

sales made under contracts dated after October 1, 1968, are set forth in table No. 1A and, subject to the additional requirements, restrictions, and authorizations provided in the orders issuing such certificates represent the area rate levels for the areas involved until such time as the Commission shall promulgate applicable just and reasonable rates in said area.

(E) Effective upon the issuance of this order, paragraphs (c) and (d) of § 2.56, part 2—General Policy and Interpretations, chapter I of title 18 of the Code of Federal Regulations are amended to strike therefrom all references to the Rocky Mountain area or any part thereof, and tables 2 and 3 are hereby modified accordingly. *Provided, however,* That nothing in this amendment of §§ 2.56 (c) and (d) shall operate to amend § 154.93 of the Commission's Regulations under the Natural Gas Act.

(F) The amendments provided for herein shall be effective as of the date of issuance of this order.

(G) The proceedings in docket Nos. R-389 and R-389A shall remain open for such other orders as the Commission may find appropriate.

(H) The Secretary of the Commission shall cause prompt publication of this order to be made in the FEDERAL REGISTER.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.73-7625 Filed 4-19-73; 8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 135—NEW ANIMAL DRUGS

Subpart E—Statements of Policy and Interpretation Regarding Animal Drugs and Medicated Feeds

ANTIBIOTIC AND SULFONAMIDE DRUGS IN THE FEED OF ANIMALS

Some 380 responses were received to the proposal published in the FEDERAL REGISTER of February 1, 1972 (37 FR 2444), regarding the use of antibiotic and sulfonamide drugs in animal feeds. Views were received from individuals, livestock and poultry producers, producer associations, State, Federal, and university personnel, and drug and feed manufacturers. Of those responses expressing support for the proposed restriction, five offered grounds for the position taken, and of those opposed, 77 offered grounds; many views expressed were related to an interpretation of the data reviewed by the task force on the use of antibiotics in animal feeds. A review of the comments submitted reflected certain issues. These issues of concern, along with the responses of the Commissioner of Food and Drugs to them, are as follows:

1. It was stated that there existed considerable difference of opinion within the task force membership and that the task

force was nearly equally divided on several major points. In spite of the various opinions expressed within the task force on various points of consideration, its members unanimously agreed to the report. All members concurred that reliable and appropriate research is needed to provide data pertinent to the conclusions of the task force. The minority reports have been evaluated in proper perspective and it is concluded that they do not provide an adequate basis on which to alter the findings of the task force.

2. It was stated that many of the antibacterial drugs have been in widespread use of approximately 20 years and in billions of animals as well as in countless studies serving to document their safety and effectiveness. Present data and experience with antibacterial drugs in animal feeds fail to satisfy the specific questions raised by the task force relating to the health of man and other animals. In addition to the task force's findings, the void of information has previously been elucidated by the National Academy of Sciences-National Research Council, Committee on Veterinary Drug Efficacy and more recently by the low-level antibacterial drug review completed by the Bureau of Veterinary Medicine. Whenever significant questions are raised about a potential or theoretical hazard, sound scientific data must be provided to resolve the issues.

3. Restricting the therapeutic uses of the antibacterial drugs in feeds to a prescription basis was questioned regarding its practicality and feasibility. The task force recommended and the Food and Drug Administration proposed that an antibacterial drug in animal feeds be restricted to prescription status only if the drug fails to satisfy the criteria dealing with human and animal safety and drug efficacy. Conversely an antibacterial drug which is confirmed to be safe and effective for its intended purpose at subtherapeutic levels will not become subject to the prescription requirement. Acknowledging that very potent drugs are involved, when data indicate hazards at low and intermediate use levels, then the proper course of action appears to be more stringent regulation of the products' use. Assuming that a drug is useful for specific clinical disease(s), it is appropriate to reserve the drug for high-level, short-term use following specific diagnosis of a disease. Restricting the drug to use under prescription requirements would insure the continued availability of a useful product while at the same time limiting the improper use of a product which has exhibited a safety hazard or has failed to show efficacy at subtherapeutic levels.

4. It was stated that administration of drugs to large numbers of individual animals by injection or oral dosage form is not practical and would result in an increase in the cost of production. Accordingly, consumer costs could be expected to increase for a smaller supply of lower quality meat, milk, and eggs. Implementation of the report of the task force would not necessarily preclude the

use of antibacterial drugs in animal feed. It is expected that effective products would continue to be available and the drug industry is actively developing effective and safe new antibacterial drugs. The economic impact, if any, is difficult to quantify. It appears that the implementation of the report would have a favorable long-term economic effect.

5. It was stated by several persons that the proposed time limits should be altered. These included individuals requesting that restrictions be immediately placed into effect, and those who stated that no time limits should be included. The Commissioner has concluded that there is sufficient proof of the safety and effectiveness of the drugs involved to justify continued approval conditioned upon the immediate undertaking of additional tests to confirm safety and effectiveness. This procedure is comparable to that set out in §§ 130.47 and 121.4000 (21 CFR 130.47 and 121.4000). Unless testing is undertaken, however, there is no acceptable basis for continued marketing.

6. Many comments were addressed to the question of the immediacy and seriousness of the human and animal health hazards. These comments ranged from personal opinions to lengthy interpretations of some of the published literature pertaining to potential health hazards. That the task force completely, thoroughly, and objectively reviewed these subjects is evidenced by the documentation reviewed by the task force. In addition, the task force included recognized experts on transferable drug resistance. No additional evidence or data were submitted which would justify a conclusion other than that arrived at by the task force regarding the question of health hazard.

7. One comment stated that it would appear to be illogical to restrict the subtherapeutic use of antibiotics in animal feeds and to continue to allow the reservoir of resistant bacteria, and bacteria which can transfer the resistance factor, to be maintained by therapeutic use of those same antibiotics in animals. It was stated that if there is a public health hazard from administration of low levels, then the same hazard would exist from administration of therapeutic levels. Antibacterial drugs used for therapeutic treatment of clinical disease produce a selection pressure which is high, of short duration, and has a high degree of universal bacterial susceptibility. The converse is true of subtherapeutic levels. The logical conclusion follows that the greatest potential hazard exists with the long-term use of an antibacterial drug at subtherapeutic levels.

8. There was comment that a quantitative guarantee for all low-level antibiotics should not be required in the absence of analytical methods of adequate sensitivity to guarantee their presence in the indicated amounts in feed. Further, it was commented that the variability of analytical results are a potential source of serious problems for industry and regulatory officials. The Commissioner recognizes that the current application of available analytical

procedures to animal feeds containing low levels of antibiotics does not provide a desirable level of precision. However, it is well known that this level of antibacterial drug is capable of selecting for transferable drug resistance determinants. The user should know the level of drug present in the feed that he purchases. The FDA concurs with this conclusion of the task force. In addition, it is recommended that improved analytical procedures be developed. Since this requirement will not be placed into effect until full implementation of the task force report, adequate time will be available for the development of improved methodology.

9. At least one food animal producer offered his own personal experience using subtherapeutic levels of antibacterial drugs in feed. He stated that his animals experienced a number of health problems when rations containing no antibacterial drugs were given. The purpose of the proposed studies is to evaluate the hazard as related to human and animal health as well as the effectiveness of antibacterial drugs for their intended use when considering benefit versus risk. Therefore, effectiveness for the intended purpose will be a major criterion for the continued use of any antibacterial drug intended for use in animal feeds.

The deliberations and actions of the FDA concerning the use of antibacterial drugs in animal feeds are only a part, and perhaps a small part, of the total picture of antibacterial use as it relates to public health. It is logical to assume that the direct use of antibacterial drugs in man has the potential for exerting considerably more impact on the health of man than the impact of antibacterial drug use in food animals. There has been a dramatic increase in the total use of antibacterial drugs in recent years. In 1960, the annual production of antibiotics in the United States was 4.16 million pounds of which 2.96 million pounds was used for therapeutic purposes in human and veterinary medicine and 1.20 million pounds in animal feed additives. Production had doubled by 1965. By 1970, the human and veterinary medical pharmaceutical use was 9.6 million pounds, a threefold increase over 1960, and the feed additive usage was 7.3 million pounds, a sixfold increase over 1960.

Since the continued effectiveness of antibacterial drugs depends in large measure on the extent to which they are reserved for appropriate use on susceptible organisms, and since the indiscriminate or inappropriate use of antibacterials is detrimental to the public health, it is in the national interest to determine with precision how antibiotics are being employed and what steps should be taken by the FDA and medical professions to promote the informed and most appropriate use of these agents. The FDA is presently increasing activities in the assessment of the use of these drugs in man and at the same time the FDA will continue to address the questions before it concerning use of antibacterial drugs in animal feeds.

The task force on the use of antibiotics in animal feeds concluded that the long-term use of subtherapeutic amounts of antibiotics in animal feeds may give rise to a potential (although not fully documented) human and animal health hazard. The task force pointed out, however, and other recognized experts who have been consulted generally agree, that a significant increase in the reservoir of salmonella organisms in food animals constitutes an increased risk to human health. A feed-use drug used on a continuing basis which significantly increases the numbers of salmonella organisms in the animal would logically affect the numbers of salmonella organisms on the animal-derived food products. Therefore, the Commissioner concludes that a significant increase in the salmonella organisms in animals would constitute an increased hazard to human health.

There is less agreement on the hazard to human health presented by other animal-source bacteria (e.g., coliforms). It is generally agreed that there are great difficulties involved in documenting the absence of risk or absolute safety from the potential hazard posed by the colonization and possible R-factor transfer in the human gastrointestinal tract. An effort to assess this potential hazard will require many large-scale studies which will address this hazard as a concept. The possibility of proving the absolute lack of hazard under actual conditions of use is questionable. The probability of the use of an antibacterial drug in animal feed enhancing the pathogenicity of bacteria by linkage of toxin production to R-factor also will be difficult to determine. Nevertheless, the task force has raised these questions and the Commissioner concludes that these theoretical hazards exist and require further study if nontherapeutic use of these drugs in feed is to be continued.

The commercial animal and poultry production practices used in this country today, including the use of medication in feed administered to the entire herd or flock, have made it possible to effectively concentrate large numbers of animals in small areas without serious losses in production efficiency. From such concentration and intensified production, benefits accrue in terms of efficient land usage, labor savings, and more efficient conversion of animal feed to animal protein, thereby making a major contribution to the abundance of food from animals. The Commissioner acknowledges the benefit from such drugs, when properly used, for increased rate of gain, improved feed efficiency, and animal disease control. Immediate and total withdrawal of these drugs from animal feeds could seriously disrupt the quality and quantity of an important portion of our total human diet.

Because of the geographical proximity of the United States and Canada and the international commerce in animal drugs, animal feed, and food between the two countries, it is essential that policies and

requirements on products such as these be uniform. An agreement has been reached which will allow for similar actions, based on similar timetables to be initiated by the Food and Drug Administration and the agency's counterpart in Canada, the Health Protection Branch. The two nations have also agreed to form a joint United States-Canada committee to review major questions which may arise in the course of evaluating study proposals submitted by drug sponsors.

The Commissioner has reviewed the information and conclusions in the report of the task force, the comments submitted in response to the proposal, the deliberations of a committee subsequently appointed by the National Academy of Sciences-National Research Council under the chairmanship of Maxwell Finland, M.D., to consider the same matter, conferences with Canadian Health officials, and other data and information available to him, in determining whether new evidence or tests, evaluated together with the evidence available when the new animal drug applications for these drugs were approved, shows that any or all of them are not shown to be safe for use under the conditions of use upon the basis of which the applications were approved, and thus should be withdrawn from use pursuant to section 512(e) (1) (B) of the act. The concept of "safety" as used in the act does not require complete certainty of the absolute harmlessness of a drug, but rather the reasonable certainty in the minds of competent scientists that it is not harmful, when balanced against the benefits to be obtained from the drug. Using these criteria, the Commissioner concludes, upon the basis of all of the evidence currently available, that these drugs have been shown to be safe under the conditions of use, within the meaning of that term as used in section 512 of the act, and thus that there is presently no basis for withdrawing any of these drugs solely on safety grounds under section 512(e) of the act.

The Commissioner recognizes that the task force report recommended withdrawal of the drugs by certain specific target dates. Those target dates are not adopted in the final regulation for two reasons. First, establishment of the testing requirements to be imposed with respect to these drugs has been far more complex than the task force realized, and therefore has taken far longer than initially contemplated. Second, in the absence of a finding of a lack of proof of safety, or failure to submit required reports, there is no legal basis for a decision arbitrarily to withdraw these drugs from the market. If the task force had found a lack of proof of safety of these drugs, withdrawal of approval would have been required immediately rather than permitting continued manufacture, absent a finding of a compelling medical justification for these products.

The Commissioner recognizes that difficult questions exist with respect to the benefit-risk analysis necessary in determining whether the safety evidence

is sufficient to approve or insufficient to justify continued approval of the safety of any drug. Questions about potential and theoretical hazard, of the nature raised with respect to the use of antibacterials in animal feed for growth promotion purposes, continually arise and obviously deserve serious consideration. Where these questions indicate a serious health hazard, withdrawal should immediately be ordered. Where, as here, only a potential or theoretical hazard is raised, which does not show that the drug is not shown to be safe, it is the opinion of the Commissioner that the proper way to proceed is to require the submission of appropriate records and reports pursuant to section 512(1) of the act, to facilitate a determination whether there is a ground for withdrawing approval of the drug in question under section 512(e) of the act. Failure to submit such required records and reports is itself a violation of the act, justifying withdrawal of approval of the drug for the manufacturer or distributor involved.

It would be chaotic, and is clearly not feasible, to withdraw approval of all food or drug substances merely because new questions have arisen, new testing is considered scientifically appropriate, or new studies raise issues that require further exploration. That is the situation involved here. The Commissioner has therefore concluded that, while there is insufficient evidence or questions to justify a finding that these drugs have not been shown to be safe, there is sufficient question to invoke the authority under section 512(1) fully to investigate these issues in order to obtain more definitive data to resolve them. The Commissioner has chosen the following course of action.

1. The antibacterial drugs commonly used in animal feed and which are recognized to cause transferable drug resistance and are commonly used to treat human and animal diseases include the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin. The use of these drugs in feeds may also affect the reservoir of salmonella organisms in food animals. An assessment of the effect of subtherapeutic levels of these drugs in feed on the salmonella reservoir can be completed in a relatively short time. Therefore, continued marketing of products containing any of these named drugs will be dependent on completion of salmonella reservoir studies by no later than 1 year following the effective date of this order. A determination that the drug promotes a significant increase in the salmonella reservoir will be considered sufficient grounds for proceeding to withdrawal approval of that drug.

2. The approval for the use of antibiotic and sulfonamide drugs in animal feeds at subtherapeutic levels will be withdrawn, unless by no later than 2 years following the date of this order there has been submitted conclusive evidence demonstrating that no human or animal health hazard exists which can be attributed to such use. Depending on

the scientific knowledge available at that time concerning (1) the colonization and R-factor transfer from animals to man, and (2) increased pathogenicity due to toxin-linkage with R-factor, the Commissioner may require further investigations of these or any other pertinent questions as a condition of continued approval of such use notwithstanding a finding that no apparent human health hazard exists.

3. By no later than 2 years following the effective date of this order, all drug efficacy data shall be submitted for any feed-use combination product containing an antibiotic or sulfonamide drug and any feed-use single ingredient antibiotic or sulfonamide product not reviewed by the National Academy of Sciences-National Research Council drug efficacy study covering drugs marketed between 1938 and 1962.

Criteria for demonstrating safety and efficacy of a product under this approach have been developed by the FDA for use by firms wishing to undertake studies, and are available upon request.

This course of action and the criteria referred to have been reviewed in joint consultation between the agency and officers of the Canadian Health Protection Branch in order to facilitate the development of a policy generally applicable to both countries.

The Commissioner recognizes the difficulty of establishing conclusively within 2 years that no human health hazard exists from subtherapeutic use in animal feeds of antibacterial drugs. Balanced against this difficulty is the fact that every expert committee that has reviewed this issue has concluded in general terms that a potential or theoretical human health hazard exists. The Commissioner therefore concludes that the 2-year time period is reasonable under the circumstances. The Commissioner further concludes that continued marketing after 2 years is contingent upon a favorable benefit-risk status following a thorough evaluation of all the data submitted to date on the particular product.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351; 21 U.S.C. 360b, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), part 135 is amended by adding thereto the following new section:

§ 135.109 Antibiotic and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than 2 years following the effective date of this order, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their ef-

fectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic and sulfonamide drugs pursuant to section 512(1) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides, and for all other antibiotic and sulfonamide drugs, by October 17, 1973. The Food and Drug Administration encourages sponsors to consult with the Bureau of Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to immediately withdraw approval.

(3) By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir, for any antibiotic or sulfonamide drugs approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic or sulfonamide not reviewed by the National Academy of Sciences-National Research Council drug efficacy study covering drugs marketed between 1938 and 1962.

(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in subparagraphs (b) (1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal feeds under section 512(1) of the act in the case of failure to submit required records and reports and under

RULES AND REGULATIONS

section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Bureau of Veterinary Medicine, 5600 Fishers Lane, Rockville, Md. 20852.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Bureau of Veterinary Medicine, Office of the Assistant to the Director for Antibiotics in Animal Feeds, 5600 Fishers Lane, Rockville, Md. 20852.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

Effective date.—This order shall be effective on April 20, 1973.

(Secs. 512, 701(a), 62 Stat. 1055, 82 Stat. 343-51; 21 U.S.C. 360b, 371(a).)

Dated April 16, 1973.

SHERWIN GARDNER,
Acting Commissioner of
Food and Drugs.

[FR Doc.73-7555 Filed 4-19-73;8:45 am]

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

Exempt Chemical Preparations

The Director of the Bureau of Narcotics and Dangerous Drugs has received applications pursuant to § 308.23 of title 21 of the Code of Federal Regulations requesting that several chemical preparations containing controlled substances be granted the exemptions provided for in § 308.24 of title 21 of the Code of Federal Regulations.

The Director hereby finds that each of the following chemical preparations and mixtures is intended for laboratory, industrial, education, or special research purposes, is not intended for general administration to a human being or other animal, and either (a) contains no narcotic controlled substance and is packaged in such a form or concentration that the package quantity does not present any significant potential for abuse, or (b) contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse. If the preparation or mixture contains a

narcotic controlled substance, the preparation or mixture is formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused, and so that the narcotic substance cannot in practice be removed. The Director further finds that exemption of the following chemical preparations and mixtures is consistent with the public health and safety as well as the needs of researchers, chemical analysts, and suppliers of these products.

Therefore, under the authority vested in the Attorney General by sections 301 and 501(b) of the Comprehensive Drug

Abuse Prevention and Control Act of 1970 (21 U.S.C. 821 and 871(b)) and delegated to the Director of the Bureau of Narcotics and Dangerous Drugs by § 0.100 of title 28 of the Code of Federal Regulations, the Director hereby orders that part 308 of title 21 of the Code of Federal Regulations be amended as follows:

a. By amending § 308.24(i) by adding the following chemical preparations:

§ 308.24 Exempt chemical preparations.

(i) * * *

Manufacturer or supplier	Product name and supplier's catalog No.	Form of product	Date of application
American Hospital Supply Corp. (Dade Division)	Fibrin Monomer Control, Catalog Nos. B4233-30 and B4233-33	Bottle: 1.5 ml.	Feb. 10, 1973
Do	Mont-Trol I-X (Normal Range), Catalog Nos.		
	B5106-1	Vial: 5 ml.	
	B5106-5	Vial: 10 ml.	Mar. 13, 1973
	B5106-3	Bottle: 25 ml.	
Do	Mont-Trol II-X (Abnormal Range), Catalog Nos.		
	B5106-2	Vial: 5 ml.	Do.
	B5106-6	Vial: 10 ml.	
	B5106-4	Bottle: 25 ml.	
Do	Thyroxine Buffer No. B5630-2	Bottle: 55 ml.	Jan. 23, 1973
Do	Thyroxine Buffer No. B5630-6	Bottle: 245 ml.	Do.
Analytical Chemists, Inc.	Sodium Barbitol Buffer, Catalog Nos. 1-5100 and 1-5200	Vial: 20.6 g.	Aug. 14, 1973
Do	Agarose Universal Electrophoresis Film, Catalog No. 1-1000	Plate: 5 ml.	Do.
Bio-Reagents & Diagnostics, Inc.	Prochex No. 700-025	Vial: 25 ml.	Mar. 8, 1973
Do	Prochex No. 1, No. 701-025	do.	Do.
Do	Prochex No. 1 (Alternate Formula) No. 702-025	do.	Do.
Do	Prochex No. 2, No. 703-025	do.	Do.
Do	Prochex No. 3, No. 704-025	do.	Do.
Do	Prochex No. 4, No. 705-025	do.	Do.
Do	Prochex No. 5, No. 706-025	do.	Do.
Do	Prochex No. 6, No. 707-025	do.	Do.
Do	Prochex No. 7, No. 708-025	do.	Do.
Do	Prochex No. 8, No. 709-025	do.	Do.
Bio-Reagents & Diagnostics, Inc.	Prochex No. 9, No. 710-025	do.	Do.
Do	Prochex No. 10, No. 711-025	do.	Do.
Do	Prochex No. 10 (Alternate Formula) No. 712-025	do.	Do.
Do	Prochex No. 11, No. 713-025	do.	Do.
Do	Prochex No. 12, No. 714-025	do.	Do.
Do	Prochex No. 13, No. 715-025	do.	Do.
Do	Prochex No. 14, No. 716-025	do.	Do.
Do	Prochex No. 15, No. 717-025	do.	Do.
Do	Prochex No. 15, (Alternate Formula) No. 718-025	do.	Do.
Do	Prochex No. 16, No. 719-025	do.	Do.
Do	Prochex No. 18, No. 721-025	do.	Do.
Do	Prochex No. 19, No. 722-025	do.	Do.
Do	Prochex No. 20, No. 723-025	do.	Do.
Brinkmann Instruments, Inc.	Brinkmann Drug Screen Standard A	Vial: 1 ml.	Jan. 20, 1973
Do	Brinkmann Drug Screen Standard B	do.	Do.
Do	Brinkmann Drug Screen Standard C	do.	Do.
Do	Brinkmann Drug Screen Standard D	do.	Do.
E. R. Squibb & Sons, Inc.	Thyrotat-4 Kit, Catalog No. 09125		Feb. 23, 1973
	To include:		
	(a) Thyrotat-4 Standard Solution	Vial: 7 ml.	
	(b) Thyrotat-4 Buffer Solution	Bottle: 60 ml.	
Instrumentation Laboratory, Inc.	Tris-Barbitol Buffer No. 33205	Vial: 12 dram.	Feb. 21, 1971
Do	Barbitol Buffer (B-2) No. 33206	do.	Do.
Do	EDTA-Barbitol Buffer No. 33207	do.	Do.
Do	Barbitol-Acetate Buffer No. 33208	do.	Do.
Millipore Corp.	Barbitol Buffer Solution No. XE21-000-42	Bottle: 120 ml.	Jan. 12, 1973

b. By amending § 308.24(i) by deleting the following chemical preparation:

§ 308.24 Exempt chemical preparations.

(i) * * *

Manufacturer or supplier	Product name and supplier's catalog No.	Form of product	Date of application
American Hospital Supply Corp. (Dade Division).	Thyroxine Buffer No. B6630-1	Bottle: 5 ml	Aug. 16, 1971

Effective date.—This order is effective on April 20, 1973. Any interested person may file written comments on or objections to the order on or before June 19, 1973. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Director shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Director shall reinstate, revoke, or amend his original order as he determines appropriate.

Dated April 12, 1973.

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

[FR Doc.73-7552 Filed 4-19-73;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL
PROTECTION AGENCY

SUBCHAPTER E—PESTICIDE PROGRAMS

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Benomyl

A petition (PP 2F1291) was filed by E. I. du Pont de Nemours & Co., Inc., Wilmington, Del. 19898, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), proposing establishment of tolerances for residues of the fungicide benomyl (methyl 1-(butylcarbamoyl)-2-benzimidazolecarbamate) in or on the raw agricultural commodities blackberries, boysenberries, dewberries, loganberries, and raspberries at 7 parts per million.

Subsequently, the petitioner amended the petition by proposing that the tolerances for benomyl be expressed as "combined residues of benomyl and its metabolites containing the benzimidazole moiety (calculated as benomyl)".

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

1. The fungicide is useful for the purpose for which the tolerances are being established.
2. There is no reasonable expectation of residues in eggs, meat, milk, or poultry, and § 180.6(a) (3) applies.
3. The tolerances 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 FR 15623), and the authority delegated by

the Administrator to the Deputy Assistant Administrator for Pesticide Programs (36 FR 9038), § 180.294 is amended by adding a new paragraph "7 parts per million * * *", after the paragraph "10 parts per million * * *", as follows:

§ 180.294 Benomyl; tolerances for residues.

7 parts per million in or on blackberries, boysenberries, dewberries, loganberries, and raspberries.

Any person who will be adversely affected by the foregoing order may, on or before May 21, 1973, file with the Hearing Clerk, Environmental Protection Agency, room 3902A, 4th and M Streets SW., Waterside Mall, Washington, D.C. 20460, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date.—This order shall become effective April 20, 1973.

(Sec. 408(d) (2), 68 Stat. 512; 21 U.S.C. 346a(d) (2).)

Dated April 16, 1973.

HENRY J. KORB,
Deputy Assistant Administrator
for Pesticides Programs.

[FR Doc.73-7685 Filed 4-19-73;8:45 am]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Cyprazine and 2-[[4-Chloro-6-(Ethylamino)-s-Triazin-2-Yl]Amino]-2-Methylproprionitrile; Republication

Two documents (FR Docs. 71-15678 and 71-15679) were published in the FEDERAL REGISTER of Thursday, October 28, 1971 (36 FR. 20687-8), establishing tolerances for residues of the herbicides cyprazine (§ 420.306) and 2-[[4-chloro-6-(ethylamino)-s-triazin-2-yl] amino]-2-methylproprionitrile (§ 420.307). At that time, this Agency's pesticide regulations were under title 21, chapter III, part 420 of the Code of Federal Regulations. Effective in the FEDERAL REGISTER of November 25, 1971 (36 FR 22369), the pesticide regulations were

transferred to title 40, chapter I, subchapter E, part 180 of the Code of Federal Regulations. The two aforesaid herbicides, however, were inadvertently omitted from the transfer and thus did not appear in either the November 25, 1971 issue of the FEDERAL REGISTER (36 FR 22540-73) or in the 1972 Code of Federal Regulations.

Therefore, the two regulations establishing tolerances for the subject herbicides are hereby republished for inclusion in the Code of Federal Regulations under the headings of this document, as follows:

§ 180.306 Cyprazine; tolerances for residues.

A tolerance of 0.1 part per million is established for negligible residues of the herbicide cyprazine (2-chloro-4-cyclopropylamino-6-isopropylamino-s-triazine) in or on the raw agricultural commodities fresh corn including sweet corn (kernels plus cob with husk removed), corn grain, and corn fodder and forage.

§ 180.307 2-[[4-Chloro-6-(ethylamino)-s-triazin-2-yl] amino]-2-methylproprionitrile; tolerances for residues.

A tolerance of 0.05 part per million is established for negligible residues of the herbicide 2-[[4-chloro-6-(ethylamino)-s-triazin-2-yl]amino]-2-methylproprionitrile in or on the raw agricultural commodities fresh corn including sweet corn (kernels plus cob with husk removed), corn grain, and corn fodder and forage.

Since this order merely provides for the republication of two previously published orders and since this matter is noncontroversial, notice, public procedure, and delayed effective date are not prerequisites to this promulgation.

Effective date.—This order shall become effective April 20, 1973.

Dated April 16, 1973.

HENRY J. KORB,
Deputy Assistant Administrator
for Pesticide Programs.

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PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Ethephon

Three petitions were filed by Amchem Products, Inc., Ambler, Pa. 19002, in accordance with provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), proposing establishment of pesticide tolerances for residues of the plant regulator ethephon ((2-chloroethyl) phosphonic acid) in or on the raw agricultural commodities, cherries at 10 parts per million, and tomatoes at 2 parts per million (PP 3F1321), grapes at 5 parts per million, and cantaloupes at 2 parts per million (PP 2F1275), and a food additive tolerance for residues in or on the processed food raisins at 10 parts per million (FAP 2E5018).