

## SUBCHAPTER C—DRUGS

## PART 135—NEW ANIMAL DRUGS

## Subpart C—Sponsors of Approved Applications

## PART 135b—NEW ANIMAL DRUGS FOR IMPLANTATION OR INJECTION

## Droperidol and Fentanyl Citrate Injection

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (30-438V) filed by McNeil Laboratories, Inc., proposing the safe and effective use of droperidol and fentanyl citrate injection as a tranquilizer in dogs. The application is approved.

To facilitate referencing, McNeil Laboratories, Inc., is being assigned a code number and placed in the list of firms in § 135.501 (21 CFR 135.501).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 135 and 135b are amended as follows:

1. Section 135.501 is amended in paragraph (c) by adding a new code No. 055, as follows:

§ 135.501 Names, addresses, and code numbers of sponsors of approved applications.

(c) \* \* \*

Code No.	Firm name and address
055	McNeil Laboratories, Inc., Camp Hill Road, Fort Washington, Pa. 19034.

2. Part 135b is amended by adding the following new section:

§ 135b.37 Droperidol and fentanyl citrate injection.

(a) *Specifications.* Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) *Sponsor.* See code No. 055 in § 135.501(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

(i) For analgesia and tranquilization administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 40 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight.

(3) For use only by or on the order of a licensed veterinarian.

*Effective date.* This order shall be effective upon publication in the FEDERAL REGISTER (10-28-71).

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i))

Dated: October 19, 1971.

C. D. VAN HOUWELING,  
Director,

Bureau of Veterinary Medicine.

[FR Doc.71-15642 Filed 10-27-71;8:47 am]

[DESI 7561]

## PART 141a—PENICILLIN AND PENICILLIN-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

## PART 141c—CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

## PART 141e—BACITRACIN AND BACITRACIN-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

## PART 146a—CERTIFICATION OF PENICILLIN AND PENICILLIN-CONTAINING DRUGS

## PART 146c—CERTIFICATION OF CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS

## PART 146e—CERTIFICATION OF BACITRACIN AND BACITRACIN-CONTAINING DRUGS

## PART 148i—NEOMYCIN SULFATE

## PART 148n—OXYTETRACYCLINE

## PART 148p—POLYMYXIN

## PART 148r—TYROTHRINICIN

## Confirmation of Order Revoking Provisions for Certification of Antibiotics in Combination With Other Drugs for Nasal Use

An order was published in the FEDERAL REGISTER of August 6, 1971 (36 F.R. 14469), amending the antibiotic drug

regulations to repeal provisions for certification of antibiotics in combination with other drugs for nasal use. The order amended Parts 141a, 141c, 141e, 146a, 146c, 146e, 148i, 148n, 148p, and 148r by revoking §§ 141a.14, 141c.215, 141e.405, 141e.414, 141e.424, 146a.32, 146c.215, 146e.405, 146e.414, 146e.424, 148i.7, 148i.21, 148i.28, 148i.40, 148i.41, 148i.42, 148i.43, 148n.16, 148p.7, and 148r.6 and all antibiotic certificates issued thereunder.

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), notice is given that no objections were filed to the above identified order. Accordingly the amendments promulgated thereby became effective September 15, 1971.

Firms affected by the order will be allowed 30 days after publication hereof in the FEDERAL REGISTER to recall outstanding stocks of the affected drugs. Certification of new stocks has been discontinued.

Dated: October 15, 1971.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc.71-15639 Filed 10-27-71;8:47 am]

## Chapter II—Bureau of Narcotics and Dangerous Drugs, Department of Justice

## PART 301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

## PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

## Phenmetrazine and Its Salts and Methylphenidate

A notice was published in the FEDERAL REGISTER of September 17, 1971 (36 F.R. 18582), proposing the transfer of phenmetrazine and its salts and methylphenidate from schedule III to schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91-513). All interested persons were given 30 days after publication to submit their objections, comments, or requests for hearing.

No objections nor requests presenting reasonable grounds for a hearing regarding the proposed order were received.

Based upon the fact no objections nor requests for a hearing were received as to the proposed transfer order and upon the investigations of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to section 201(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811 (b)), the Director of the Bureau of Narcotics and Dangerous Drugs, in view of

the order transferring amphetamines and methamphetamine to schedule II published in the FEDERAL REGISTER of July 7, 1971 (36 F.R. 12734), and the resulting strict production and distribution controls imposed upon amphetamines and methamphetamine by this transfer, finds that persons disposed to abuse amphetamines and methamphetamine now may direct their attention to methylphenidate and phenmetrazine, drugs which presently are not known to be the subject of substantial abuse in the United States. Further, there is no evidence to indicate that there is any abuse of methylphenidate and phenmetrazine when administered with proper medical supervision.

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 redelegated to the Director, Bureau of Narcotics and Dangerous Drugs by § 0.100 of Title 28 of the Code of Federal Regulations: *It is ordered, That:*

1. Section 301.02 of Title 21 of the Code of Federal Regulations be amended by adding new paragraphs (b) (8) and (9) to read:

§ 301.02 Definitions.

(b) \* \* \*

(8) Phenmetrazine and its salts.

(9) Methylphenidate.

\* \* \* \* \*

2. Section 308.12(d) of Title 21 of the Code of Federal Regulations be deleted and replaced with a new paragraph to read:

§ 308.12 Schedule II.

\* \* \* \* \*

(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:

- (1) Amphetamine, its salts, optical isomers, and salts of its optical isomers ..... 1,100
- (2) Methamphetamine, its salts, isomers, and salts of its isomers..... 1,105
- (3) Phenmetrazine and its salts..... 1,630
- (4) Methylphenidate..... 1,726

3. Section 308.13(b) (4) of Title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

\* \* \* \* \*

(b) *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:

- (1) 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 composi-

tion shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances.

(4) The additional requirements imposed upon Phenmetrazine and its salts and Methylphenidate by virtue of their reclassification into schedule II shall become effective as follows:

(a) *Labeling and packaging.* All labels and seals on commercial containers of, and all labeling of, the above-controlled substances, which are packaged on and after May 1, 1972, shall comply with the requirements of 21 CFR Part 302.

(b) *Order forms.* All orders for the above-controlled substances received after December 31, 1971, shall comply with the order form requirements of 21 CFR Part 305.

(c) *Records and inventories.* All separate and other recordkeeping requirements of 21 CFR Part 304 for the above-controlled substances shall be complied with by January 1, 1972. Records maintained and inventories taken prior to the above compliance date, which are in compliance with the recordkeeping requirements for schedule III controlled substances, shall not be affected by this order. No new inventories of the above-controlled substances, in addition to that of May 1, 1971, is required as a result of this order. Where a positive conflict exists between State and Federal laws and regulations, so that the two cannot stand together, Federal law governs in accordance with section 708 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 903).

(d) *Prescriptions.* All prescriptions for the above-controlled substances shall comply with 21 CFR 306.01-306.15 by January 1, 1972. Any prescriptions for the above-controlled substances, which are entitled to be refilled under § 306.22, shall not be entitled to such refill in accordance with § 306.12 on and after the above compliance date.

(e) *Importation and exportation.* All importation and exportation of the above controlled substances shall be in compliance with 21 CFR Part 312, specifically as to import and export permits, by January 1, 1972.

(f) *Security.* All security requirements of 21 CFR 301.71-76 for the above-controlled substances shall be complied with by March 1, 1972.

(g) *Registration.* Any registrant presently not authorized to handle Phenmetrazine and its salts or Methylphenidate or both and/or schedule II controlled substances should apply to modify his registration to authorize the handling of such controlled substances by submitting, by January 1, 1972, a letter of request to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Post Office Box 28083, Central Station, Washington, DC 20005. The letter shall contain the registrant's name, address, registration number, and the substances and/or schedules to be added to his registration, and shall be signed by the same person who signed the most recent

application for registration or re-registration. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration.

This order is effective on the date of its publication in the FEDERAL REGISTER (10-28-71).

Dated: October 18, 1971.

JOHN FINLATOR,  
Acting Director, Bureau of  
Narcotics and Dangerous Drugs.

[FR Doc.71-15654 Filed 10-27-71;8:51 am]

Chapter III—Environmental  
Protection Agency

PART 420—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

2-(4-Chloro-6-Ethylamino-s-Triazin-2-Ylamino)-2-Methylpropionitrile

A petition (PP 0F0998) was filed by the Shell Chemical Co., Suite 1103, 1700 K Street NW., Washington, DC 20006, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) proposing the establishment of a tolerance for negligible residues of the herbicide 2-(4-chloro-6-ethylamino - s - triazin-2-ylamino)-2-methylpropionitrile in or on the raw agricultural commodities fresh corn including sweet corn (kernels plus cob with husk removed), corn grain, and corn forage and fodder at 0.1 part per million.

Subsequently, the petitioner amended the petition by requesting a lower tolerance level of 0.05 part per million.

Prior to December 2, 1970, the Secretary of Agriculture certified that the pesticide is useful for the purpose for which a tolerance is proposed, and the Fish and Wildlife Service, Department of the Interior, stated that they have no objection to the proposed tolerance.

Part 120, Chapter I, Title 21, was redesignated Part 420 and transferred to Chapter III (36 F.R. 424).

Based on consideration given data submitted in the petition and other relevant material, it is concluded that:

1. The proposed usage is not reasonably expected to result in residues of the pesticide in meat, milk, poultry, and eggs. The usage is classified in the category specified in § 420.6(a) (3).

2. The tolerance established by this order will protect the public health.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(d) (2), 68 Stat. 512; 21 U.S.C. 346a(d) (2)), the authority transferred to the Administrator of the Environmental Protection Agency (35 F.R. 15623), and the authority delegated by the Administrator to the Deputy Assistant Administrator for Pesticides Programs (36 F.R. 9038), Part 420 is amended by adding a new section to Subpart C, as follows: