

environmental assessment nor an environmental impact statement is required.

In accordance with Executive Order 12291, the economic effects of this rule have been carefully analyzed, and it has been determined that the rule is not a major rule as defined by the Order.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 584 consisting of § 584.200, to read as follows:

**PART 584—FOOD SUBSTANCES  
AFFIRMED AS GENERALLY  
RECOGNIZED AS SAFE IN FEED AND  
DRINKING WATER OF ANIMALS**

**Subpart A [Reserved]**

**Subpart B—Listing of Specific Substances  
Affirmed as GRAS**

Sec.  
584.200 Ethyl alcohol containing ethyl acetate.

Authority: Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).

**Subpart A [Reserved]**

**Subpart B—Listing of Specific  
Substances Affirmed as GRAS**

§ 584.200 Ethyl alcohol containing ethyl acetate.

The feed additive ethyl alcohol containing ethyl acetate meets the requirement of 27 CFR 212.45, being not less than 92.5 percent ethyl alcohol, each 100 gallons having had added the equivalent of 4.25 gallons of 100 percent ethyl acetate. It is used in accordance with good feeding practices in ruminant feed supplements as a source of added energy.

*Effective date.* This regulation is effective October 27, 1981.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: October 8, 1981.

William F. Randolph,  
*Acting Associate Commissioner for  
Regulatory Affairs.*

[FR Doc. 81-30823 Filed 10-26-81; 8:45 am]

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**Schedules of Controlled Substances;  
Rescheduling of Mazindol Into  
Schedule IV**

**AGENCY:** Drug Enforcement  
Administration, Justice.

**ACTION:** Final rule.

**SUMMARY:** This is a final rule removing mazindol from Schedule III of the Controlled Substances Act and placing it into Schedule IV. As a result of this rule, mazindol will be subject to the manufacture, distribution, security, registration, recordkeeping, inventory, criminal liability, exportation and importation controls of Schedule IV.

**EFFECTIVE DATE:** November 27, 1981.

**FOR FURTHER INFORMATION CONTACT:** Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537; Telephone: (202) 633-1366.

**SUPPLEMENTARY INFORMATION:** A notice was published in the Federal Register on Friday, April 17, 1981 (46 FR 22393), proposing that mazindol be removed from Schedule III of the Controlled Substances Act and that it be placed into Schedule IV. Interested persons were given until June 16, 1981 to submit comments or objections regarding this proposal. One comment was received from Merrell Dow Pharmaceuticals, Inc., the manufacturer of another anorectic preparation, diethylpropion. Merrell Dow urged DEA to delay any decision on the rescheduling of mazindol pending the receipt and evaluation of the forthcoming recommendation of the Department of Health and Human Services (DHHS) regarding possible rescheduling of diethylpropion and phentermine, other Schedule IV anorectics. The Merrell Dow response raised issues which were deemed worthy of further discussion and the comment was forwarded to Dr. J. Richard Crout, Director of the Food and Drug Administration's Bureau of Drugs for his consideration. By letter dated September 10, 1981 to the Director of DEA's Office of Compliance and Regulatory Affairs, Dr. Crout explained that although a comprehensive review of all available anorectics has been recommended and although periodic class reviews for scheduled drugs is desirable, he believed that a review focusing on one drug and comparing it to other drugs in the class (i.e., the mazindol review) was adequate for scheduling recommendations. He further

stated that he did not consider diethylpropion and phentermine to be appropriate benchmark Schedule IV anorectics for comparison with mazindol since both have been on interim status in this schedule for sometime now. He added that fenfluramine would be a more appropriate Schedule IV agent for comparison.

No other comments or objections were received in response to this proposal, nor were there any requests for a hearing. Based on the scientific and medical evaluation and recommendation of the Secretary of Health, Department of Health and Human Services, received in accordance with section 201(b) of the Controlled Substances Act (21 U.S.C. 811(b)), the Acting Administrator of the Drug Enforcement Administration, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Based on information now available, mazindol has a lower "potential for abuse" than Schedule III anorectics;

(2) Mazindol has a currently accepted medical use in treatment in the United States; and,

(3) Abuse of mazindol would lead to limited psychological dependence relative to the anorectics in Schedule III.

The above findings are consistent with the placement of mazindol in Schedule IV of the Controlled Substances Act. All regulations applicable to Schedule IV substances are applicable on November 27, 1981.

As a result of this action, mazindol will continue to be subject to the same manufacture, distribution, security, registration, inventory, records, prescription, importation and exportation controls and criminal liability as in the past. All labels and labeling for commercial containers after (6 months after publication) shall comply with the requirements of §§ 1302.03-1302.05 and 1302.08 of Title 21, Code of Federal Regulations. In the event this effective date imposes special hardships on the manufacturer as defined in section 102(14) of the Controlled Substances Act (21 U.S.C. 802(14)), the Drug Enforcement Administration will entertain any justified requests for an extension of time.

Pursuant to Title 5, United States Code, Section 605(b), the Acting Administrator certifies that control of mazindol, as ordered herein, will have no significant impact upon small business or other entities whose interests must be considered under the Regulatory Flexibility Act. Such entities



will distribute, dispense or prescribe mazindol in precisely the same manner as they had in the past. No additional recordkeeping, security or other reports are required by this action.

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 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirements of Executive Order 12291.

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Under the authority vested in the Attorney General by section 201(a) of the Act (21 U.S.C. 811(a)) and delegated to the Acting Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), the Acting Administrator hereby orders that Part 1308, Title 21, Code of Federal Regulations (CFR) be amended as follows:

### § 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 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

\* \* \* \* \*

Dated: October 19, 1981.

Francis M. Mullen, Jr.,  
Acting Administrator, Drug Enforcement Administration.

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 51

[T.D. 7790]

#### Excise Tax; Net Income Limitation on Windfall Profit; Crude Oil

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

**SUMMARY:** This document provides final regulations relating to the computation of the net income limitation on windfall profit under section 4988(b) of the Internal Revenue Code of 1954. These regulations provide the public with the guidance needed to compute the net income limitation. They are contained in a new Part 51 of Title 26 of the Code of Federal Regulations for final regulations under the Crude Oil Windfall Profit Tax Act of 1980.

**DATE:** The regulations are effective for periods after February 29, 1980.

**FOR FURTHER INFORMATION CONTACT:** Donald W. Stevenson of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, D.C. 20224, Attention: CC:LR:T, 202-566-3516, not a toll-free call.

#### SUPPLEMENTARY INFORMATION:

##### Background

On January 7, 1981, the Federal Register published amendments (46 FR 1754) to proposed Excise Tax Regulations (26 CFR Part 51) that had been published on April 4, 1980 (45 FR 23400). The January 7, 1981, amendments were proposed under section 4988(b) of the Internal Revenue Code of 1954 to prescribe rules for computing the net income limitation on windfall profit pursuant to section 101(a) of the Crude Oil Windfall Profit Tax Act of 1980 (94 Stat. 230). Numerous comments were received suggesting a number of changes to the proposed amendments. A public hearing on the proposed amendments was held on June 18, 1981. After consideration of the suggested changes to the proposed amendments, those amendments are adopted as revised by this Treasury decision.

##### Two-Month Rule

The proposed regulations provided that in computing the taxable income from the property for the taxable year the taxpayer shall take into account all income received or accrued and all expenses paid or incurred during the taxable year and 2 months after the

close of the taxable year for oil removed during the taxable year (or during a previous taxable year if the gross income therefrom was received or accrued or the expenses were paid or incurred during the current taxable year more than 2 months after the close of the taxable year of removal).

Commenters stated that this rule requires a cash basis taxpayer to maintain additional sets of records using a modified accrual method of accounting. The commenters argued that the statute did not require a strict matching of income and expenses for each barrel produced within a calendar year. They suggested that the Congressional intent would be served if taxable income from the property were determined under section 613(a), using the taxpayer's taxable year and method of accounting. This would minimize administrative burdens for all producers.

These comments were found to be persuasive. Consequently, this Treasury decision eliminates the 2-month rule and substitutes a rule that is based upon the section 613(a) taxable income from the property concept. It uses the taxpayer's own taxable year and method of accounting. The new rule further provides that, in computing the net income attributable to a barrel, the taxpayer shall divide taxable income from the property by the number of barrels of taxable crude oil sold within the taxable year.

##### Attribution of Expenditures to Gas and Oil

In computing taxable income from the property attributable to taxable crude oil where both taxable crude oil and gas or exempt oil are produced from the property, the proposed regulations required the producer to allocate all expenditures incurred in that year among taxable and exempt crude oil and gas based on a relative gross income ratio. Several commenters stated that in many instances the producer can specifically identify certain expenses which relate solely to taxable crude oil or solely to other production and recommended that the proposed regulations be modified to provide that if an incurred expense can be specifically attributed to gas, or to exempt or taxable crude oil production, then the producer should allocate those expenses directly to that production.

The final regulations are modified to provide for allocation to taxable crude oil production of those expenditures which are attributable solely to taxable crude oil production and of a proportionate amount (determined by