March 12" should have read "March 13".

BILLING CODE 1505-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Denial of Petition To Decontrol Mazindol; Rescheduling of Mazindol into Schedule IV

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Proposed rule and denial of petition.

SUMMARY: This is a denial of the petition, filed by Sandoz, Inc., to deschedule mazindol (Sanorex), Schedule III, from the list of substances covered by the Controlled Substances Act.

This denial is by the Administrator of the Drug Enforcement Administration, and, based upon receipt of a scientific and medical evaluation and recommendation from the Assistant Secretary for Health, Department of Health and Human Services, and in accordance of the Controlled Substances Act, the Administrator of the Drug Enforcement Administration has determined that mazindol should remain on the list of substances covered by the Controlled Substances Act, and therefore declines to initiate proceedings to deschedule it. The Secretary recommended that the Administrator remove mazindol from Schedule III of the CSA and place it into Schedule IV and the Administrator issues this notice of Proposed Rulemaking to initiate that action.

DATE: All interested persons may submit their comments on or before June 16, 1981.

ADDRESS: Comments should be submitted in quintuplicate to the

Administrator, Drug Enforcement Administration, Department of Justice, 1405 Eye Street, N.W., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: On November 18, 1975, Sandoz Inc. filed a petition with the Administrator of the Drug Enforcement Administration to initiate administrative proceedings to deschedule mazindol, from the list of substances covered by the Controlled Substances Act. By agreement, proceedings on the Sandoz Inc. petition were postponed pending completion of DEA's then ongoing review of mazindol and other anorectic drugs controlled in Schedule III and Schedule IV of the CSA. Sandoz Inc. supplemented its petition with additional correspondence to DEA dated April 7, 1978 which included an update of Drug Experience Reports through April 4, 1978. On May 25, 1978, following completion of DEA's general anorectic review and an analysis and review of the Sandoz Inc. petition, the Drug Enforcement Administration transmitted the petition and materials related to the issue of mazindol decontrol to the Food and Drug Administration, Department of Health and Human Services, for further analysis and review by the Secretary as to the medical and scientific aspects of the petition, and for subsequent receipt by the Administrator of the Secretary's scientific and medical evaluation and recommendation. On November 9, 1978, at DEA's request, a supplemental petition was filed by Sandoz Inc., and made a part of the record.

The Secretary's evaluation and recommendation were provided by the Assistant Secretary for Health in his letter dated January 16, 1981 to the Administrator; the January 16, 1981 letter is set forth here in its entirety:

January 16, 1981.

Mr. Peter B. Bensinger,
Administrator, Drug Enforcement Administration, 1405 "Eye" Street, N.W., Washington, D.C.

Dear Mr. Bensinger: In November 1978, Sandoz, Inc., petitioned the Drug Enforcement Administration to deschedule mazindol (Sanorex), Schedule III, from the list of substances covered by the Controlled Substances Act "CSA". This petition was forwarded to the Secretary of HEW for a medical and scientific evaluation.

The Bureau of Drugs within the Food and Drug Administration reviewed the relevant data on mazindol pursuant to Section 201 of the CSA and recommended that mazindol be

removed from Schedule III of the CSA and placed into Schedule IV of the same. The Commissioner of Food and Drugs agrees with this recommendation.

I concur with this scientific and medical evaluation. A summary of the basis for this recommendation is enclosed.

Sincerely yours,

Julius B. Richmond,
Assistant Secretary for Health and Surgeon General.

Enclosure: Basis for the recommendation for rescheduling for mazindol.

In essence and in effect, this recommendation from the Assistant Secretary is not to decontrol mazindol as the petitioner has requested.

Consequently, the Administrator of the Drug Enforcement Administration, in accordance with the provisions of Section 201(b) of the Act, will not institute proceedings to deschedule mazindol and, in lieu thereof, mazindol shall remain in Schedule III as currently listed.

In the Assistant Secretary's evaluation and recommendation letter of January 16, 1981, he recommended that mazindol be removed from Schedule III of the CSA and placed into Schedule IV of the same. The above-referenced enclosure to his letter set forth the basis for the recommendation for rescheduling mazindol.

Accordingly, the Administrator of the Drug Enforcement Administration, under the authority of the Act and regulations of the Department of Justice and the Drug Enforcement Administration, hereby proposes that Part 1308, Title 21, Code of Federal Regulations (CFR), be amended:

§ 1308.13 [Amended]

(1) By removing mazindol as item (5) of § 1308.13(b) and renumbering item (6) phendimetrazine as item (5); and

(2) By revising paragraph (e) of § 1308.14 of Title 21, Code of Federal Regulations (CFR), to include mazindol therein as item (2), to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(e) *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 and salts of isomers:

(1) Diethylpropion.....	1610
(2) Mazindol.....	1605
(3) Pemoline (including organometallic complexes and chelates thereof)....	1530
(4) Phentermine.....	1640

* * * * *

All interested persons are invited to submit their comments regarding this proposal on or before June 16, 1981. These comments should state with particularity the issues concerning which the person desires to be heard. Comments should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, Department of Justice, 1405 Eye Street, N.W., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

Pursuant to Title 5, United States Code, Section 605(b), the Administrator certifies that removal of mazindol from Schedule III of the Controlled Substances Act and placement of it into Schedule IV of the same, will have no significant impact upon small businesses or other entities whose interest must be considered under the Regulatory Flexibility Act. This action involves continuing control of a substance previously approved for marketing in the United States.

In accordance with the provisions of Section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)), this scheduling action is a formal rulemaking "on the record after opportunity for a hearing." Such formal proceedings are conducted pursuant to the provisions of 4 U.S.C. 556 and 557 and as such, have been exempted from the consultation requirements of Executive Order 12291.

Dated: April 10, 1981.

Peter B. Bensinger,
Administrator, Drug Enforcement Administration.

[FR Doc. 81-11700 Filed 4-16-81; 8:45 am]
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DEPARTMENT OF STATE

22 CFR Ch. I

[Docket No. SD-170]

Semiannual Agenda of Regulations and Regulatory Flexibility Agenda

AGENCY: Department of State.

ACTION: Publication of regulatory agenda.

SUMMARY: As required by section 5 of Executive Order No. 12291, Federal Regulation, the first 1981 agenda of regulations is set forth below. The agenda also contains regulatory flexibility information required by the Regulatory Flexibility Act of 1980 (Pub. L. 96-354).

FOR FURTHER INFORMATION CONTACT: K. E. Malmborg, Assistant Legal Adviser for Management, Department of State, Room 4427A, 2201 C Street, NW,

Washington, D.C. 20520, telephone (202) 632-2350.

Regulatory Agenda

A notice inviting public comment on the proposed International Traffic in Arms Regulations (ITAR) was published December 19, 1980 (45 FR 83970). The Authority for these regulations is contained in 22 U.S.C. 2778 and 2779. Because these regulations concern export licensing of munitions control items and thus competition with foreign based firms, they are being reconsidered under the criteria of Executive Order 12291 before being made final, even though they involve a foreign affairs function and, therefore, are excluded from mandatory review by Section 1(a)(2) of the order.

The point of contact for this regulation in the Department is Mr. William B. Robinson, Director, Office of Munitions Control, Department of State, 2201 C Street, NW, Washington, D.C. 20520, telephone (202) 632-9755.

There are no Department of State rules under consideration or in existence which would be considered major rules.

Two existing actions are scheduled for review in accordance with Section 2 of Executive Order 12291.

First, there are regulations to implement the Hostage Relief Act of 1980 (Pub. L. 96-449). These regulations, after review by the Office of Management and Budget under E.O. 12291, entered into force as an interim rule (46 FR 17543). They: (1) extend certain provisions of the Soldiers' and Sailors' Relief Act (50 U.S.C. App. section 547) to United States Government employees who have been taken captive abroad, such as those seized at the American Embassy in Iran; (2) provide for medical benefits to these hostages and members of their families; and (3) provide for education and training for the hostages and members of their families. The President's Commission on Hostage Compensation is conducting a study which could result in new legislation, modification in the regulations, or both. Any such recommendations would take account of E.O. 12291.

The point of contact for these regulations is Mr. Walter F. Weiss, Special Assistant to the Assistant Secretary for Administration, Department of State, 2201 C Street, NW., Washington, D.C. 20520, telephone (202) 632-1728.

The Department published notice of revisions in its procedures, prepared pursuant to Executive Order 12114, relating to assessment of environmental impacts abroad of Department actions (September 9, 1980; 45 FR 59469).

The point of contact in the Department is Ms. Irene Dybalski, Office of Environment and Health, Department of State, 2201 C Street, NW., Washington, D.C. 20520, telephone (202) 632-9267.

Flexibility Agenda

The Department of State has reviewed presently planned regulations in the light of the interim guidance issued December 10, 1980, by the Office of Management and Budget on incorporating regulatory flexibility into the regulatory process. We have not identified any which will have a significant economic impact on a substantial number of small entities.

The Department plans to publish its next semiannual agenda in October 1981.

Dated: April 10, 1981.

For the Secretary of State,
Richard T. Kennedy,
Under Secretary of State for Management.

[FR Doc. 81-11694 Filed 4-16-81; 8:45 am]
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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Part 235

[Docket No. R-81-916]

Mortgage Insurance and Assistance Payments for Home Ownership and Project Rehabilitation

AGENCY: Office of the Secretary (HUD).

ACTION: Notice of Congressional Waiver request.

SUMMARY: Section 7(o)(4) of the Department of HUD Act permits the Secretary to request waiver of the legislation's requirements in appropriate instances. This Notice lists and briefly summarizes for public information an interim rule with respect to which the Secretary is presently requesting waiver.

FOR FURTHER INFORMATION CONTACT: Burton Bloomberg, Director, Office of Regulations, Office of the General Counsel, 451 Seventh Street SW., Washington, D.C. 20410 (202) 755-6207.

SUPPLEMENTARY INFORMATION: Concurrently with issuance of this Notice, the Secretary is forwarding to the Chairmen and Ranking Minority Members of both Congressional Banking Committees the interim rule listed below. The purpose of the transmittal is to request waiver of the 15-day prepublication review period under