Proposed Rule Making

DEPARTMENT OF JUSTICE

Bureau of Narcotics and Dangerous Drugs

[21 CFR Part 308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Removal of Exceptions from Amphetamine Combination Products

An order was published in the FEDERAL REGISTER of July 7, 1971 (36 F.R. 12734), transferring from Schedule III to Schedule II all materials, compounds, mixtures, and preparations containing any quantity of amphetamine (or its salts, optical isomers, or salts of its optical isomers) or methamphetamine (or its salts, isomers, or salts of isomers), with two types of exceptions: First, from specific products (Eskatrol, Fetamin, Biphetamine, and Biphetamine-T), and second, "those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances which are currently listed as excepted compounds under 21 CFR 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that contains a lesser quantity of controlled substances." The specific products listed were later transferred to Schedule II by orders published in the FEDERAL REGISTER of July 23, 1971 (36 F.R. 13686), and August 18, 1971 (36 F.R. 15744).

The "excepted compounds" listed in 21 CFR 308.32, and the other drugs of similar or lesser quantitative composition, were excepted from application of certain parts of the Controlled Substances Act and the Controlled Substances Import and Export Act by order of the Director published in the FEDERAL REGISTER of April 24, 1971 (36 F.R. 7805, § 308.32(a)). This was done for administrative purposes only until criteria could be adopted by which the Bureau could determine whether to except any compound under section 202(d) of the Act. The order expressly stated that "The excepting of these drugs by the Director should not be construed as an adoption or rejection of the criteria by which these drugs were originally excepted."

The Director has determined that no compound, mixture, or preparation containing any quantity of amphetamine (or its salts, optical isomers, or salts of its optical isomers) or methamphetamine (or its salts, isomers or salts of its isomers) and one or more active medicinal ingredients not having a stimulant effect on the central nervous system, contains such ingredients in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the amphetamine or methamphetamine substances.

Therefore, under the authority vested in the Attorney General by section 202 (d) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 812(d)), and redelegated to the Director, Bureau of Narcotics and Dangerous Drugs by § 0.100 of Title 28 of the Code of Federal Regulations, the Director hereby proposes that:

1. Section 308.13(b)(3) of Title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

* * * * * *

(b) * * *

(3) These compounds, mixtures, or preparations in dosage unit form containing any stimulant substances which compounds, mixtures or preparations were listed on August 25, 1971, as excepted compounds under 21 CFR 308.32, and any other drug of the quantitative composition shown in that list for those drugs on which is the same except that it contains a lesser quantity of controlled substances.

2. Section 308.32(b) of Title 21 of the Code of Federal Regulations be amended by deleting the following drugs:

§ 308.32 Excepted compounds.

* * * * *

Trade name or other designation	Composition	Manufacturer or supplier
* * *	* * *	* * *
Edrisal	Tablet: Dextroamphetamine sulfate 2.5 mg.; aspirin, 0.16 gm.; phenacetin 0.16 gm.	Smith Kline & French Laboratories.
* * *	* * *	* * *
Genegesic Capsules	Capsule: Methamphetamine hydrochloride, 1.2 mg.; chlorpheniramine maleate, 3.8 mg.; phenacetin, 120.0 mg.; salicylamide, 180.0 mg.; caffeine, 30.0 mg.; ascorbic acid, 60.0 mg.	General Pharmaceutical Products Inc.
* * *	* * *	* * *
Hovizyme	Tablet: Methamphetamine hydrochloride, 0.5 mg.; conjugated estrogen-equine, 0.125 mg.; methyl testosterone, 1.25 mg.; amylase, 10.0 mg.; protease, 6.0 mg.; cellulase, 2.0 mg.; nicotinyl alcohol tartrate, 7.5 mg.; dehydrocholic acid, 50.0 mg.; ascorbic acid, 60.0 mg.; ferrous fumarate, 6.0 mg.	Ayerst Laboratories.
* * *	* * *	* * *
Mediatric	Tablet or capsule: Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyl testosterone, 2.5 mg.	Ayerst Laboratories.
Mediatric Liquid	Solution (15 cc.): Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyl testosterone, 2.5 mg.	Do.
* * *	* * *	* * *
Special Formula 711	Tablet: d-Amphetamine sulfate, 2.5 mg.; methacin, 500 mg.; salicylamine, 500 mg.	Detroit First Aid Co.
* * *	* * *	* * *
Thora-Dex No. 1	Tablet: Dextroamphetamine sulfate, 2 mg., chlorpromazine hydrochloride, 10 mg.	Smith Kline & French Laboratories.
Thora-Dex No. 2	Tablet: Dextroamphetamine sulfate, 5 mg., chlorpromazine hydrochloride, 25 mg.	Do.
* * *	* * *	* * *

In his order published July 7, 1971 in the FEDERAL REGISTER (36 F.R. 12736), the Director recognized that certain combination drugs containing amphetamine or methamphetamine exempted under the Drug Abuse Control Amendments of 1965 were not expressly excepted under § 308.32. The Director stated that, as a matter of policy, those substances would be deemed excepted under § 308.32 pending further action of the Bureau. This proposed rule would apply to those substances as well.

The effect of this proposed order would be to subject the so-called "excepted compounds" containing amphetamine and methamphetamine to all of the requirements of sections 305, 307, and 309 of the Controlled Substances Act (relating to labeling, recordkeeping, and prescription requirements for controlled substances), sections 1002, 1003, and 1004 of the Controlled Substances Import and Export Act (relating to importation, exportation, transshipment, and in-transit shipment of controlled substances), and § 301.74(d) of Title 21 of the Code of Federal Regulations (relating to sampling of controlled substances). This proposal is not intended to transfer, and will not have the effect of transferring any "excepted compound" containing amphetamine from Schedule III to Schedule II.

All interested persons are invited to submit their comments or objections in writing regarding this proposal. These 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 Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Room 611, 1405 Eye Street NW., Washington, D.C. 20537, and must be received no later than 30 days after publication of this proposal in the FEDERAL REGISTER.

In the event any person desires to comment on or object to this proposal as it applies to a particular compound, mixture, or preparation, he should submit as part of his comments or objections the following information:

(1) The complete quantitative composition of the dosage form.
(2) Description of the unit dosage form together with complete labeling.
(3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).
(4) Details of synergisms and antagonisms among ingredients.
(5) Deterrent effects of the noncontrolled ingredients.
(6) Complete copies of all literature in support of claims.
(7) Reported instances of abuse.
(8) Reported and anticipated adverse effects.
(9) Number of dosage units produced for the past 2 years.

After consideration of the comments on or objections to this proposal, the Director shall issue and publish in the FEDERAL REGISTER his final order on this matter. In the event that an interested party submits objections to this proposal which present grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 316.74, the Director may, in his discretion, order a hearing on such issues as the Director deems it necessary and desirable to have a hearing. If a hearing is so ordered, the party will be notified by registered mail of the time and place that the hearing will be held. If objections submitted do not present grounds which the Director deems sufficient to justify a hearing, the party will be so advised by registered mail.

Dated: September 13, 1971.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

[FR Doc.71-13728 Filed 9-20-71;8:45 am]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 1]

INCOME TAX

Advertising and Other Activities

Correction

In F.R. Doc. 71-13253, appearing at page 18316 in the issue of Saturday, September 11, 1971, the following changes should be made:

1. In § 1.512(a)-1(b) the following language should be inserted between the existing 10th and 11th lines: "Thus, for example, salaries of personnel employed full-time in carrying on unrelated business activities are directly".

2. In § 1.512(a)-1(h) the word "he" in the penultimate line should read "it".

DEPARTMENT OF THE INTERIOR

Oil Import Administration

[32A CFR Ch. X]

ALLOCATIONS OF CRUDE OIL IN DISTRICTS I-IV AND REFINERY INPUTS IN DISTRICTS I-IV AND DISTRICT V

Notice of Proposed Rule Making

Paragraphs (a) and (b) of section 10 of Oil Import Regulation 1 (Revision 5), as amended, provide for the making of allocations of imports of crude oil and unfinished oil to refiners in Districts I-IV. The present schedule for computing allocations contained in paragraph (b) of section 10 consists of a four-step sliding scale. Review of the present system indicates that a revision of the system, working toward a more fair and equitable method in the distribution of allocations, may be in order. Accordingly, it has been determined that public comments on a proposed new allocation procedure should be solicited. No action in respect to the allocation system in District V is being taken at this time.

It is proposed that the current four-step scale as set forth in paragraph (b) of section 10 of the Oil Import Regulation 1, as revised and amended, be reduced to a two-step sliding scale (0-30,000 b/d and 30,000 b/d plus). It is contemplated that the percentage allocated under the first step in the proposed schedule, paragraph (b) of section 10, for the upcoming allocation period and for each succeeding allocation period thereafter, would remain constant at 20 percent. Under this concept, the second step under the schedule would, by necessity, be adjusted annually, consistent with the quantity of imports of crude oil and unfinished oils available for distribution after allocations have been computed and satisfied under the first step of the scale.

A determination has not yet been made as to the quantity of imports of crude oil and unfinished oils that will be available for allocation under section 10 for the allocation year beginning January 1, 1972. Because applications for allocations containing actual qualified refinery inputs for the year ending September 30, 1971, have not been received, actual refinery inputs for that period are unknown. However, for the purpose of illustration, there follows an example of the allocation method proposed for the allocation period beginning January 1, 1972 and ending December 31, 1972; it is based upon the following assumptions:

(1) 700,000 b/d of crude oil and unfinished oils available for allocation under paragraph (a) and (b) of section 10.
(2) 9,900,000 b/d=Total qualified "refinery inputs" for the year ending September 30, 1971.
(3) 1,600,000 b/d=Aggregate of "refinery inputs" covered by the first step (0 to 30,000 b/d).
(4) 8,300,000 b/d=Balance of aggregate quantity of "refinery inputs" (i.e., above 30,000 b/d).

The following illustrates the computation which would determine the percent factor for the second step of the scale:

(a) 1,600,000 b/d×20 percent=320,000 b/d of imports available under the first step.

(b) 700,000 b/d minus 320,000 b/d=380,000 b/d of imports available under the second step.

(c) 380,000÷8,300,000=0.0458.

(d) 0.0458×100=4.58 percent factor of the second step. Hence, the allocation of an eligible application having a total of 200,000 b/d of "refinery inputs" would be determined as follows:

30,000 b/d×20%	= 6,000 b/d
170,000 b/d×4.58%	= 7,786 b/d
200,000 b/d allocation	=13,786 b/d

In addition, it is proposed to amend section 22(k)(1)(ii) of the oil import regulations to define more specifically the extent and nature of the processing required of unfinished oils imported pursuant to an allocation before such imports qualify as "refinery inputs" as a basis for making allocations.

Final action upon these proposals will be subject to the concurrence of the Director, Office of Emergency Preparedness. Comments should be submitted to the Administrator, Oil Import Administration, Department of the Interior, Washington, D.C. 20240, by October 20, 1971. Persons submitting comments are asked to supply fifteen (15) copies.

RALPH W. SNYDER, Jr.,
Acting Administrator, Oil Import Administration.

SEPTEMBER 17, 1971.

1. Paragraphs (a) and (b) of section 10 would be amended to read as follows:

Sec. 10 Allocations; refiners; Districts I-IV.

(a) For the allocation period January 1, 1972 through December 31, 1972, the Administrator shall allocate, as provided in paragraph (b) of this section, approximately 700,000 b/d of imports of crude oil into Districts I-IV among eligible persons having refinery capacity in these districts.

(b) Each eligible applicant shall receive an allocation of imports of crude oil based on refinery inputs for the year ending September 30, 1971, and computed according to the following schedule:

Average b/d		Percent of input		Number of days
0-30,000	×	20.0	×	365
30,000-plus	×	4.58		

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