The tax credit reductions in 26 U.S.C. 3302(c)(3) are inapplicable when the conditions of 20 CFR 601.5(f) are met. Since the reductions apply to advances made to States from the Federal Unemployment Account in the Unemployment Trust Fund which are outstanding on January 1 of a taxable year and remain outstanding on November 10 of that year, and since Congress has directed the Secretary to promptly prescribe and publish in the FEDERAL REGISTER regulations implementing section 110 (a) of the Act, I find there is good cause to make the benefit conferred by this amendment effective immediately upon publication in the FEDERAL REGISTER.

Accordingly, 20 CFR Part 601 is amended by adding to § 601.5 a new paragraph (f) as set forth below.

Effective date. 20 CFR Part 601 is amended effective November 7, 1975.

Signed at Washington, D.C. this 4th day of November, 1975.

WILLIAM H. KOLBERG,
Assistant Secretary for Manpower.

Part 601 of Title 20, Code of Federal Regulations, is amended by adding to § 601.5 a new paragraph (f) to read as follows:

§ 601.5 Withholding payments and certifications.

* * * * *

(f) *Tax credit reductions.* (1) Section 3302(c)(3) of the Internal Revenue Code of 1954 prescribes the conditions under which the total credits otherwise allowable under section 3302 for a taxable year in the case of a taxpayer subject to the unemployment compensation law of a State shall be reduced on account of an outstanding balance of advances made to the State pursuant to Title XII of the Social Security Act. As amended by section 110(a) of the Emergency Compensation and Special Unemployment Assistance Extension Act of 1975 (Pub. L. 94-45, approved June 30, 1975; 89 Stat. 236, 239), the incremental reductions in total credits will not apply to a State with respect to each of the taxable years beginning on January 1, 1975, January 1, 1976, and January 1, 1977, if the Secretary of Labor finds as to such year or years that the State has studied and taken appropriate action with respect to the financing of its unemployment compensation program so as substantially to accomplish the purpose of restoring the fiscal soundness of the State's unemployment account in the Unemployment Trust Fund and permitting the repayment within a reasonable time of any advances made to the State's account pursuant to Title XII of the Social Security Act.

(2) The Secretary of Labor's finding with respect to a State as to any of the taxable years 1975, 1976, and 1977, will be based on his determination as to whether the State has taken appropriate action resulting in—

(i) Amendment of its unemployment compensation law, effective in or prior to the taxable year with respect to which the finding is made, or effective at the beginning of the succeeding taxable year, increasing the State's unemployment tax rate, increasing the State's unemployment tax base, or changing the State's experience rating formula, or a combination of such changes, so as to be estimated by the Secretary to achieve for the taxable year with respect to which the finding is made or for the period following the effective date of the amendment—

(A) An average employer tax rate, computed as a percentage of the total wages in employment covered by the State's unemployment compensation law, which exceeds the State's average annual benefit cost rate, computed as a percentage of the total wages in employment covered by the State's unemployment compensation law, for the ten calendar years immediately preceding the year with respect to which the finding is made; and

(B) An effective minimum employer tax rate which is not less than 1.0 percent of the wages of any employer which are subject to tax under the Federal Unemployment Tax Act for the same year; and

(C) An effective maximum employer tax rate which exceeds 2.7 percent of the wages of any employer which are subject to tax under the Federal Unemployment Tax Act for the same year, or provision for no reduced rate of contributions for any employer subject to the State unemployment compensation law; or

(ii) (A) Amendment of its unemployment compensation law increasing the State's unemployment tax rate, increasing the State's unemployment tax base, or changing the State's experience rating formula, or a combination of such changes, so as to be estimated by the Secretary of Labor to result in increasing contributions to the State's unemployment fund, for the taxable year with respect to which the finding is made, and the allocation from such increased contributions of a sum sufficient to make the repayment in the amount and within the time limit prescribed in paragraph (f)(2)(ii)(B) of this section; and

(B) Repayment to the Treasury of the United States, for credit to the Federal unemployment account in the Unemployment Trust Fund, prior to November 10 of the taxable year with respect to which the finding is made, of an amount equal to the amount of the additional tax which would be payable by all taxpayers subject to the unemployment compensation law of the State for that taxable year if the reduction in total credits prescribed by section 3302(c)(3) of the Internal Revenue Code of 1954 for that taxable year was applied without regard to the amendment added by section 110(a) of the Emergency Compensation and Special Unemployment Assistance Extension Act of 1975. The amount determined under the preceding sentence shall be reduced by the amount of any additional tax payable for that taxable year by taxpayers subject to the unemployment compensation law of the State by reason of the reduced credit provisions of section 3302(c)(3) of the Internal Revenue Code of 1954, as amended by section 110(a) of the Emergency Compensation and Special Unemployment Assistance Extension Act of 1975.

(3) A finding by the Secretary of Labor with respect to any State shall be made as of November 10 of the taxable year with respect to which the finding is made, and such finding shall be published in the FEDERAL REGISTER together with the reasons for the finding.

[FR Doc.75-30059 Filed 11-6-75;8:45 am]

Title 21—Food and Drugs

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

SUBCHAPTER C—DRUGS: GENERAL

[Docket No. 75N-0293]

PART 201—LABELING

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

Drug Listing Act of 1972; Revision of Implementing Regulations

In a notice published in the FEDERAL REGISTER of September 5, 1974 (39 FR 32146), the Commissioner of Food and Drugs proposed to amend the regulations (21 CFR Part 132, recodified as 21 CFR Part 207 in the FEDERAL REGISTER of March 27, 1975 (40 FR 13996)) implementing the Drug Listing Act of 1972 to: (1) adopt the single character "N" to replace the present NDC (National Drug Code) prex; (2) permit the NDC number to appear as part of and contiguous to the grocery UPC (Universal Product Code) symbol wherever such symbol appears on consumer packages for over-the-counter drugs in addition to the placement as stated in § 132.8(b)(3)(i) (recodified as § 207.35(b)(3)(i)); (3) clarify that a list of drugs containing a particular active ingredient will be available for public disclosure; and (4) delete the requirement that the prefix "NDC" or "N", as the proposed prefix, be in a different color or different type style (front) from that used to print the NDC number if the label is printed rather than typewritten. This proposal was in response to a petition filed by Bristol-Myers Company of New York, N.Y. Interested persons were invited to submit comments on the proposal by November 4, 1974.

The Commissioner is now issuing a final regulation that permits the NDC number to appear as part of and contiguous to the UPC symbol wherever the symbol appears on consumer packages for over-the-counter drugs. When the UPC symbol appears prominently and in a conspicuous place, other than on the natural bottom of the immediate or outside container or wrapper, and the NDC num-

ber appears as part of and contiguous to the symbol, this placement will be regarded as meeting the labeling requirements of section 502(c) of the Federal Food, Drug, and Cosmetic Act as to prominence and conspicuousness. Whenever the NDC number is used on a label or in the labeling of a drug product, either alone or as part of and contiguous to the UPC symbol, it must be preceded by either the prefix "NDC" or "N." Under this final regulation, it is no longer necessary for the prefix to the NDC number to be in a different color or different type style (font) from that used to print the number, if the label is printed rather than typewritten. Also under this final regulation, a list of drugs containing a particular active ingredient will be regarded as information available for public disclosure.

Because 21 CFR Part 132 was recodified as 21 CFR Part 207 since the proposal was published, where specific sections and paragraphs of the proposed regulation are cited in the comments in this preamble the recodified number is used.

In response to the proposal, comments were received from 14 manufacturers, 3 trade associations, and 2 members of the Drug Ad Hoc Committee. The Commissioner has reviewed all of the comments. A summary of the comments and the Commissioner's conclusions are as follows:

1. One comment stated that the proposal should be reissued to convey that the petition was actually a recommendation of the Drug Ad Hoc Committee. The comment further stated that without such indication, significant support for the petition by representative drug industry groups would not be apparent to readers of the FEDERAL REGISTER.

The Commissioner disagrees with that contention. The proposal stated that the petition was filed by Bristol-Myers Company, a major drug manufacturer, and that copies of the petition were available to the public. Although the Drug Ad Hoc Committee (a private association of drug manufacturers) supported the recommendation, it was not indicated as being a co-petitioner. According to the petition, the recommendation was also supported by other trade associations. The Commissioner concludes that omission in the proposal of a statement that the petition was developed and endorsed by the Drug Ad Hoc Committee was not misleading to anyone reading the proposal as to the type of party supporting the proposed changes. The Commissioner concludes that the comments set forth issues that would undoubtedly have been raised regardless of who supported the recommendations of the petition; therefore, he does not find a compelling reason to reissue the proposal in the FEDERAL REGISTER.

2. Several comments asserted that adoption of the proposal would be extremely costly and time consuming in view of the necessity of revising printing plates, redesigning labels and disgarding the present inventory of printed labels. The comments argued that many firms have already placed the NDC prefix on their labels in accordance with regulations previously promulgated by the Food and Drug Administration. To compel industry members to again expend considerable sums of money for new label plates introduces an inflationary element without any redeeming features. The comments further suggested that industry be given the option to use either the prefix "NDC" or "N." This would remove the burden on companies in complying with current regulations and fulfill the objectives of this proposed change. These comments suggested that, if such an option is rejected, effective dates for the proposed change to be from 1 to 5 years from the date of publication of the final regulation or whenever existing label plates are revised, whichever comes first. The comments also suggested that, if the option was not allowed, there be a provision for intermixing the prefixes "NDC" and "N" during the transition period.

The Commissioner recognizes that many firms did revise their labeling, or are in the process of doing so, to include the NDC number in the format set forth by the implementing regulations to the Drug Listing Act of 1972. He has also considered the economic impact that the requirements of this regulation will have on industry. The Commissioner concludes that to provide compatibility with the UPC and to remove the burden of additional labeling expenditures from firms who are currently complying with the implementing regulations of the Drug Listing Act of 1972, the final regulation should allow the NDC number, when used alone or as part of and contiguous to the UPC symbol, to be preceded by either the prefix "NDC" or "N" whenever the NDC number is used on a label or in the labeling of a drug product. He also concludes that the prefix used for a drug product should be used consistently on the label of the immediate container, outer container, or wrapper, if any, and other labeling for that drug product. Section 207.35(b)(3)(ii) has been revised accordingly. To provide firms time to comply with these requirements regarding use of the prefix "NDC" or "N," the final regulation provides that current labeling shall be revised on or before November 7, 1977, or at the next revision of printing plates in the normal course of business, whichever occurs first.

3. Several comments expressed the view that any revision of the implementing regulations for the Drug Listing Act of 1972, with regard to the NDC number, should specify that section 502(c) of the Federal Food, Drug, and Cosmetic Act should be considered satisfied as to "prominence" and "conspicuousness" when the placement of the NDC number as an integral part of the UPC symbol appears in labeling or on the package in a prominent location other than the natural bottom of the package. Comments stated that the adoption of such a provision would encourage the use of NDC and HRI numbers by those companies who plan to otherwise utilize the UPC symbol. If such a provision is rejected, firms may be reluctant to provide labeling space on products for an NDC number, in addition to space already provided for a UPC symbol.

The Commissioner agrees with the comment and advises that it is the policy of the Food and Drug Administration to encourage use of the NDC number on all drug product labels and labeling. To ensure that this regulation reflects this policy, compatability with the UPC must be achieved, where possible. The Commissioner recognizes that the UPC was developed for products sold in retail establishments, i.e., products directly available to consumers, including over-the-counter drug products, as opposed to prescription drug products which are dispensed by a pharmacist in a retail establishment. He also recognizes that the guidelines for placing the UPC symbol on a consumer package suggest locations that will be compatible with checkout counter operations and that such locations may differ from the one required for the NDC number when used alone on a drug product label. Therefore, the Commissioner concludes that, for over-the-counter drug products, the requirements of section 502(c) of the Federal Food, Drug, and Cosmetic Act regarding prominence and conspicuousness will be satisfied if the NDC number, preceded by the prefix "NDC" or "N," appears as part of and contiguous to the UPC symbol and the symbol is displayed in a prominent and conspicuous location other than the natural bottom of the drug product package.

4. One comment stated that § 207.35(b)(3)(i) clearly indicates that the placement of the NDC number on the label of the immediate container must be in the top third of the center panel, but its intended location on the outer container or wrapper is not clearly defined since an outer container such as a carton has no "center panel." The comment suggested that if the location for an outer container is intended to be on the main panel this might be clarified by using the term "principal display panel."

The Commissioner has reviewed the wording of § 207.35(b)(3)(i) and concludes that the term "principal display panel" should be used to indicate the location of the NDC number on both the immediate and outer container or wrapper. The term "center panel" has been deleted. Therefore, whenever the NDC number is voluntarily placed on a label, it shall be placed prominently in the top third of the principal display panel of the immediate container and of the outer container or wrapper, if there is one. To assure compatibility with the UPC symbol location guidelines, where possible, and to comply with the requirements of the act regarding prominence and conspicuousness, the UPC symbol shall be placed prominently and in a conspicuous location other than the natural bottom of the immediate container and of the outer container or wrapper, if any, when the NDC number appears as part of and contiguous to this symbol for over-the-counter drug products. The term "principal display panel" as it applies here

means that part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display to the consumer (for over-the-counter drug products) or to the dispenser (for prescription drug products). Section 207.35(b)(3)(i) has been revised accordingly.

5. One comment expressed concern as to how the Food and Drug Administration proposed to deal with those manufacturers of health-related items who have adopted the HRI prefix for their product labeling. The comment recognized that the use of the HRI prefix was entirely voluntary.

The Commissioner advises that, although the use of the NHRIC (National Health Related Items Code) number is voluntary and not subject to this regulation, either the prefix "HRI" or "H" may precede the NHRIC number when such a number is placed on the label of a product listed under the NHRIC System. Specific questions relating to the use of the NHRIC number and its prefix should be directed to the Food and Drug Administration, Bureau of Medical Devices and Silver Spring, MD 20910.

6. One comment saw little or no rationale for separately identifying HRI codes from NDC codes with an "H" and "N" respectively. The comment further stated that the original intention of the letters NDC and HRI was strictly to distinguish this code from other numbers on packages and suggested that an "N" would be sufficient to identify both NDC and HRI codes. Another comment pointed out that the single character prefixes "N" and "H" were structurally very similar and would lead to more confusion than using the prefixes "NDC" and "HRI," which are sufficiently different to permit adequate distinction between them.

As stated in the preamble to the proposal, products listed in compliance with the Drug Listing Act of 1972 and products listed under the National Health Related Items Code System comprise two separate operating systems. At the present time, separate publications would be issued if the code numbers used to represent the products in these two systems are published. To facilitate identification of a product from its code number by reference to a published list of such code numbers, it would be necessary to know whether the code number represented a drug product or a health-related item. Although the code formats for drug products and health-related items differ, this is not considered to be the most desirable method of identifying these two categories of products. Thus, although the use of the single prefix "N" to designate both NDC and HRI codes would be sufficient for distinguishing these codes from other numbers on packages, it would not provide adequate information from which a person could determine the proper list of codes. The Commissioner, therefore, concludes that the NDC number should be preceded by either the prefix "NDC" or "N" and the NHRIC number should be preceded by either the prefix "HRI" or "H." The Commissioner rejects the comment that the prefixes "N" and "H" would lead to confusion because of their similarity in structure.

7. One comment requested the Food and Drug Administration interpretation of section 502(c) of the act relating to conspicuous placement of any information required to appear on drug labels and § 207.35(b)(3) of the current regulations, which states that the NDC number is requested but not required to appear on all drug labels and in all drug labeling. The comment also requested a restatement of the reasons why the NDC number is not appropriate as an integral part of the UPC symbol.

The Commissioner recognizes that placement of the NDC number on the label or in the labeling of a drug product is voluntary; however, if the NDC number is shown on a drug product label, the regulation sets forth the requirements for the position and format of the NDC number. Therefore, if a firm chooses to place the NDC number on a drug product label, the requirements of § 207.35(b)(3) shall be complied with. These requirements are consistent with section 502(c) of the act as to prominence and conspicuousness.

As previously stated in paragraph 3 above, the NDC number may be included as part of and contiguous to the UPC symbol provided the symbol is displayed prominently and in a conspicuous location other than the natural bottom of the drug product package.

8. In regard to proposed § 207.37(a)(2)(iii), which would clarify that a list of drugs containing a particular active ingredient will be available for public disclosure, one comment contended that section 510(f) of the Federal Food, Drug, and Cosmetic Act requires that a denial of the confidential status of a list of drugs containing a particular ingredient must be based upon a specific finding that it would be inconsistent with the protection of the public health and that the proposal did not relate any such finding. The comment refers to a letter of December 22, 1971, from the Assistant General Counsel of the Department of Health, Education, and Welfare, Food and Drug Division, to the Senate Committee considering H.R. 9936, in which the type of information the Food and Drug Administration intended for disclosure and nondisclosure is discussed. The comment stated that in listing the types of information subject to disclosure, a list of drugs containing a particular active ingredient was conspicuously absent. For the Commissioner now to state that § 207.37(a)(2)(iii) was never intended to prevent public disclosure of lists of drugs containing a particular active ingredient, according to the comment, is a complete departure from the position stated in the legislative history.

The Commissioner does not concur with this comment. Section 510(f) of the Federal Food, Drug, and Cosmetic Act permits the Secretary to disclose information where confidentiality would be inconsistent with protection of the public health and is intended to permit greater public disclosure, rather than greater confidentiality of product information. Section 502(e) of the act requires that the established name of each active ingredient be stated on the label of a drug product; therefore, such information has been previously disclosed to the public, and a list of drugs containing a particular active ingredient would be available for public disclosure. In active ingredients, except those named in section 502(e) of the act, are not required to be stated on the label of a drug product, may not have previously been disclosed to the public, and are, therefore, not available for public disclosure. Section 207.37 has been amended to clarify this point.

9. In addition to amending Part 207, the Commissioner is also amending Subpart A of Part 201 by establishing a new § 201.2 *Drugs and devices; National Drug Code numbers* to include under the labeling provisions of Chapter I of Title 21 of the Code of Federal Regulations a reference to the requirements regarding the use of National Drug Code numbers in the labeling of drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 506, 507, 510, 512, 701(a), 704, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055, 1057 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 76 Stat. 794 as amended, 82 Stat. 343–351 (21 U.S.C. 321, 352, 355, 356, 357, 360, 360b, 371(a), 374)); the Public Health Service Act (sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262)); and the Drug Listing Act of 1972 (Public Law 92–387; 86 Stat. 559–562) and under authority delegated to the Commissioner (21 CFR 2.120), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. In Part 201, Subpart A is amended by adding a new section to read as follows:

§ 201.2 Drugs and devices; National Drug Code numbers.

The National Drug Code (NDC) number is requested but not required to appear on all drug labels and in all drug labeling, including the label of any prescription drug container furnished to a consumer. If the NDC number is shown on a drug label, it shall be displayed as required in § 207.35(b)(3) of this chapter.

2. In Part 207:

a. Section 207.35 is amended by revising paragraph (b)(3)(i), (ii), and (iii) to read as follows:

§ 207.35 Notification of registrant; drug establishment registration number and drug listing number.

* * * * *

(b) * * *

(3) * * *

(i) The NDC number shall be placed prominently in the top third of the principal display panel of the label of the immediate container and of the outside container or wrapper, if any. However, the NDC number may appear as part of and contiguous to the UPC (Universal Product Code) symbol for over-the-counter drug products if such symbol appears prominently and in a conspic-

uous location, other than the natural bottom, of the immediate container and of the outside container or wrapper, if any. The term "principal display panel," as used in this paragraph, means that part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display to the consumer (for over-the-counter drug products) or to the dispenser (for prescription drug products).

(ii) The NDC number shall be preceded by either the prefix "NDC" or "N" whenever it is used on a label or in labeling. The prefix used for a drug product shall be used consistently on the label of the immediate container, outside container or wrapper, if any, and on other labeling for that drug product.

(iii) The Product-Package Code configuration shall be indicated and the segments of the number shall be separated by a dash, e.g., NDC 15643–542–12 or N 15643–542–12.

* * * * *

b. Section 207.37 is amended by adding a new paragraph (a)(1)(x), and by revising paragraph (a)(2)(iii) to read as follows:

§ 207.37 Inspection of registrations and drug listings.

(a) * * *

(1) * * *

(x) A list of drug products containing a particular active ingredient.

(2) * * *

(iii) A list of drugs containing a particular inactive ingredient.

* * * * *

Effective date. This regulation shall become effective on December 8, 1975, except that the effective date for revising current labeling to comply with § 207.35 (b)(3)(ii) regarding the use of the prefix "NDC" or "N" shall be November 7, 1977, or at the next revision of printing plates in the normal course of business, whichever occurs first.

(Secs. 201, 502, 505, 506, 507, 510, 512, 701(a), 704, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055, 1057 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 76 Stat. 794 as amended, 82 Stat. 343–351 (21 U.S.C. 321, 352, 355, 356, 357, 360, 360b, 371(a), 374); sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262); Pub. L. 92-387 (86 Stat. 559–562))

Dated: October 31, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-29228 Filed 11-6-75;8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

STERILE BLEOMYCIN SULFATE

The Commissioner of Food and Drugs has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act, as amended, with respect to approval of the antibiotic drug sterile bleomycin sulfate.

The Commissioner concludes that data supplied by the manufacturer concerning the subject antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended to provide for the certification of this drug, effective November 7, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 430, 431, 436, and 450 are amended to provide for certification of sterile bleomycin sulfate as follows:

PART 430—ANTIBIOTIC DRUGS: GENERAL

1. Part 430 is amended:

a. In § 430.4 by adding new paragraph (a)(41), as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(41) *Bleomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces verticillus* and each of the same substances produced by any other means is a kind of bleomycin.

b. In § 430.5 by adding new paragraphs (a)(57) and (b)(57), as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(57) *Bleomycin.* The term "bleomycin master standard" means a specific lot of bleomycin designated by the Commissioner as the standard of comparison in determining the potency of the bleomycin working standard.

(b) * * *

(57) *Bleomycin.* The term "bleomycin working standard" means a specific lot of a homogeneous preparation of bleomycin.

c. In § 430.6 by adding new paragraph (a)(5), as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

(a) * * *

(5) *Bleomycin.* The term "unit" applied to bleomycin means the bleomycin activity (potency) contained in 0.637 milligram of the bleomycin master standard.

* * * * *

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

2. In Part 431 by amending § 431.53 (b)(1), by alphabetically inserting the three following items into the table:

§ 431.53 Fees.

* * * * *

(b) * * *

(1) * * *

Test:	*Chargeable fee per test*
* * * *	*
Bleomycin fractions	$1,725.00
Bleomycin potency	35.00
* * * *	*
Copper content	36.00
* * * *	*

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

3. Part 436 is amended:

a. In § 436.33(b) by alphabetically inserting a new item in the table, as follows:

§ 436.33 Safety test.

* * * * *

(b) * * *

Antibiotic drug	Diluent (diluent number as listed in sec. 436.31)	Test dose: Concentrations in units or milligrams of activity per milliliter	Test dose: Volume in milliliters to be administered to each mouse	Route of administration as described in par. (c) of this section
* * *	*	*	*	*
Bleomycin sulfate	4	5 units	0.5	Intravenous.
* * *	*	*	*	*

b. In § 436.35(c) by alphabetically inserting a new item in the table, as follows:

§ 436.35 Histamine test.

* * * * * * *

(c) * * *

Antibiotic	Diluent (diluent number as listed in sec. 436.31(b))	Concentration of test solution (milligrams of activity per milliliter)	Volume of test solution to be injected (milliliters per kilogram of body weight)
Bleomycin sulfate	4	[1]0.5	1.0
* * *	*	*	*

[1] The concentration of the test solution is expressed in units per milliliter in lieu of milligrams of activity per milliliter.

* * * * * * *

c. In § 436.101 by adding new paragraph (a) (16) to read as follows:

§ 436.101 Solutions.

(a) * * *

(16) *Solution 16 (0.1 M potassium phosphate buffer, pH 7.0).*

Dibasic potassium phosphate: 13.6 gm.
Monobasic potassium phosphate: 4.0 gm.
Distilled water, q.s.: 1,000.0 ml.

Adjust with 18 *N* phosphoric acid or 10 *N* potassium hydroxide to yield a pH 6.8 to 7.2 after sterilization.

* * * * *

d. In § 436.102 by adding paragraphs (b) (34), (35), and (36) to read as follows:

§ 436.102 Culture media.

* * * * *

(b) * * *

(34) *Medium 34.*

Glycerol: 10.0 gm.
Peptone: 10.0 gm.
Beef extract: 10.0 gm.
Sodium chloride: 3.0 gm.
Distilled water q.s.: 1,000.0 ml.
pH 7.0 after sterilization.

(35) *Medium 35.* Same as medium 34, except add 17.0 grams of agar to each liter of medium.

(36) *Medium 36.*

Pancreatic digest of casein	grams	15
Papaic digest of soybean	grams	5
Sodium chloride	grams	5
Agar	grams	15
Distilled water, q.s.	milliliters	1,000

pH 7.3 after sterilization.

e. In § 436.103 by alphabetically inserting a new item in the table in paragraph (a) and by adding paragraph (b) (8) to read as follows:

§ 436.103 Test organisms.

(a) * * *

Test organisms	Method used	Medium used for the—		Incubation period of Roux bottle	Suggested dilution factor	Suggested storage period of suspensions under refrigeration
		Slants	Roux bottles			
* * *	*	*	*	*	*	*
Test organism X—*Mycobacterium smegmatis* (ATCC 607).	8	36				2 weeks.

(b) * * *

(8) *Method 8.* Maintain organisms on agar slants containing 10 milliliters of the appropriate medium and transfer to a fresh slant about once a week. Incubate the slants at 37° C for 48 hours. Using 3 milliliters of sterile U.S.P. saline T.S., wash the growth from the agar slant into a 500-milliliter Erlenmeyer flask containing 100 milliliters of medium 34, as described in § 436.102(b) (34), and 50 grams of glass beads. Agitate the culture by rotation at a speed of 130 cycles per minute and a radius of 3.5 centimeters at 27° C for 5 days. Determine the amount of suspension to be added to each 100 milliliters of agar by the use of test plates. Store the test organism suspension under refrigeration.

f. In § 436.105 (a) and (b) by alphabetically inserting a new item in the respective tables, as follows:

§ 436.105 Microbiological agar diffusion assay.

* * * * * * *

(a) * * *

Antibiotic	Media to be used (as listed by medium number in sec. 436.102(b))		Milliliters of media to be used in the base and seed layers		Test organism	Suggested volume of standardized inoculum to be added to each 100 mls of seed agar	Incubation temperature for the plates (° C)
	Base layer	Seed layer	Base layer	Seed layer			
* * *	*	*	*	*	*	*	*
Bleomycin	35	35	10	6	X	1.0	32-35
* * *	*	*	*	*	*	*	*

(b) * * *

Antibiotic	Working standard stock solutions						Standard response line concentrations	
	Drying conditions (method number as listed in sec. 436.200)	Initial solvent	Diluent (solution number as listed in sec. 436.101(a))	Final concentration units or milligrams per milliliter	Storage time under refrigeration		Diluent	Final concentrations, units or micrograms of antibiotic activity per milliliter
* * *	*	*	*	*	*	*	*	*
Bleomycin	7		16	2 units	2 weeks		16	0.01, 0.02, 0.04, 0.08, 0.16 unit.
* * *	*	*	*	*	*	*	*	*

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

4. In Part 450 by adding new §§ 450.10a and 450.210, to read as follows:

§ 450.10a Sterile bleomycin sulfate.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Sterile bleomycin sulfate is the amorphous sulfate salt of bleomycin. Bleomycin has been separated into several similar glyco-peptide molecules. It is a cream-colored powder that is so purified and dried that:

(i) Its potency is not less than 1.5 units and not more than 2.0 units of bleomycin per milligram. If it is packaged for dispensing, the content of the ampoule or vial is not less than 90 percent and not more than 120 percent of the number of units of bleomycin that it is represented to contain.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) It contains no histamine nor histamine-like substances.

(vi) Its loss on drying is not more than 6.0 percent.

(vii) Its pH in an aqueous solution containing 10 units per milliliter is not less than 4.5 and not more than 6.0.

(viii) Its copper content is not greater than 0.1 percent.

(ix) Its content of various bleomycins is as follows: Bleomycin A_2 is not less than 60 percent and not more than 70 percent; bleomycin B_2 is not less than 25 percent and not more than 32 percent; bleomycin B_1 is not more than 1 percent. Bleomycins A_2 and B_2 should comprise not less than 90 percent of the total bleomycins.

(x) It passes the identity test.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, histamine, loss on drying, pH, copper, content of various bleomycins, and identity.

(ii) Samples required:

(*a*) For all tests except sterility: A minimum of 20 immediate containers.

(*b*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 0.1*M* potassium phosphate buffer, pH 7.0 (solution 16), to provide a stock solution of convenient concentration; if it is packaged for dispensing, reconstitute as directed in the labeling. Then, using a suitable hypodermic needle and syringe, remove all of the withdrawable contents. Dilute the sample thus obtained with solution 16 to provide a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 16 to the reference concentration of 0.04 unit of activity per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except use the entire contents of each of the immediate containers tested.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 0.5 unit of bleomycin per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Histamine.* Proceed as directed in § 436.35 of this chapter.

(6) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter, using the total contents of 2 or 3 vials.

(7) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 10 units per milliliter.

(8) *Copper content—*(i) *Reagents.* Dissolve 10 milligrams of zinc dibenzyldithiocarbamate in 100 milliliters of carbon tetrachloride.

(ii) *Preparation of standard copper solution.* Accurately weigh 1.965 grams of cupric sulfate pentahydrate and transfer to a 1-liter volumetric flask. Dissolve the material in 0.1*N* hydrochloric acid, dilute to volume with 0.1*N* hydrochloric acid and mix well. Transfer 3 milliliters of this stock solution to a 1-liter volumetric flask, dilute to volume with 0.1*N* hydrochloric acid, and mix well. This standard copper solution contains 0.0015 milligram of copper per milliliter. Transfer 10 milliliters of the standard copper solution to a 60-milliliter separatory funnel.

(iii) *Preparation of the sample.* Accurately weigh approximately 15 milligrams of sample into a 60-milliliter separatory funnel. Dissolve the sample in 10 milliliters of 0.1*N* hydrochloric acid.

(iv) *Procedure.* To the separatory funnels containing the sample solution and standard copper solution, add 10 milliliters of the zinc dibenzyldithiocarbamate solution and shake the funnels vigorously for 1 minute. Allow the phases to separate. Filter the carbon tetrachloride phase (lower phase) through 1 gram of anhydrous sodium sulfate to remove excess water. Using a suitable spectrophotometer equipped with 1-centimeter cells, and carbon tetrachloride as a blank, measure the absorbance of the standard copper solution and the sample solution at 435 nanometers. Calculate the percent copper as follows:

$$\text{Percent copper} = \frac{\text{Absorbance of sample solution} \times 1.5}{\text{Absorbance of standard copper solution} \times \text{Sample weight in milligrams}}$$

(9) *Content of various bleomycin fractions—*(i) *Apparatus and reagents—*(*a*) *Column.* Precision glass chromatographic column (1.5±0.0005 centimeters ID×45 centimeters long) equipped with two column end units.

(*b*) *Column end units.* Plastic cylinders (approximately 15 centimeters long), which must fit snugly in the glass chromatographic column. Each end unit contains a barrel and sleeve assembly, and a sealing piston at the end of which is a porous polyethylene disc. A viton O-ring between the barrel and the piston can be expanded to grip the unit in position. A teflon feed tube in the hole in the center of the barrel can be connected to the pump or other equipment. A Whatman Precision Chromatography column or equivalent is suitable.[1]

(*c*) *Extension tube.* Glass tube same dimensions as the column.

(*d*) *Gradient elution device.* Two vertically mounted 500-milliliter glass cylinders connected by means of a glass capillary (1 millimeter ID), which extends from the bottom of the first cylinder to the bottom of the second cylinder. The second cylinder is positioned on a magnetic stirrer and contains a stirring bar. A polyethylene capillary (2 milliliters ID) connects the bottom of the second cylinder to a peristaltic pump. A stock-cock valve between the two cylinders, and one between the second cylinder and the pump, control the solution flow.

(*e*) *Solution A.* 0.025 *M* ammonium formate.

(*f*) *Solution B.* 0.5 *M* ammonium formate.

(*g*) *Column support.* Transfer approximately 50 grams of carboxymethyl cellulose ion exchanger (Whatman CM 52* or equivalent) to a coarse-porosity fritted glass funnel, 600 milliliter, mounted on a 1,000-milliliter suction flask. Add approximately 325 milliliters of solution A and equilibrate for 10 to 15 minutes with occasional stirring. Draw off the solution with gentle suction. Repeat with the addition of 325 milliliters of solution A as above, as many times as necessary until the pH of the eluate is around 6.5.

(*h*) *Peristaltic pump with very little pulsing.*

(*i*) *Fraction collector.*

(*j*) *Ultraviolet spectrophotometer for recording absorbance versus time.*

(*k*) *Ultraviolet spectrophotometer.*

(ii) *Preparation of the chromatographic column.* Fit a column end unit into the bottom of the column and tighten in place. Place the extension tube on top of the column via a suitable connector, such as clamped rubber tubing, so as to make a smooth joint inside. Set the column in a vertical position. Add approximately 100 milliliters of solution A to the column support in the funnel, prepared as described in paragraph (b)(9)(i)(*g*) of this section, and stir to make a slurry. Pour the slurry into a beaker and then into the extension tube. Allow the effluent to run to waste through the lower end unit. Im-

[1] Available from: Whatman, 9 Bridewell Pl., Clifton, N.J. 07014.

* Available from: Whatman, 9 Bridewell Pl., Clifton, N.J. 07014.

mediately after the slurry has been added, insert a column end unit into the extension tube, tighten and connect it to the pump. Pump solution A from a flask containing several hundred milliliters of the solution through the extension tube and column at a flow rate of at least 150 milliliters per hour. Allow the column to pack until the bed height reaches a stable value. Shut off the flow from the bottom of the column by tap, or clamp, or valve. Stop the pump. Disconnect the feed tube from the pump. Release and withdraw the column end unit from the extension tube. Siphon off the solution in the extension tube and remove the extension tube from the column. The column should be overflowing with solution. Insert the column end unit into the top of the column being careful to exclude air. Carefully push the end unit down until it just touches the top of the bed allowing the displaced solution to escape via the top feed tube. Tighten the end unit in place on the column. Reconnect the feed tube of the top column end unit to the pump and open the flow from the bottom of the column. Pump solution A down through the column at approximately 150 milliliters per hour until the bed height reaches a stable value. Shut off the flow from the bottom of the column. Stop the pump. Disconnect the feed tube from the pump. Release and loosen the top column end unit. Push it down gently into the column until it firmly touches the top of the bed and tighten it. Reconnect the top column end unit to the pump and open the flow from the bottom of the column. Pump the solution through the column at a rate of 20 milliliters per hour for several hours. Add 535 milliliters of solution A to the cylinder of the gradient elution device to be connected to the pump. Stir the solution in this cylinder continuously. Add 500 milliliters of solution B to the other cylinder of the gradient elution device.

(iii) *Procedure.* Dissolve a sample containing approximately 15 units of bleomycin in 1 milliliter of solution A in a small conical centrifuge tube. Pump this sample solution to the top of the column. Wash the centrifuge tube three times with 1 milliliter of solution A and pump each wash to the top of the column. Do not pump air into the column. Connect the cylinder of the gradient elution device containing solution A to the pump. Maintain a flow rate of 20 milliliters per hour. Monitor the absorbance of the column effluent at 292 nanometers with a recording spectrophotometer. Collect seven 5-milliliter effluent fractions. Open the stop-cock between the two cylinders of the gradient elution device; then collect 170 5-milliliter effluent fractions from the column. By inspection of the monitored absorbances, identify the fraction numbers for each bleomycin peak by reference to the relative migration rates given in paragraph (b)(9)(iv) of this section. Measure the absorbance of each tube of the identified fractions at 292 nanometers with distilled water as a blank.

(iv) *Calculations.* Determine the migration rate (Rm) of each bleomycin fraction relative to the migration rate of the bleomycin A_2 as follows:

$$\text{Rm (Migration rate relative to bleomycin } A_2) = \frac{\text{Test tube number of each bleomycin fraction at its peak}}{\text{Test tube number of bleomycin } A_2 \text{ at its peak}}$$

The approximate Rm values of the bleomycin fractions are:

Fractions	Rm
Bleomycinic acid	0.16
Bleomycin A_3	0.48
Demethyl bleomycin A_2	0.52
Bleomycin B_1	0.58
Bleomycin A_2	1.00
Bleomycin A'_2	1.12
Bleomycin B_2	1.22
Bleomycin A_5	1.65
Bleomycin B_4	1.85

Add the absorbances of each tube of each bleomycin fraction to obtain the total absorbance of the particular bleomycin fraction. Add the absorbances of all the bleomycin fractions to obtain the grand total absorbance.

$$\text{Percent of a particular bleomycin fraction in the bleomycin sample} = \frac{\text{(Total absorbance of all tubes of a particular fraction } \times 100)}{\text{(Grand total of absorbances of all bleomycin fractions)}}$$

(10) *Identity test.* Proceed as directed in § 436.211 of this chapter, using the method described in paragraph (b)(1) of that section, using a 1 percent mixture.

§ 450.210 Sterile bleomycin sulfate.

The requirements for certification and the tests and methods of assay for sterile bleomycin sulfate packaged for dispensing are described in § 450.10a.

Since the conditions prerequisite to providing for certification of the subject antibiotic drug have been complied with, and since the matter is noncontroversial in nature, notice and public procedures and delayed effective date are not prerequisites to this promulgation.

Effective date. This regulation shall be effective on November 7, 1975.

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357))

Dated: October 31, 1975.

MARY A. MCENIRY,
Assistant to the Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc.75-29849 Filed 11-6-75;8:45 am]

[FRL 453-7; FAP5H5098/T6]

PART 561—TOLERANCES FOR PESTICIDES IN ANIMAL FEED ADMINISTERED BY THE ENVIRONMENTAL PROTECTION AGENCY

Thiabendazole

On August 1, 1975, notice was given (40 FR 32377) that Merck & Co., Inc., Rahway, NJ 07065, had filed a pesticide petition (FAP 5H5098) with the Environmental Protection Agency (EPA). This petition proposed that 21 CFR 123 & 561 be amended to permit the postharvest use of the fungicide thiabendazole (2-(4-thiazolyl) benzimidazole) on sugar beets with tolerance limitations of 0.5 part per million (ppm) in sugar beet sugar, 50 ppm in dry sugar beet pulp, and 40 ppm in sugar beet molasses, in a proposed experimental use program in accordance with an experimental use permit that is being issued concurrently under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The tolerance limitations are being established and the experimental use permit is being issued to:

1. Evaluate the control of fungal organisms in piled sugar beet storage

2. Obtain data on residue concentration in sugar beet pulp and molasses from postharvest treatment of sugar beets with thiabendazole

3. Permit the marketing of dry sugar beet pulp and molasses produced from sugar beets which have received postharvest treatment with thiabendazole.

Merck & Co. subsequently amended the petition by withdrawing the request for a food additive tolerance in sugar beet sugar.

The scientific data reported have been evaluated. Residues of the fungicide will result in dry sugar beet pulp and sugar beet molasses from the uses as provided for by the experimental use permit issued under FIFRA, and therefore tolerance limitations are being established to coincide with this experimental use to protect the public health.

Any person adversely affected by this regulation may, on or before December 8, 1975, file written objections with the Hearing Clerk, Environmental Protection Agency, Room 1019, East Tower, 401 M St. SW., Washington, D.C. 20460. Such objections should be submitted in quintuplicate and should specify both the provisions of the regulation deemed to be 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.

Effective November 7, 1975. Part 561, § 561.380, is amended to read as follows:

(Sec. 409(c)(1) and (4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346(c)(1) and (4)) transferred to the Administrator EPA in Reorganization Plan No. 3 (35 FR 15623))

Dated: November 4, 1975.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

Part 561 is amended by adding the tolerance limitations "50 parts per million . . ." and "40 parts per million . . ." as follows:

§ 561.380 Thiabendazole.

* * * * *

50 parts per million in dry sugar beet pulp resulting from postharvest application of the fungicide to sugar beets. Such residues may be present therein only as a result of application of the fungicide in an experimental use program which expires November 4, 1976. Residues not in excess of this tolerance limitation remaining after expiration of this experimental use program will not be considered actionable if the fungicide is legally applied during the term and in accordance with the provisions of the experimental use permit/feed additive tolerance limitation.

40 parts per million in sugar beet molasses resulting from postharvest application of the fungicide to sugar beets. Such residues may be present therein only as a result of application of the fungicide in an experimental use program which expires November 4, 1976. Residues not in excess of this tolerance limitation remaining after expiration of this experimental use program will not be considered actionable if the fungicide is legally applied during the term and in accordance with the provisions of the experimental use permit/feed additive tolerance limitation.

[FR Doc.75-30068 Filed 11-6-75;8:45 am]

SUBCHAPTER J—RADIOLOGICAL HEALTH

[Docket No. 75N-0043]

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIOFREQUENCY EMITTING PRODUCTS

Microwave Ovens

The Commissioner of Food and Drugs is amending the performance standard in § 1030.10 (21 CFR 1030.10) for microwave ovens to indicate clearly that concealed interlocks must meet the commonly accepted definition of concealment, i.e., being hidden from view and undisclosed. The amendment allows microwave ovens to have, as an alternative to a concealed interlock, an interlock that cannot be actuated when access to it is possible. Also, the requirement that prohibits insertion of objects into the oven, which can cause excess radiation emission, is being changed to better define the term "object" and to cover parts of microwave oven interiors other than the cavity. The amendment also corrects a minor technical inconsistency in the requirements for magnetically operated interlocks. The amendment applies to all microwave ovens manufactured on or after November 7, 1976.

A proposed rule published in the FEDERAL REGISTER of June 26, 1975 (40 FR 27038), provided that interested persons had until August 25, 1975 to file written comments with the Hearing Clerk, Food and Drug Administration, regarding the proposal. Two comment letters were received in response to the proposal. One comment, from a manufacturer of microwave ovens, indicated no objection to the proposed amendment.

The second comment, from a manufacturers' association, reaffirmed the views of the association as presented at a public meeting held on December 10, 1974. At that meeting, the association's representative opposed the proposed amendment. Furthermore, the comment stated that in proposed § 1030.10(c)(2)(iv) a new phrase, "* * * or other microwave energy containing spaces * * *", had been added, and that this phrase was not understood by the industry and must be explained.

The Commissioner has determined that there was no documented information brought forth at the December 10, 1974 public meeting to change the decision to proceed with amendment of the standard. Regarding the phrase, "* * * or other microwave energy containing spaces * * *", it should be noted that this phrase was included in the draft amendment made public prior to the December 10, 1974 meeting and included in background material made available to meeting participants. The phrase is intended to extend the prohibition against insertion of objects to all interior oven spaces that are designed to contain microwave energy or can reasonably be expected to contain microwave energy. The present § 1030.10(c)(2)(iv) refers only to the microwave oven cavity and therefore does not take into account the possibility that insertion of objects into other microwave - energy - containing spaces may result in excessive emission.

In the proposed § 1030.10(c)(2)(i), the dimensions of the armature, used to determine test magnet strength, were inadvertently given as 60 millimeters by 50 millimeters by 8 millimeters. The dimensions in the present standard are 80 millimeters by 50 millimeters by 8 millimeters. The change from the present standard was unintentional and has been corrected in the regulation.

The Commissioner concludes that promulgation of this amendment to the performance standard for microwave ovens will not significantly affect the quality of the human environment and, therefore, that no environmental impact statement is necessary pursuant to 21 CFR Part 6 and 40 CFR Part 1500. The environmental impact analysis report and environmental assessment, along with other pertinent background data and information supporting the Commissioner's conclusions about this amendment are available for public review in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

The regulation has been reviewed and no major inflation impact has been found, as defined in Executive Order 11821, OMB Circular A-107, and guidelines issued April 1, 1975, by the Department of Health, Education, and Welfare.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to him (21 CFR 2.120), Part 1030 is amended in § 1030.10 by revising paragraph (c)(2)(i) and (iv), to read as follows:

§ 1030.10 Microwave ovens.

* * * * *

(c) * * *

(2) *Safety interlocks.* (i) Microwave ovens shall have a minimum of two operative safety interlocks. At least one operative safety interlock on a fully assembled microwave oven shall not be operable by any part of the human body, or any object with a straight insertable length of 10 centimeters. Such interlock must also be concealed, unless its actuation is prevented when access to the interlock is possible. Any visible actuator or device to prevent actuation of this safety interlock must not be removable without disassembly of the oven or its door. A magnetically operated interlock is considered to be concealed, or its actuation is considered to be prevented, only if a test magnet held in place on the oven by gravity or its own attraction cannot operate the safety interlock. The test magnet shall be capable of lifting vertically at zero air gap at least 4.5 kilograms, and at 1 centimeter air gap at least 450 grams when the face of the magnet, which is toward the interlock when the magnet is in the test position, is pulling against one of the large faces of a mild steel armature having dimensions of 80 millimeters by 50 millimeters by 8 millimeters.

* * * * *

(iv) Microwave radiation emission in excess of the limits specified in paragraph (c)(1) of this section shall not be caused by insertion of an insulated wire through any opening in the external surfaces of a fully assembled oven into the cavity, waveguide, or other microwave-energy-containing spaces while the door is closed, provided the wire, when inserted, could consist of two straight segments forming an obtuse angle of not less than 170 degrees.

* * * * *

Effective date. This regulation shall become effective on November 7, 1976.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

Dated: October 31, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-29927 Filed 11-6-75;8:45 am]

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

[Order No. 627-75]

PART 16—PRODUCTION OR DISCLOSURE OF MATERIAL OR INFORMATION

Protection of Privacy of Individuals Records

Correction

In FR Doc. 75-28905, appearing at page 50642 in the issue for Thursday, October 30, 1975, "or his delegate." should be added to the end of the second full sentence in § 16.48(b), appearing on page 50644.

Title 29—Labor

CHAPTER XXV—EMPLOYEE BENEFITS SECURITY, OFFICE OF DEPARTMENT OF LABOR

SUBCHAPTER B—DEFINITIONS AND COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

PART 2510—DEFINITIONS OF TERMS USED IN SUBCHAPTERS C, D, E, F, AND G OF THIS CHAPTER

Guidance To Determine Coverage

● **Purpose: The purpose of these amendments to chapter XXV of the Department of Labor regulations is to provide guidance to determine coverage under the Employee Retirement Income Security Act of 1974 (hereinafter "the Act").** ●

On December 4, 1974, notice was published in the FEDERAL REGISTER (39 FR 42234) of proposed regulations concerning the definition of the term "multiemployer plan" under section 3(37) of the Act.

On May 12, 1975, a final rule (40 FR 20629) and proposed rule (40 FR 20653) redesignating both final and proposed subchapters, parts and sections were published in the FEDERAL REGISTER. Under this redesignation system, the section numbers of proposed and adopted regulations promulgated under Chapter XXV are based on the section numbers of the Act to which each regulation relates. The December 4 proposed regulations have been redesignated in accordance with this system.

The regulations contained in this document are both temporary regulations effective immediately and proposed regulations for final adoption. The primary reason for making these regulations effective immediately on a temporary basis is that plans not in existence on January 1, 1974 must meet the requirements of the Act for plan years beginning after September 2, 1974. For many plans the first plan year beginning after September 2, 1974 will be a plan year beginning on September 1, 1975, as a result of procedures set forth by the Internal Revenue Service in Revenue Procedures 74–38, 74–39, and 74–40 issued September 10 and 11, 1974. These procedures classified plans as "pre-existing plan" (adopted and put into effect by an employer on or before January 1, 1974), "new plan subject to prior law" (adopted and put into effect by an employer after January 1, 1974, whose first plan year begins on or before September 2, 1974, whether or not it is adopted and put into effect by an employer before September 2, 1974), and "new plan subject to new law" (adopted and put into effect by an employer after January 1, 1974, whose first plan year begins after September 2, 1974). The effect of these procedures was to permit plans adopted after January 1, 1974 to meet the requirements of prior law rather than the requirements of the Act by making the plan year begin on or before September 2, 1974. Many of these plans will now have plan years beginning September 1, 1975, during which they will be required to meet the standards of the Act. In addition, preexisting plans must meet the requirements of the Act for plan years beginning after December 31, 1975. The regulations in Part 2530 will allow these plans to make the necessary adjustments. Any changes or modifications contained in "final" regulations will be prospective only.

For the foregoing reasons, the undersigned finds that good cause exists for making these regulations temporarily effective without advance publication as specified in the Administrative Procedure Act (5 U.S.C. 553(d)(3)).

These regulations are also proposed for final adoption as soon as possible. Interested persons are invited to submit written data, views, or arguments concerning any or all of the proposed regulations contained in this document on or before December 3, 1975. Such data, views and comments should be submitted to the Office of Employee Benefits Security DEVD–ME, Labor Management Services Administration, U.S. Department of Labor, Washington, D.C. 20216. All comments should be clearly referenced to the numbers of the sections to which the comments are directed.

The regulation provides that all multiemployer plans must meet the tests set forth in section 3(37)(a)(i)–(iv), and in addition a plan not in existence prior to the effective date of the Act must meet the test that it was established for a substantial business purpose. With one exception, all changes in this regulation from the December 4 proposal are editorial in nature and made in the interest of clarity.

The exception, contained in subsection (b), is a newly added set of rules for determining whether a plan was in existence prior to the effective date of the Act. These rules are consistent with those contained in § 1.411(a)–2(c) of the proposed regulations of of the Internal Revenue Service concerning vesting (26 CFR 1.411(a)–2(c). Comments are specifically solicited on these new provisions.

(Sec. 505, Pub. L. 93–406, 88 Stat. 894, 29 U.S.C. 1135; Secretary of Labor's Order No. 27–74, and Labor Management Services Administration Order No. 2–6.)

Accordingly, Chapter XXV of Title 29 of the Code of Federal Regulations is amended by adding a new § 2510.3–37.

§ 2510.3–37 Multiemployer plan.

(a) *General.* Section 3(37) of the Act contains in subparagraph (a)(i)–(iv) a number of criteria which an employee benefit plan must meet in order to be a multiemployer plan under the Act. Section 3(37) also provides that the Secretary may prescribe by regulation other requirements in addition to those contained in subparagraph (a)(i)–(iv). The purpose of this regulation is to establish such requirements.

(b) *Plans in existence before the effective date.* (1) A plan in existence before September 2, 1974, will be considered a multiemployer plan if it satisfies the requirements of section 3(37)(A)(i)–(iv) of the Act.

(2) For purposes of this section, a plan is considered to be in existence if:

(i) (A) The plan was reduced to writing and adopted by the participating employers and the employee organization (including, in the case of a corporate employer, formal approval by an employer's board of directors or shareholders, if required), even though no amounts had been contributed under the plan, and

(B) The plan has not been terminated; or

(ii) (A) There was a legally enforceable agreement to establish such a plan signed by the employers and the employee organization, and

(B) The contributions to be made to the plan were set forth in the agreement.

(iii) If a plan was in existence within the meaning of paragraph (b)(i) or (ii) of this section, any other plan with which such existing plan is merged or consolidated shall also be considered to be in existence.

(c) *Plans not in existence before the effective date.* In addition to the provisions of section 3(37)(A)(i)–(iv) of the Act, a multiemployer plan established on or after September 2, 1974, must meet the requirement that it was established for a substantial business purpose. A substantial business purpose includes the interest of a labor organization in securing an employee benefit plan for its members. The following factors are relevant in determining whether a substantial business purpose existed for the establishment of a plan; any single factor may be sufficient to constitute a substantial business purpose:

(1) The extent to which the plan is maintained by a substantial number of unaffiliated contributing employers and covers a substantial portion of the trade, craft or industry in terms of employees or a substantial number of the employees in the trade, craft or industry in a locality or geographic area;

(2) The extent to which the plan provides benefits more closely related to years of service within the trade, craft or industry rather than with an employer, reflecting the fact that an employee's relationship with an employer maintaining the plan is generally short-term although service in the trade, craft or industry is generally long-term;

(3) The extent to which collective bargaining takes place on matters other than employee benefit plans between the employee organization and the employers maintaining the plan; and

(4) The extent to which the administrative burden and expense of providing benefits through single employer plans would be greater than through a multiemployer plan.

Issued in Washington, D.C. this 4th day of November 1975.

JAMES D. HUTCHINSON,
Administrator for Pension and Welfare Benefit Programs.

[FR Doc.75–30082 Filed 11–6–75;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

[FRL 411-8]

PART 79—REGISTRATION OF FUELS AND FUEL ADDITIVES

Requirements

On March 7, 1974, the Environmental Protection Agency published a notice of proposed rulemaking in the FEDERAL REGISTER (39 FR 8929) setting forth proposed regulations for the registration of fuels and fuel additives. Pursuant to this notice, many written comments were received during an extended public comment period. The proposed registration requirements have been reviewed in the light of these comments, and numerous changes have been made. The Agency's responses to the issues raised in the comments are set forth below.

Definition of fuels and designation of engine oils for registration. Industry trade associations and other interested persons have asserted that the definition of fuels contained in the regulations is impermissibly broad. They contend that section 211 of the Clean Air Act, as amended, authorizes registration of fuels for use in motor vehicles only and that the definition of fuel must be confined to substances or materials intended for use as a source of propulsion for motor vehicles. They object, therefore, to the designation of additives used in motor vehicle engine oils as subject to registration.

First, neither the language nor the legislative history of section 211 supports limiting the registration authority of section 211(a) to motor vehicle fuels and additives. While only motor vehicle fuels are subject to regulation under section 211(c), the Administrator's authority to require registration of "any fuel or fuel additive" was established in the Clean Air Act of 1967 and retained in the 1970 Amendments. EPA has designated only motor vehicle fuels for registration at this time, but this choice is dictated by research priorities and not by a lack of authority to regulate other types of fuels.

Section 79.2(c) of the registration regulations contains the definition of "fuel" as promulgated in the original fuel registration regulations issued in 1970. The word "fuel" is defined as "any material which is capable of releasing energy or power by combustion or other chemical or physical reaction." EPA believes that this broad definition of fuel reflects the intent of Congress in providing for the registration of fuels and fuel additives to grant authority encompassing all materials which might affect the emission products of combustion and thus the public health and welfare.

The function of motor vehicle engine oils is to lubricate the cylinder walls and the intake and exhaust valves of both standard piston and rotary engines. Although these oils are not introduced into the combustion chamber for the purpose of providing power for the engine, a portion of the oil is in fact combusted in the normal operation of the engine. This quantity increases in older, partially worn engines.

Most of the parties commenting on the regulations conceded that engine oils are combusted in the normal operation of both standard piston and rotary engines. They argued, however, that the quantities of engine oil consumed in the piston engine are not great enough to have a significant impact on emissions or emission control devices. While a relatively large volume of engine oil is deliberately introduced into the fuel and combustion process of the rotary engine, some persons commenting asserted that EPA should wait until larger numbers of rotary engines appear on the market.

The total quantity of engine oils consumed in vehicles is, of course, less than that of gasoline. However, the concentrations of additives containing various elements, especially metals, whose emission products are of concern to EPA are much higher in engine oils than in gasoline. Engine oils contain large quantities of additives, averaging 15 percent of total product volume and ranging as high as 40 percent. Gasoline additives, by contrast, average only 0.1 percent of total product volume. Considering both the consumption rates and the average additive content of engine oils and gasoline, the combustion and emission products of engine oil additives are, on the average, somewhat lower than that of gasoline additives; but they are of the same order of magnitude and are readily detectable in the exhaust.

There is ample evidence in the literature that lubricant composition and additive materials influence exhaust composition. Some investigators have found that lubricant consumption greatly increased emission of polynuclear aromatic hydrocarbons.[1] [2] Another researcher found zinc and barium in exhaust particles due to lubricant trace metals.[3] High lubricant consumption in rotary engines has also been a matter of considerable concern. A current EPA-funded program seeks to determine the impact on diesel exhaust products of the current commercial practice of adding used motor oil to diesel fuel.[4] EPA must monitor the composition of engine oil additives to guard against the introduction into engine oil of additives which could result in exhaust products damaging to emission control devices, as well as to insure that potentially toxic (as, for example, carcinogenic) products in significant levels do not enter the ambient air, particularly in regions of high traffic density.

Finally, many of the comments suggest that EPA should not require registration of particular fuels or additives such as engine oil additives unless EPA has reason to believe that their emission products impair the effectiveness of emission control devices or endanger public health or welfare. These comments misconceive the purpose of the registration requirements. The principal purpose of section 211(a) is to provide the Agency with information on fuel or additive composition before the emission products of such materials develop into a problem possibly requiring regulation under section 211(c). Thus, the fact that the rotary engine, for example, is not yet in widespread use has little bearing on whether to require registration of additives for engine oils. The regulations being promulgated, therefore, retain the requirement of registration of additives for motor vehicle engine oil. An effort has been made, however, to reduce the reporting burden imposed by the regulations where possible.

Testing to determine the effect of fuels or fuel additives on emission control systems or the public welfare. Section 79.6(b) of the proposed regulations states that the Administrator may require a fuel manufacturer or an additive manufacturer to conduct tests in accordance with protocols based on generally accepted test methods and procedures in order to determine the fuel's or additive's effects on emissions, emission control performances of motor vehicles, or the extent to which such emissions affect welfare. Several persons commented that this provision is unauthorized because section 211(b)(2)(A) authorizes requiring tests "to determine potential public health effects" of a fuel or additive and does not refer to requiring tests to ascertain the effects on emissions, emission control systems, or public welfare.

EPA believes that requiring the latter tests is amply supported by section 211(b)(2)(B) which requires a registrant to furnish "such other information as is reasonable and necessary to determine the emissions resulting from the use of the fuel or additive contained in such fuel, the effect of such fuel or additive on the emission control performance of any vehicle or engine, or the extent to which such emissions affect the public health or welfare." It is clear from the legislative history of section 211 that the authority of section 211(b)(2)(B) is not limited to obtaining information already developed by the registrant but extends to information that could readily be developed by test methods and procedures having general acceptance in the scientific community.

The specific authority of section 211(b)(2)(A) to require tests to determine "potential public health effects . . . (including, but not limited to, carcinogenic, teratogenic, or mutagenic effects) . . ." is directed at an area of more esoteric information where test procedures and research parameters are not well established or generally accepted. Consequently, testing requirements in the field of potential public health effects may not be imposed until such time as the Administrator has prescribed specific protocols and procedures for conducting the research. These protocols and procedures will be proposed for public com-

[1] Begeman, C. R. and J. M. Colucci, SAE Trans., 79, 1682 (1970).

[2] Gross, G., Final Report on CRC-APRAC Project CAPE-6-68, Oct. 31, 1973.

[3] Ninomiya, J. S., W. Bergman, and B. H. Simpson, Paper No. EN-106, presented at the Second International Clean Air Congress, Washington, D.C., Dec. 6-11, 1970.

[4] EPA grant 802425-01-02, Pennsylvania State University, May 1974.

ment. Requests to registrants for information to be developed by generally accepted test methods will not be subject to notice and comment procedures.

Fuel "processors". Several commentators asserted that a fuel "processor" may not be required to perform tests because the word "processor" appears only in section 211(a), which prohibits any fuel or additive manufacturer or processor from selling unregistered fuels or additives, but is omitted from section 211(b)(2), which authorizes the Administrator to require tests.

By enacting section 211 (a) and (b), Congress intended to establish authority for the Administrator to obtain information on health and welfare effects and effects on emission control devices of fuels and additives from the firms and individuals who introduce such fuels and additives into the marketplace. The combining of additives and/or fuels holds the potential of creating previously unidentified combustion by-products, and those who engage in this activity must be viewed in the same light as those who produce the substances which are combined. That the Congress chose to apply the broadest possible scope to its prohibition against marketing unregistered fuels or additives does not, in the Agency's view, suggest that the Administrator was to be barred from obtaining necessary information from those who in fact produce new fuels or additives by combining other fuels or additives. Broad applicability of the registration regulations is essential to assure that EPA receives complete information on the composition of designated fuels and additives from those who sell or introduce such products into commerce.

The Act does not define either "manufacturer" or "processor" as used in section 211, and nothing in the legislative history suggests that Congress intended to distinguish between manufacturers and processors for the purpose of reporting or testing requirements under the registration program. Indeed, there is no indication that the terms "manufacturer" and "processor" were meant to denote separate classes of producers. EPA has considered the term "manufacturer" to include "processor," and the existing registration regulations reflect that view. We find no legal or policy considerations compelling a departure from this interpretation in the revised regulations. To eliminate any further confusion of terminology, EPA has deleted the term "processor" from the definition of fuel manufacturer.

Registration of packaged additives. A group of persons commenting has recommended that packaged additives sold to consumers for addition to fuels be exempted from reporting and registration. Although the usage of packaged additives is limited, EPA has an obligation to be aware of the composition of every additive being used in motor vehicles in order to take appropriate action if an ingredient harmful to health, welfare, or an emission control device is included. This can only be assured by requiring the registration of all packaged additives. The reporting burden for manufacturers of packaged additives should be reduced in some cases by the more limited classes of information required from additive manufacturers who use only registered components with or without substances containing only hydrogen and carbon.

EPA has also consulted with representatives of the Consumer Product Safety Commission and was advised that regulation of packaged additives under the Federal Hazardous Substances Act does not require submission to that Agency of the information required under EPA's registration program.

Test fuels or additives; spot purchases from foreign sources. The Agency concurs with the recommendation of a number of persons commenting to exempt fuels and additives in test or developmental status from registration, and provisions exempting such fuels and additives not offered for sale to the public have been added. Also, an exemption for factory fill fuel has been included. The possibility of spot purchases of fuels of foreign manufacture to ease shortages is recognized, and a provision for simplified reporting of such purchases has been added. From time to time, a fuel manufacturer or processor may find himself in a special or unusual situation where he needs to use a registered additive which he has not previously reported. A provision for the use under such circumstances of any additive on the list of registered additives has been included.

Information required for registering fuels and additives. Many fuel or additive producers commented that the registration requirements impose an excessive burden. This objection is based in part on a misunderstanding of the regulations. In other cases, EPA has modified the requirements to avoid duplicative reporting of information where possible and to eliminate information requirements where the utility of the data is marginal at this time.

Some parties overlooked the fact that all information specified in Subpart D was to be furnished only to the extent such information is already known to the manufacturer, as was stated in §§ 79.11(f) and 79.21(e). The regulations being promulgated have been modified to clarify this point. The phrase "to the extent known to the manufacturer" has been shifted to the specific listings of desired information in Subpart D. In addition, the intent of this phrase has been clarified by explaining that (1) specified data are to be furnished only if known to the manufacturer "as a result of testing conducted for reasons other than fuel or additive registration or reporting" and (2) specified information is considered to be "known" only when "a report thereon has been prepared and circulated or distributed outside the research department or division."

Since a number of persons misinterpreted the request for information regarding any analytical technique that can be used to detect the presence of an additive in a fuel and to measure its concentration as a requirement to develop such a technique, it has been reworded to state that the manufacturer shall submit a suitable technique only if one is already known to him. It has also been pointed out that in some cases an additive manufacturer cannot be sure of the final chemical reaction products in his additive. Such a manufacturer may furnish the chemical composition "to the extent known," provided he also furnishes a description of the manufacturing process resulting in the final reaction products of the additive.

Several changes affecting the requirements and procedures for the registration of fuel additives have been made. New developments in additives containing carbon, hydrogen, and oxygen make it technically impossible to justify their exemption from registration in spite of recommendations to this effect. Some compounds having only carbon, hydrogen, and oxygen are known to have toxic or carcinogenic properties. B-propriolactane is a widely known carcinogen; some epoxides are also known to have toxic effects. Unsaturated carbonyl compounds which may be generated as partial combustion products are highly toxic and may also have carcinogenic activity. Thus, it is important to monitor the composition of fuel additives which contain only carbon, hydrogen, and oxygen. The additive definition has, however, been changed to exclude substances containing only carbon and/or hydrogen to avoid any uncertainty concerning the status of refinery blending streams. Refinery process chemicals are also excluded from the registration requirements.

In operations under the current regulations, additive manufacturers have understood that they are not required to furnish information about purchased components, provided such information can be obtained from the component manufacturer upon request; and a provision covering this has been inserted in these regulations. Another new provision will permit an additive manufacturer to register only the individual components of mixtures of additives that he markets only to fuel manufacturers rather than each of the mixtures, provided he will identify the components in any particular mixture upon request.

In addition, an additive manufacturer who sells under his own name a registered additive purchased from another manufacturer or a blend of such registered additive with other such registered additives and/or substances containing only carbon and/or hydrogen will be required to register his additive(s) but will not be required to furnish annual reports thereafter. This change is intended to limit potential duplicative reporting of information.

To ease the reporting burden on manufacturers of motor vehicle engine oil additives, those manufacturers are exempted from the requirement to furnish the chemical compounds in each additive to be registered and will be required to give a breakdown by chemical element only. Information on the chemical elements contained in such additives is considered sufficient for the program at this time.

Certain changes in fuel manufacturer reporting requirements have been made. The provision for reporting geographic variation in additive usage has been eliminated because of the difficulty and/or impossibility of obtaining meaningful and useful data. The only data to be required on a quarterly basis will be on additive usage, as is being provided under the current regulations, and fuel production. In addition, quarterly reports will be for calendar quarters. Other data as listed in Subpart D are to be furnished on an annual basis.

The types of gasoline being designated have been reduced to three: (1) Unleaded; (2) leaded, premium; and (3) leaded, nonpremium. The Agency feels that at the present time there is sufficient leaded premium gasoline on the market to warrant its classification but will consider elimination of this classification when the amount of leaded, premium gasoline sold is substantially reduced. The designated grades of motor vehicle diesel fuels have been reduced to two: (1) grade 1-D and (2) grade 2-D.

As requested by a number of persons commenting, time limits in which EPA will take specified actions to register fuels or additives have been set forth.

Procedural issues; confidentiality of information. Several persons requested that EPA hold a hearing on the record with the right of cross examination by interested members of the public. It is well established that a formal hearing is not required unless the statute calls for rulemaking on the record after opportunity for an agency hearing. To adopt the requirements of formal procedural rulemaking would be contrary to congressional intent and would serve only to delay the issuance of the regulations. In addition, neither the Administrative Procedure Act nor section 211 of the Clean Air Act requires that any public hearing, formal or informal, be held in addition to the opportunity to submit written comments on the proposed amendments to the fuel registration regulations. While the Agency recognizes that oral presentations may be beneficial in particular cases where a hearing is not required by law, the parties requesting a hearing have made no showing that the issues involved in the fuel registration program compel a departure from the procedures for informal rulemaking calling for written submissions only.

There is similarly no legal requirement that an environmental impact statement be prepared on the proposed amendments. See Amoco Oil v. EPA, 501 F.2d 722, 749-50 (D.C. Cir. 1974). Moreover, the Agency's published statement of policy that such statements will be prepared voluntarily in connection with specified rulemaking activities is applicable (a) to regulations proposed after October 15, 1974, and (b) to major regulatory actions involving establishment of substantive standards or criteria (39 FR 16186). The proposed amendments to the fuel registration program at issue in this rulemaking are excluded from the policy statement on both grounds.

Concern has been expressed that the provisions of EPA's regulations on Public Information (40 CFR Part 2) referenced in § 79.3 of the proposed registration regulations may not afford notice to a registrant that a request has been made for release of information considered by the registrant to be a trade secret. The preliminary determination as to potential exemption from disclosure on grounds of trade secrecy is made in this case by the Office of Fuel and Fuel Additive Registration. If the information "may be exempt" from disclosure, the matter is referred to the EPA Office of General Counsel, and the registrant is notified. It has been the policy of the Office of Fuel and Fuel Additive Registration to regard all information designated by the registrant as trade secret as potentially exempt. Thus, the registrant would be notified of any request for data that would call the trade secret status of such information into question.

The regulations promulgated below shall be effective on November 7, 1975. (Sections 211 and 301(a) of the Clean Air Act, 42 U.S.C. 1857f-6c and 1857g).

Dated: October 31, 1975.

JOHN QUARLES,
Acting Administrator.

Part 79, Chapter I of Title 40 of the Code of Federal Regulations, is revised to read as follows:

Subpart A—General Provisions

Subpart B—Fuel Registration Procedures

Subpart C—Additive Registration Procedures

Subpart D—Designation of Fuels and Additives

AUTHORITY: Secs. 211 and 301(a) of the Clean Air Act, 42 U.S.C. 1857f-6c and 1857g.

Subpart A—General Provisions

§ 79.1 Applicability.

The regulations of this part apply to the registration of fuels and fuel additives designated by the Administrator, pursuant to section 211 of the Clean Air Act (42 U.S.C. 1857f-6c, asamended by section 9, Pub. L. 91-604).

§ 79.2 Definitions.

As used in this part, all terms not defined herein shall have the meaning given them in the Act:.

(a) "Act" means the Clean Air Act (42 U.S.C. 1857 et seq., as amended by Pub. L. 91-604).

(b) "Administrator" means the Administrator of the Environmental Protection Agency.

(c) "Fuel" means any material which is capable of releasing energy or power by combustion or other chemical or physical reaction.

(d) "Fuel manufacturer" means any person who, for sale or introduction into commerce, produces or manufactures a fuel or causes or directs the alteration of the chemical composition of, or the mixture of chemical compounds in, a bulk fuel by adding to it an additive.

(e) "Additive" means any substance, other than one composed solely of carbon and/or hydrogen, that is intentionally added to a fuel named in the designation (including any added to a motor vehicle's fuel system) and that is not intentionally removed prior to sale or use.

(f) "Additive manufacturer" means any person who produces or manufactures an additive for use as an additive and/or sells an additive under his own name.

(g) "Range of concentration" means the highest concentration, the lowest concentration, and the average concentration of an additive in a fuel.

(h) "Chemical composition" means the name and percentage by weight of each compound in an additive and the name and percentage by weight of each element in an additive.

(i) "Chemical structure" means the molecular structure of a compound in an additive.

(j) "Impurity" means any chemical element present in an additive that is not included in the chemical formula or identified in the breakdown by element in the chemical composition of such additive.

§ 79.3 Confidentiality of information.

Information obtained by the Administrator or his representatives pursuant to this part shall be treated, insofar as its confidentiality is concerned, in accordance with regulations in 40 CFR Part 2. Results of tests required under § 79.6(a) to determine potential public health effects of fuels or additives shall in no case be considered confidential.

§ 79.4 Requirement of registration.

(a) Fuels. (1) No manufacturer of any fuel designated under this part shall, after the date prescribed for such fuel in this part, sell, offer for sale, or introduce into commerce such fuel unless the Administrator has registered such fuel.

(2) No manufacturer of a registered fuel shall add or direct the addition to

it of an additive which he has not previously reported unless he has notified the Administrator of such intended use, including the expected or estimated range of concentration. If necessary to meet an unforeseen production problem, however, a fuel manufacturer may use an additive that he has not previously reported provided that (i) the additive is on the current list of registered additives and (ii) the fuel manufacturer notifies the Administrator within 30 days regarding such unforeseen use and his plans regarding continued use, including the expected or estimated range of concentration.

(3) Any designated fuel that is (i) in a research, development, or test status; (ii) sold to automobile, engine, or component manufacturers for research, development, or test purposes; or (iii) sold to automobile manufacturers for factory fill, and is not in any case offered for commercial sale to the public, shall be exempt from registration.

(4) A domestic fuel manufacturer may purchase and offer for commercial sale foreign-produced fuel containing unidentified additives provided that within 30 days of his offer for sale he notifies the Administrator of the purchase, the source of purchase, the quantity purchased, and summarized results of any tests performed to determine the acceptability of the purchased fuel to the fuel manufacturer.

(b) Additives. (1) No manufacturer of any additive designated under this part shall, after the date prescribed for such additive in this part, sell, offer for sale, or introduce into commerce such additive for use as an additive unless the Administrator has registered such additive.

(2) Any designated additive that is either (i) in a research, development, or test status or (ii) sold to petroleum, automobile, engine, or component manufacturers for research, development, or test purposes, and in either case is not offered for commercial sale to the public, shall be exempt from registration.

(3) Process chemicals used by refineries during the refinery process are exempted from the requirement for registration.

(4) If an additive manufacturer prepares for sale only to fuel manufacturers a mixture of two or more registered additives (with or without substances containing only carbon and/or hydrogen), he will not be required to register such mixture provided he will, upon request, furnish the Administrator with the names and percentages by weight of all components of such mixture.

§ 79.5 Periodic reporting requirements.

(a) Fuel manufacturers. (1) For each calendar quarter (January through March, April through June, July through September, October through December) commencing after the date prescribed for a particular fuel in Subpart D, fuel manufacturers shall submit to the Administrator a report for each registered fuel showing (i) the range of concentration of each additive reported under § 79.11(a) and (ii) the volume of such fuel produced in the quarter. Reports shall be submitted within 45 days after the close of the reporting period on forms supplied by the Administrator upon request.

(2) Fuel manufacturers shall submit to the Administrator a report annually for each registered fuel providing additional data and information as specified in § 79.31 (c) and (d) in the designation of the fuel in Subpart D. Reports shall be submitted on or before March 31 for the preceding year or part thereof on forms supplied by the Administrator upon request. If the date prescribed for a particular fuel in Subpart D or the later registration of a fuel is between October 1 and December 31, no report will be required for the period to the end of that year.

(b) Additive manufacturers. Additive manufacturers shall submit to the Administrator a report annually for each registered additive providing additional data and information as specified in subparagraphs (c) and (d) in the designation of the additive in Subpart D. Additive manufacturers shall also report annually the volume of each additive produced. Reports shall be submitted on or before March 31 for the preceding year or part thereof on forms supplied by the Administrator upon request. If the date prescribed for a particular additive in Subpart D or the later registration of an additive is between October 1 and December 31, no report will be required for the period to the end of that year. These periodic reports shall not, however, be required for any additive that is (1) an additive registered under another name, (2) a blend or mixture of two or more registered additives, or (3) a blend or mixture of one or more registered additives with one or more substances containing only carbon and/or hydrogen.

§ 79.6 Requirement for testing.

(a) The Administrator may establish procedures and protocols for the conduct of tests to determine potential public health effects of a designated fuel or additive (including, but not limited to, carcinogenic, teratogenic, or mutagenic effects) and may thereafter require a fuel manufacturer or an additive manufacturer to conduct tests in conformance with such test procedures and protocols.

(b) In order to obtain such information as is reasonable and necessary to determine the emissions resulting from the use of a fuel or an additive in a fuel, the effect of such fuel or additive on the emission control performance of any motor vehicle or motor vehicle engine, or the extent to which such emissions affect the public welfare, the Administrator may require a fuel manufacturer or an additive manufacturer to conduct tests in accordance with protocols based on generally accepted test methods and procedures.

(c) Any test required under this section shall be performed in accordance with a time schedule prescribed by the Administrator, after consultation with the manufacturer involved.

(d) The Administrator may require a fuel manufacturer to perform tests under this section on any fuel registered for such manufacturer or an additive manufacturer to perform tests under this section on any additive registered for such manufacturer. He may not require any test as a prerequisite of registration unless it is part of a test protocol established by regulation a reasonable time prior to notification by the manufacturer.

§ 79.7 Samples for test purposes.

When the Administrator requires for test purposes a fuel or additive which is not readily available in the open market, he may request the manufacturer of such fuel or additive to furnish a sample in a reasonable quantity. The fuel or additive manufacturer shall comply with such request within 30 days.

§ 79.8 Penalties.

Any person who violates section 211(a) of the Act or who fails to furnish any information required under this part shall forfeit and pay to the United States a civil penalty of $10,000 for each and every day of the continuance of such violation, which shall accrue to the United States and be recovered in a civil suit in the name of the United States, brought in the district in which such person does business. The Administrator may, upon application therefor, remit or mitigate any such forfeiture; and he shall have authority to determine the facts upon all such applications.

Subpart B—Fuel Registration Procedures

§ 79.10 Notification of fuel manufacturer.

Any manufacturer of a designated fuel who wishes to have such fuel registered shall notify the Administrator in accordance with § 79.11 at least 60 days prior to the date prescribed for such fuel in Subpart D or, after such prescribed date, at least 30 days prior to the date on which such fuel manufacturer proposes to begin to sell, offer for sale, or introduced into commerce such fuel. If a fuel manufacturer produces more than one grade or brand of a designated fuel, only one notification or report is required for that designated fuel, showing highest, lowest, and average values for all such grades or brands. Each notification shall be signed by the fuel manufacturer or his agent and shall be submitted on such forms as the Administrator will supply on request.

§ 79.11 Information and assurances to be provided by the fuel manufacturer.

Each notification submitted by a fuel manufacturer shall include the following:

(a) The commercial identifying name of each additive that will or may be used in a designated fuel subsequent to the date prescribed for such fuel in Subpart D;

(b) The name of the additive manufacturer of each additive named;

(c) The range of concentration of each additive named, as follows:

(1) In the case of an additive which has been or is being used in the designated fuel, the range during any 3-month or longer period prior to the date of submission;

(2) In the case of an additive which has not been used in the designated fuel, the expected or estimated range;

(d) The purpose-in-use of each additive named;

(e) The description (or identification, in the case of a generally accepted method) of a suitable analytical technique (if one is known) that can be used to detect the presence of each named additive in the designated fuel and/or to measure its concentration therein;

(f) Such other data and information as are specified in the designation of the fuel in Subpart D;

(g) Assurances that the fuel manufacturer will notify the Administrator in writing and within a reasonable time of any change in:

(1) The name of any additive previously reported;

(2) The name of the manufacturer of any additive being used;

(3) The purpose-in-use of any additive;

(4) Information submitted pursuant to paragraph (e) of this section;

(h) Assurances that the fuel manufacturer will not represent, directly or indirectly, in any notice, circular, letter, or other written communication, or any written, oral, or pictorial notice or other announcement in any publication or by radio or television, that registration of the fuel constitutes endorsement, certification, or approval by any agency of the United States.

§ 79.12 Determination of noncompliance.

Whenever the Administrator determines that a notification fails to comply with the regulation of this part, he shall within 30 days (60 days in the case of initial registrations prior to the date prescribed for the fuel in Subpart D) of receipt of the notification inform the noncomplying fuel manufacturer of the reasons for such determination.

§ 79.13 Registration.

(a) If the provisions of this part requiring the submission of information and the giving of assurances have been complied with for a particular fuel, the Administrator shall register that fuel and within 30 days (60 days in the case of initial registrations prior to the date prescribed for the fuel in Subpart D) of receipt of the notification notify the fuel manufacturer of such registration.

(b) The Administrator shall maintain a list of registered fuels, which shall be available to the public upon request.

§ 79.14 Termination of registration of fuels.

Registration may be terminated by the Administrator if the fuel manufacturer requests such termination in writing.

Subpart C—Additive Registration Procedures

§ 79.20 Notification by additive manufacturer.

Except as provided in § 79.23(b), any manufacturer of a designated additive who wishes to have such additive registered shall notify the Administrator in accordance with § 79.21 at least 90 days prior to the date prescribed for such additive in Subpart D or, after such prescribed date, at least 30 days prior to the date on which such additive manufacturer proposes to begin to sell, offer for sale, or introduce into commerce such additive. Each notification shall be signed by the additive manufacturer or his agent and shall be submitted on such forms as the Administrator will supply upon request.

§ 79.21 Information and assurances to be provided by the additive manufacturer.

Each notification submitted by an additive manufacturer shall include the following:

(a) The chemical composition of the additive with the methods of analysis identified, except that

(1) If the chemical composition is not known, full disclosure of the chemical process of manufacture will be accepted in lieu thereof;

(2) In the case of an additive for engine oil, only the name, percentage by weight, and method of analysis of each element in the additive are required;

(3) In the case of a purchased component, only the name, manufacturer, and percent by weight of such purchased component are required if the manufacturer of the component will, upon request, furnish the Administrator with the chemical composition thereof.

(b) The chemical structure of each compound in the additive if such structure is known and is not adequately specified by the name given under "chemical composition." Nominal identification is adequate if mixed isomers are present.

(c) The description (or identification, in the case of a generally accepted method) of a suitable analytical technique (if one is known) that can be used to detect the presence of the additive in any fuel named in the designation and/or to measure its concentration therein.

(d) Fuels in which the use of the additive is recommended and the manufacturer's recommended range of concentration and purpose-in-use in each.

(e) Such other data and information as are specified in the designation of the additive in Subpart D.

(f) Assurances that any change in information submitted pursuant to (1) paragraphs (a), (b), (c), and (d) of this section will be provided to the Administrator in writing within 30 days of such change; and (2) paragraph (e) of this section as provided in § 79.5(b).

(g) Assurances that the additive manufacturer will not represent, directly or indirectly, in any notice, circular, letter, or other written communication or any written, oral, or pictorial notice or other announcement in any publication or by radio or television, that registration of the additive constitutes endorsement, certification, or approval by any agency of the United States.

§ 79.22 Determination of noncompliance.

Whenever the Administrator determines that a notification fails to comply with the regulations of this part, he shall within 30 days (90 days in the case of initial registrations prior to the date prescribed for the additive in Subpart D) of receipt of the notification inform the noncomplying additive manufacturer of the reasons for such determination.

§ 79.23 Registration.

(a) If the provisions of this part requiring the submission of information and the giving of assurances have been complied with for a particular additive, the Administrator shall register that additive and within 30 days (90 days in the case of initial registrations prior to the date prescribed for the additive in Subpart D) of receipt of the notification notify the additive manufacturer of such registration.

(b) Any additive which had been registered under the provisions of this part prior to the promulgation date of these regulations shall be deemed registered under these regulations upon such promulgation date. The information requirements of § 79.21 must be complied with for any such additive within 6 months after the promulgation of this part.

(c) The Administrator shall maintain a list of registered additives, which shall be available to the public upon request.

§ 79.24 Termination of registration of additives.

Registration may be terminated by the Administrator if the additive manufacturer requests such termination in writing.

Subpart D—Designation of Fuels and Additives

§ 79.30 Scope.

Fuels and additives designated and dates prescribed by the Administrator for the registration of such fuels and additives, pursuant to section 211 of the Act, are listed in this subpart. In addition, specific informational requirements under §§ 79.11(f) and 79.21(e) are set forth for each designated fuel or additive. Additional fuels and/or additives may be designated and pertinent dates and additional specific informational requirements prescribed as the Administrator deems advisable.

§ 79.31 Additives.

(a) All additives produced or sold for use in motor vehicle gasoline, motor vehicle diesel fuel, and/or motor vehicle engine oil are hereby designated.

(b) All designated additives must be registered within 6 months after the promulgation of this part, except as provided in § 79.23(b).

(c) In accordance with §§ 79.5(b) and 79.21(e), and to the extent such information is known to the additive manufacturer as a result of testing conducted for reasons other than additive regis-

tration or reporting purposes, the additive manufacturer shall furnish the highest, lowest, and average values of the impurities in each designated additive, if greater than 0.1 percent by weight. The methods of analysis in making the determinations shall also be given.

(d) In accordance with §§ 79.5(b) and 79.21(e), and to the extent such information is known to the additive manufacturer, he shall furnish summaries of any information developed by or specifically for him concerning the following items:

(1) Mechanisms of action of the additive;

(2) Reactions between the additive and the fuels listed in paragraph (a) of this section;

(3) Identification and measurement of the emission products of the additive when used in the fuels listed in paragraph (a) of this section;

(4) Effects of the additive on all emissions;

(5) Toxicity and any other public health or welfare effects of the emission products of the additive;

(6) Effects of the emission products of the additive on the performance of emission control devices/systems. Such submissions shall be accompanied by a description of the test procedures used in obtaining the information. Information will be considered to be known to the additive manufacturer if a report thereon has been prepared and circulated or distributed outside the research department or division.

§ 79.32 Motor vehicle gasoline.

(a) The following fuels commonly or commercially known or sold as motor vehicle gasoline are hereby individually designated:

(1) Motor vehicle gasoline, unleaded—motor vehicle gasoline that contains no more than 0.05 gram of lead per gallon;

(2) Motor vehicle gasoline, leaded, premium—motor vehicle gasoline that contains more than 0.05 gram of lead per gallon and is sold as "premium;"

(3) Motor vehicle gasoline, leaded, non-premium—motor vehicle gasoline that contains more than 0.05 gram of lead per gallon but is not sold as "premium."

The Act defines the term "motor vehicle" to mean any self-propelled vehicle designed for transporting persons or property on a street or highway. For purposes of this registration, however, gasoline specifically blended and marketed for motorcycles is excluded.

(b) All designated motor vehicle gasolines must be registered within 8 months after promulgation of this part.

(c) In accordance with § 79.5(a)(2) and 79.11(f), and to the extent such information is known to the fuel manufacturer as a result of testing conducted for reasons other than fuel registration or reporting purposes, the fuel manufacturer shall furnish the data listed below. The highest, lowest, and average values of the listed characteristics/properties are to be reported. For initial registration, data shall be given for any 3-month or longer period prior to the date of submission. For annual reports thereafter, data shall be for the calendar year, except that if the first required annual report covers a period of less than a year, the data may be for such shorter period.

(1) Hydrocarbon composition (aromatic content, olefin content, saturate content), with the methods of analysis identified;

(2) Polynuclear organic material content, sulfur content, and trace element content, with the methods of analysis identified;

(3) Reid vapor pressure;

(4) Distillation temperatures (10 percent point, end point);

(5) Research octane number and motor octane number.

(d) In accordance with § 79.5(a)(2) and 79.11(f), and to the extent such information is known to the fuel manufacturer, he shall furnish summaries of any information developed by or specifically for him concerning the following items:

(1) Mechanisms of action of each additive he reports;

(2) Reactions between such additives and motor vehicle gasoline;

(3) Identification and measurment of the emission products of such additives when used in motor vehicle gasoline;

(4) Effects of such additives on all emissions;

(5) Toxicity and any other public health or welfare effects of the emission products of such additives;

(6) Effects of the emission products of such additives on the performance of emission control devices/systems. Such submissions shall be accompanied by a description of the test procedures used in obtaining the information. Information will be considered to be known to the fuel manufacturer if a report thereon has been prepared and circulated or distributed outside the research department or division.

§ 79.33 Motor vehicle diesel fuel.

(a) The following fuels commonly or commercially known or sold as motor vehicle diesel fuel are hereby individually designated:

(1) Motor vehicle diesel fuel, grade 1-D;

(2) Motor vehicle diesel fuel, grade 2-D.

The Act defines the term "motor vehicle" to mean any self-propelled vehicle designed for transporting persons or property on a street or highway.

(b) All designated motor vehicle diesel fuels must be registered within 12 months after promulgation of this part.

(c) In accordance with §§ 79.5(a)(2) and 79.11(f), and to the extent such information is known to the fuel manufacturer as a result of testing conducted for reasons other than fuel registration or reporting purposes, the fuel manufacturer shall furnish the data listed below. The highest, lowest, and average values of the listed characteristics/properties are to be reported. For initial registration, data shall be given for any 3-month or longer period prior to the date of submission. For annual reports thereafter, data shall be for the calendar year, except that if the first required annual report covers a period of less than a year, the data may be for such shorter period.

(1) Hydrocarbon composition (aromatic content, olefin content, saturate content), with the methods of analysis identified;

(2) Polynuclear organic material content, sulfur content, and trace element content, with the methods of analysis identified;

(3) Distillation temperatures (90 percent point, end point);

(4) Cetane number or cetane index.

(d) In accordance with §§ 79.5(a)(2) and 79.11(f), and to the extent such information is known to the fuel manufacturer, he shall furnish summaries of any information developed by or specifically for him concerning the following items:

(1) Mechanisms of action of each additive he reports;

(2) Reactions between such additives and motor vehicle diesel fuel;

(3) Identification and measurement of the emission products of such additives when used in motor vehicle diesel fuel;

(4) Effects of such additives on all emissions;

(5) Toxicity and any other public health or welfare effects of the emission products of such additives.

Such submission shall be accompanied by a description of the test procedures used in obtaining the information. Information will be considered to be known to the fuel manufacturer if a report thereon has been prepared and circulated or distributed outside the research department or division.

[FR Doc.75-30070 Filed 11-6-75;8:45 am]

SUBCHAPTER N—EFFLUENT GUIDELINES AND STANDARDS

[FRL 453-2]

PART 406—GRAIN MILLS POINT SOURCE CATEGORY

Pretreatment Standards for New Sources

On pages 37052-37054 of the FEDERAL REGISTER of August 25, 1975, there was published a proposal to amend § 406.16, the pretreatment standards for new sources in the Corn Wet Milling Subcategory (Subpart A). The change to § 406.16 provides a formula that has been developed to quantify excessive loads for new corn wet mills to publicly owned treatment works (POTW). This change is in response to the remand to the Environmental Protection Agency (EPA) of new source pretreatment standards by the United States Circuit Court of Appeals for the Eighth Circuit made on May 5, 1975. See CPC International Inc. v. Train, 515 F.2d 1032 (8th Cir. 1975). The remand required EPA to review paragraph (d) of § 128.131 of the general pretreatment standards (40 CFR