EFFECTIVE DATE: 0901 UTC, November 30, 2000.

FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018; telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Friday, June 16, 2000, the FAA proposed to amend 14 CFR part 71 to establish Class E airspace at Soldiers Grove, WI (65 FR 37726). The proposal was to create controlled airspace extending upward from 700 feet above the surface to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace at Soldiers Grove, WI, to accommodate aircraft executing instrument flight procedures into and out of Leeward Farm Airport. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 95665, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL WI E5 Soldiers Grove, WI [New]

Soldiers Grove, Leeward Farm Airport, WI
(Lat. 43°21′10″ N., long. 90°40′51″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Leeward Farm Airport, excluding that airspace within the Boscobel, WI, Class E airspace area.

* * * * *

Issued in Des Plaines, Illinois on August 7, 2000.

Christopher R. Blum,

Manager, Air Traffic Division.

[FR Doc. 00–21816 Filed 8–24–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 71, 170, and 171

[Docket No. 95N–0220]

RIN 0910–AA58

Substances Approved for Use in the Preparation of Meat and Poultry Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on petitions for the use of food ingredients and sources of radiation. This regulatory change will permit an efficient, joint review by both FDA and the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA), of petitions for approval to use a food ingredient or source of radiation in or on meat or poultry products.

DATES: This rule is effective August 25, 2000, except for the amendments to §§ 71.1 and 171.1 (21 CFR 71.1 and 171.1), which contain collection of information provisions subject to review and clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). The amendments to these sections will be made effective after OMB approval is received, at which time, FDA will announce the effective date in the **Federal Register**. Submit written comments on the collection of information provisions by October 24, 2000.

ADDRESSES: Submit written comments on the information collection provisions of this final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Arletta M. Beloian, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3082.

SUPPLEMENTARY INFORMATION:

I. Background

In the**Federal Register** of December 29, 1995 (60 FR 67459), FSIS proposed to amend the Federal meat and poultry products inspection regulations containing the procedures for reviewing the safety and suitability of food and color additives used in meat and poultry products. In that same issue of the **Federal Register** (60 FR 67490), FDA proposed to make changes to its regulations regarding submission of petitions for the use of food ingredients and sources of radiation to accommodate a simultaneous review by the two agencies. Those proposals reflected interagency coordination to ease the burden on regulated industries and consumers. Such a coordinated effort by the two agencies, through streamlining the Government's food ingredient approval process, showed a commitment to achieving goals for the

Reinventing Food Regulations part of the President's National Performance Review.

FDA received seven comments to the proposal during the comment period that closed on March 14, 1996. In response to a request for additional time to submit comments, and for consistency with an FSIS comment period extension, the FDA comment period was reopened for 60 days, closing June 3, 1996. Two comments were received during the extension period. The comments all generally supported FDA's proposal but added specific comments on issues of regulatory authority, policy, and the procedures that both agencies will use to harmonize the review of petitions to authorize the use of substances in meat and poultry products.

Over the years, FDA and FSIS have conferred and cooperatively addressed food ingredient issues on an as needed, substance-specific, case-by-case basis. Nonetheless, because the agencies have different statutory mandates, the regulations of the two agencies that govern the use of food and color additives and generally recognized as safe (GRAS) substances added to meat and poultry products sometimes include conditions, formats, and terms that are not fully consistent with one another. This absence of consistency may cause difficulty and inconvenience people who need to comply with both agencies' laws and regulations on use of substances in meat and poultry products.

Section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) requires FDA to evaluate the safety and regulate the use of food additives in or on all foods; section 721 of the act (21 U.S.C. 379e) provides FDA with comparable authority over color additives. The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 601(m)(2) and 21 U.S.C. 453(g)(2)) authorize the administrator of FSIS to determine the suitability and regulate the use of ingredients and sources of radiation in or on meat and poultry products in federally inspected facilities. Under the current process, FDA and FSIS conduct separate, sequential reviews, each agency applying its respective procedures to ascertain that a substance is lawful for the use intended in or on meat or poultry products. Both agencies agree that their respective regulations may be harmonized and simplified.

FDA and FSIS have developed a memorandum of understanding (MOU) for handling submissions on the use of food ingredients in meat and poultry products. Under the terms of the MOU, FDA will be the petitioner's regulatory contact and conduct a safety review, and FSIS will simultaneously conduct a suitability determination. On completion of its determination, FSIS will provide FDA with its review on suitability, describing its conclusions in terms of any restrictions or conditions of use that FSIS determines to be necessary to comply with its various regulations and policies with regard to meat and poultry products. When issuing a new regulation or amending an existing one in title 21 of the Code of Federal Regulations (CFR), FDA will carefully and fully consider the FSIS recommendations and will specify in the regulation whether use of a substance is allowed in meat and poultry products along with any necessary restrictions or conditions of use.

Current FDA regulations provide a petition procedure for interested parties to obtain affirmation by FDA that the use of a substance is GRAS and, thus, exempt from the requirement for premarket approval that applies to food additives. This rule amends those regulations by establishing specific procedures regarding petitions to affirm the use of ingredients in meat or poultry products as GRAS. On April 17, 1997 (62 FR 18938), FDA proposed to replace the GRAS affirmation process with a GRAS notification procedure. This procedure would allow a manufacturer to make a determination that the use of a substance in food is GRAS and to notify FDA of such determination along with a submission of summary information that provides support for that determination. If FDA adopts the GRAS notification proposal as a final rule, the section listed below in 21 CFR 170.35 would be revoked. Under the MOU, if and when GRAS notification becomes FDA's established practice, FDA and FSIS will consult with each other on GRAS notifications for use of an ingredient in meat and poultry products, as necessary and appropriate. The notifier will be informed of any concerns about the suitability of the use of the substance in meat and poultry products and, when applicable, will be informed of any restrictions or conditions of use in meat and poultry products required by the act.

II. Response to Comments

A. Regulatory Authority

(Comment 1) Several comments stated that one agency should have exclusive responsibility for determining whether a substance may or may not be used in meat and poultry products. The comments stated that because FDA has the scientific staff, institutional expertise, and regulatory structure for reviewing the safety of food ingredients, FDA's broad jurisdiction over foods should be extended to cover substances in meat and poultry products. In support of this opinion, one comment argued that if the FSIS conducts their review out of synchronization with FDA's review, the goal of streamlining the approval process would fail. Another argued that requiring concurrent reviews does not necessarily eliminate review time but is really a layering of one agency's approvals on top of the other agency's approvals.

Under the act, FDA is authorized to evaluate the safety of substances added to food, including the addition to meat and poultry, and to approve the safe use of food and color additives. This rule has no effect on that authority. However, the laws that FSIS administers (FMIA and PPIA) may preclude the use of a substance in meat or poultry products for reasons other than safety. In particular, provisions regarding efficacy and suitability of substances for use in meat and poultry products are the province of FSIS. For instance, there are cases where the use of a substance, even if safe, may promote deception when used in a meat or poultry product and, accordingly, such use would be prohibited by FSIS. For example, although paprika is considered GRAS by FDA and is also listed for use as a color additive, FSIS regulations prohibit the use of this spice on fresh, uncooked meat products because such use adds color that may make the meat appear fresher than it actually is.

FDA and FSIS have concluded that a single submission, joint review, and single rulemaking procedure will eliminate duplicate review and reduce the time it takes to authorize a food ingredient for use in meat and poultry products.

B. Reporting Procedures and Requirements

(Comment 2) One comment asserted that when FDA approves a substance for use in food generally, with no limitation other than good manufacturing practice, the general use of the food ingredient should also include the use in meat and poultry components.

The agency agrees with this comment with respect to safety under the act. However, safety is not the only criterion governing the lawful use of an ingredient in foods subject to FMIA or PPIA. Historically, food and color additive petitions generally were reviewed and regulations were written without input from FSIS regarding any

regulatory issues raised under FMIA or PPIA. Thus, the ingredients were subjected to a second review by FSIS after FDA review was completed. To make the review process more efficient, FDA concludes that future petition reviews should address explicitly the concern raised by the comment. Therefore, a new substance to be listed by FDA for general food use would require an explicit request for the use in meat and poultry products, accompanied by appropriate supporting data so both agency reviews can occur concurrently.

(Comment 3) One comment expressed concern that the petition format for FDA food additive petition review is more complicated and extensive than that currently used by FSIS and its completion is expected to be more time consuming. The comment asked what modifications in procedure and reporting requirements would be made for simultaneous review of petitions for use of food and color additives in meat and poultry products. The comment also asked whether FDA's regulations would be modified to reflect the FSIS product classes relevant to the use of substances in meat and poultry products.

First, this rule does not impose any reviews that have not been required previously. Second, the issues in petitions addressed by FDA and FSIS are different, in that FDA primarily addresses safety, while the FSIS addresses efficacy and suitability. Substances whose uses would have required a safety review by FDA in the past would require, under this final rule, the submission of the same safety data. At this time, FDA sees no need to modify its regulations or to impose new requirements for the review of petitions regarding the use of substances in meat and poultry products with one exception. That is, if a petition seeks approval of the use of a substance in meat and poultry products, the petitioner should state that fact explicitly and should submit to FDA appropriate data in support of such use as part of the petition rather than to FSIS separately. This procedure will facilitate a more expeditious review of the petition by both agencies. If, after some experience is gained with this procedure, FDA and FSIS see a need for additional specific information, FDA will revise its guidance documents for petitioners.

C. GRAS Determination

(Comment 4) Several comments pointed out that numerous substances that have been accepted as GRAS by FDA for use in food generally are not listed in Title 21 CFR. One comment urged that a clear allowance for a self-determined GRAS status of substances for use in meat and poultry products be included in the interagency MOU.

FDA acknowledges that not all uses of substances that are GRAS are listed in Title 21 of FDA's regulations. This results from the fact that substances whose use is GRAS are excepted from the definition of a food additive and, therefore, do not require approval by FDA. As noted above, under the interagency MOU, FDA and FSIS are developing operational procedures to review GRAS notices and to identify which agency will be responsible for different aspects of the review.

D. Other Comments

(Comment 5) Some comments objected to FSIS continuing to be responsible for assessing, independently of FDA, a manufacturer's basis for determining that use of a substance is GRAS on the basis that such a procedure would be in conflict with streamlining the approval process and would continue the duplicative review by both agencies.

FDA finds that because these comments relate specifically to FSIS statutory obligations and role regarding food ingredients intended for use in meat and poultry products, they are outside the scope of FDA's proposal. Indeed, FSIS has responded to similar comments in their final rule published in the **Federal Register** of December 23, 1999 (64 FR 72168).

III. Conforming Amendments

Current FDA regulations require that a petition for approval of the use of a food additive or a color additive be submitted in triplicate. This final rule amends §§ 71.1(a) and 171.1(a) of the agency's regulations to require the submission of one additional copy of a petition where the proposed use includes use in meat or poultry; this additional copy will be provided to FSIS so that FDA and FSIS can perform concurrent reviews. This final rule also provides that FDA will list any uses of food and color additives that are suitable for use in meat or poultry and will describe conditions of use under which the substances may be safely used.

In preparing this final rule, FDA became aware that §§ 71.1(a) and 171.1(a) also describe the number of copies of a petition to be submitted to FDA. This final rule also amends §§ 71.1(a) and 171.1(a) to require the submission of petitions in quadruplicate where the proposed use includes use in meat or poultry. Although FDA did not explicitly propose to amend these two provisions of the regulations, the substance of the change was proposed. Therefore, FDA is amending §§ 71.1(a) and 171.1(a) to make them consistent with other provisions of the regulations, as amended.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

A. Requirement of Cost-Benefit Analysis

FDA has examined the impacts of this final rule to amend 21 CFR parts 71, 170, and 171 under Executive Order 12866, the Unfunded Mandates Reform Act of 1995 (UMRA), the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), and the Regulatory Flexibility Act (RFA) (Public Law 96–354).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues.

UMRA (Public Law 104–4) requires certain cost-benefit and other analyses; section 1531(a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year.''

SBREFA (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of

United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

RFA (5 U.S.C. 601–612) requires agencies to analyze regulatory options that would lessen the economic effect of a rule on small entities if a rule has a significant economic impact on a substantial number of small entities.

Under the guidelines of Executive Order 12866, UMRA, SBREFA, and RFA, FDA finds that this final rule would not have a significant adverse economic impact. However, the Office of Information and Regulatory Affairs (OIRA) of OMB has determined this rule to be a significant regulatory action as defined by section 3(f)(4) of Executive Order 12866 because it raises novel legal or policy issues arising out of the President's priorities, namely the reinvention of Government and regulatory reform initiatives. Therefore, this final rule has been formally reviewed by OIRA in accordance with the provisions of Executive Order 12866.

B. The Costs and Benefits of This Rule

1. Costs

FDA believes that there are no significant new costs associated with this rule.

2. Benefits

This rule will benefit the regulated industry, the Federal Government, and consumers. Administrative costs for both industry and the Federal Government will fall with the elimination of duplicative approval processes. Also, this rule will benefit both industry and consumers by facilitating the more timely introduction of safe food additives, color additives, and other substances lawfully used in food.

One effect of this rule is to eliminate the current duplicative administrative costs of the additive approval process for the Federal Government. Under the current regulatory framework, firms seeking to use food additives or color additives in meat or poultry must sequentially seek the approval of the FDA and then FSIS. This rule simplifies the process by requiring that only one petition be submitted to the FDA for the entire Federal Government.

Industry will also benefit from this rule. As with the Federal Government, the industry's administrative costs will fall with the implementation of this rule. Fewer required petitions translate into lower overall costs. Furthermore, having a more efficient approval process will increase the expected profits from the use and sale of the food and color additives that are the subject of this process. The resulting increase in expected profits could act as an incentive to increase effort in the research and development of new food and color additives with a net result of an increase in the quantity and quality of additives on the market.

Having an increased number of safe additives on the market sooner will also benefit consumers. First, the introduction of new additives will increase consumer choice. Thus, the typical consumer will be better off. Second, the expected cost of a product using an additive of a given quality level will fall. This is because greater innovation will lead to more low cost alternatives and a competitive industry will use its lowest cost alternative.

3. Summary

FDA believes that this rule is economically justified because this rule has no costs and has positive benefits. In fact, consumers, industry, and government will all benefit from this rule.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Petition for Approval of Substances for Use in the Preparation of Meat and Poultry Products.

Description: The act (sections 409 and 721) requires FDA to evaluate the safety and regulate the use of food and color additives used as ingredients in or on all foods. These sections also authorize FDA to accept petitions for approval of food and color additives. FMIA and PPIA (21 U.S.C. 601(m)(2) and 21 U.S.C. 453(g)(2)) authorize the administrator of FSIS, USDA, to determine the suitability of the use of a substance in meat and poultry products. Regulations of the two agencies at times include conditions, formats, and terms that are not fully consistent with one another because of the different statutory mandates. Under the current process FDA and FSIS conduct separate, sequential reviews, each agency applying its respective procedures to ascertain that a substance is lawful for the use intended in or on products containing meat or poultry.

This final rule requires applicants that petition for approval for the use of substances in meat and poultry products to provide four copies of the petition to FDA, rather than the three copies as currently specified in §§ 71.1 and 171.1. FDA will then forward a copy of the petition or relevant portions of the petition to FSIS so that both agencies can perform the necessary reviews simultaneously, thus reducing the time it takes to authorize an ingredient for use in meat and poultry products. The rule does not require petitioners to submit any new information to either FDA or FSIS.

This final rule results from a coordinated effort by the two agencies to ease the paperwork burden on regulated industries through streamlining the Government's food ingredient approval process for substances used in meat and poultry products.

Description of Respondents: Businesses or other for profit.

TABLE 1.—ESTIMATED ANNUAL INCREASE IN REPORTING HOUR BURDEN [1]

21 CFR Section	Number of Respondents	Annual Frequency of Response	Total Annual Responses	Increase in Hours per Response	Total Increase in Hours
71.1 and 171.1	10	1	10	2	20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA's past experience with food and color additive petitions and on discussions with FSIS about its past experience, it will receive 10 petitions annually that request approval for use of a substance in meat and poultry products. Submission of a petition for the use of a substance in meat and poultry products is a one-time event.

FDA estimates that the respondent would expend 2 hours to make a fourth photocopy of the petition, necessary for FDA to send to FSIS to conduct a simultaneous review. FDA, therefore, estimates that the total burden of data collection under §§ 71.1 and 171.1 will increase by 20 hours per year because of the requirement to submit a fourth copy of petitions for use of a substance in meat or poultry products.

The December 29, 1995 (60 FR 67490), proposed rule provided a general comment period that closed on March 14, 1996, and reopened for another 60 days ending June 3, 1996. However, because of an oversight, FDA did not specifically solicit comments on the information collection provisions of the proposed rule, as required by the PRA. Therefore, FDA is providing an opportunity for public comment under the PRA at this time. FDA now invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Individuals and organizations may submit comments on the information collection provisions of this final rule by October 24, 2000. Comments should be sent to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of this final rule, FDA will publish in the **Federal Register** a notice of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the information collection provisions of this final rule by October 24, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 71

Administrative practice and procedure, Color additives, Confidential business information, Cosmetics, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 71, 170, and 171 are amended as follows:

PART 71—COLOR ADDITIVE PETITIONS

1. The authority citation for 21 CFR part 71 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 351, 355, 360, 360b–360f, 360h–360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

2. Section 71.1 is amended in paragraph (a) by revising the third sentence, in paragraph (c) in the petition by revising the introductory paragraph preceding paragraph A., and by adding paragraph (j) to read as follows:

§ 71.1 Petitions.

(a) * * * The petition shall be submitted in triplicate (quadruplicate, if intended uses include uses in meat, meat food product, or poultry product). * * *

* * * * *

(c) * * *

Attached hereto, in triplicate (quadruplicate, if intended uses include uses in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

* * * * *

(j)(1) If intended uses of the color additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) or the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA or, if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

3. Section 71.20 is amended by adding paragraph (a)(3) to read as follows:

§ 71.20 Publication of regulation.

* * * * *

(a) * * *

(3) The regulation shall list any use or uses in meat, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection (PPIA) (21 U.S.C. 451 *et seq.*) for which the color additive has been found suitable and for which it may safely be employed.

* * * * *

PART 170—FOOD ADDITIVES

4. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

5. Section 170.35 is amended by redesignating paragraphs (c)(3) through (c)(6) as paragraphs (c)(4) through (c)(7), respectively, and by adding new paragraph (c)(3) to read as follows:

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c) * * *

(3)(i) If intended uses of the substance include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(ii) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA or, if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

* * * * *

PART 171—FOOD ADDITIVE PETITIONS

6. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

7. Section 171.1 is amended in paragraph (a) by revising the first sentence, in paragraph (c) in the petition by revising the introductory paragraph preceding paragraph A., and by adding paragraph (n) to read as follows:

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the Federal Food, Drug, and Cosmetic Act (the act) shall be submitted in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product). * * *

* * * * *

(c) * * *

Attached hereto, in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

* * * * *

(n)(1) If intended uses of the food additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) or the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

8. Section 171.100 is amended by redesignating paragraph (b) as paragraph (c) and by adding new paragraph (b) to read as follows:

§ 171.100 Regulation based on petition.

* * * * *

(b) The regulation shall describe the conditions under which the substance may be safely used in any meat product, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*).

* * * * *

Dated: August 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21693 Filed 8–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AI74

Veterans Training: Vocational Rehabilitation Subsistence Allowance Rates

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: By statute, VA must determine each fiscal year what increase, if any, VA will pay in the monthly rates of basic subsistence allowance payable under 38 U.S.C. chapter 31. The statute provides a formula for this increase. We are changing the regulations governing the rates of basic subsistence allowance VA will pay under 38 U.S.C. chapter 31 to show the increases in these rates for fiscal years 1996 through 2000. To reflect a statutory change, we are also changing the regulations to include rates for fiscal years 1995 through 2000 for certain training or work experience in a facility of an agency of a federally recognized Indian tribe. In addition, we are correcting a typographical error in the fiscal year 1995 rates, making changes to conform to statutory language, and making nonsubstantive changes to improve clarity.

DATES: *Effective Date:* This final rule is effective August 25, 2000.

Applicability Dates: To conform to statutory requirements, the changes to rate provisions apply retroactively to the dates shown in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Charles Graffam, Vocational Rehabilitation and Employment Service, Veterans Benefits Administration, (202) 273–7410.

SUPPLEMENTARY INFORMATION: VA must annually determine what increase, if any VA will pay in the rates of subsistence allowance under 38 U.S.C. chapter 31 for programs of education under a formula in 38 U.S.C. 3108. The formula specifies the base subsistence allowance rates that were effective for the fiscal year beginning October 1, 1993. Under the formula, the effective date of any later annual increase is October 1, beginning October 1, 1994. Each October 1, subsistence allowance rates have increased by a percentage. To find this percentage increase for a particular fiscal year, look at the total of the monthly Consumer Price Index—W (CPI–W) for the 12-month periods that ended on the preceding June 30 and on the June 30 before that. If the CPI–W for the later year exceeds the earlier year, subtract the earlier year's CPI–W from the later year's CPI–W. The result is the allowable percentage increase in subsistence allowance for that fiscal year.

Under that formula, we are changing the regulations in 38 CFR 21.260 governing monthly rates to reflect increases for fiscal years 1996 through 2000, the fiscal years beginning on October 1 of 1995, 1996, 1997, 1998, and 1999, respectively:

Percentage increase	Effective date
2.9	October 1, 1995.
2.7	October 1, 1996.
2.8	October 1, 1997.
1.6	October 1, 1998.
1.6	October 1, 1999.

Also, we are adding language to the regulations governing monthly rates to reflect a statutory change by Public Law 103–446, effective November 2, 1994. This change adds rates for subsistence allowance for nonpay or nominal pay on-job training or work experience in a facility of a federally recognized Indian tribal agency.

In addition, in 38 CFR 21.260(b) the table concerning rates effective October 1, 1994 (but not the information used in making actual payments) had a typographical error. The table should have shown $465.08 instead of $465.88. We are correcting that error.