this title requires the signature of a producer; landowner; landlord; or tenant, a husband or wife may sign all such FSA or CCC documents on behalf of the other spouse, unless such other spouse has provided written notification to FSA and CCC that such action is not authorized. The notification must be provided to FSA with respect to each farm.'' This section is corrected to change ''this chapter and parts 1410 and 1413 of'' to ''this chapter or Chapter XIV of'' to insure full coverage in all commodity programs, unless exempted by more specific rules.

2. *Quality loss payments for hay.* This document corrects 7 CFR part 1480, Crop Disaster Program, published in the **Federal Register** on June 26, 2003, under the authority of the Agricultural Assistance Act of 2003 (Public Law 108–7) (2003 Act). Section 1480.17(m) states ''Quantity adjustments for diminished quality shall also not apply under this section to: Hay, honey, maple sap, turfgrass sod, crops marketed for a use other than an intended use for which there is not an established county price or yield, or any other crop that the Deputy Administrator deems it appropriate to exclude.'' This section is being amended to remove the word ''hay.'' The 2003 Act required CCC to follow section 815 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001 (Public Law 106–387; 114 Stat. 1549A–55) (2001 Act), stating that the new program shall use ''the same loss thresholds for quantity and quality losses as were administered in that section.'' The 2001 Act did not exclude hay from payments for diminished quality. This document amends the rule accordingly.

These changes clarify and correct recently published regulations. Delay of their publication for public comment is unnecessary and contrary to the public interest. Further, 7 U.S.C. 7991(c)(2)(C), and section 217 of Title II, Division N, of Public Law 108–7, exempt these changes from notice and comment rulemaking. So that they may apply equally with existing regulations, these changes are effective as of the original filing of the rules they correct, as described below, implementing the 2002 Act.

List of Subjects

7 CFR Part 718

Acreage allotments, Agricultural commodities, Marketing quotas.

7 CFR Part 1480

Agricultural commodities, Disaster assistance, Emergency assistance, Reporting and record keeping requirements.

■ Accordingly, the **Federal Register** is corrected as follows:

■ 1. In the final rule FR Doc. 03–8025 published on April 3, 2003, (68 FR 16170–16185), make the following corrections:

■ a. On page 68 FR 16173, in the first column, in § 718.2, correct the introductory text of the definition of ''Extra Long Staple Cotton,

■ b. On page 68 FR 16174, in the second column, in § 718.2, correct the definition of ''Rice'', and

■ c. On page 68 FR 16174, in the third column, in § 718.2, correct the definition of ''Upland cotton,'' to read as follows:

§ 718.2 Definitions.

* * * * *

Extra Long Staple (ELS) Cotton means cotton that follows the standard planting and harvesting practices of the area in which the cotton is grown, and meets all of the following conditions:

* * *

* * * * *

Rice means rice that follows the standard planting and harvesting practices of the area excluding sweet, glutinous, or candy rice such as Mochi Gomi.

* * * * *

Upland cotton means planted and stub cotton that is not considered extra long staple cotton, and that follows the standard planting and harvesting practices of the area and is produced from other than pure strain varieties of the Barbadense species, any hybrid thereof, or any other variety of cotton in which one or more of these varieties predominate. For program purposes, brown lint cotton is considered upland cotton.

■ d. On page 68 FR 16175, in the second column, correct § 718.6 by removing paragraph (b)(3) and correcting paragraph (b)(2) to read as follows:

§ 718.6 Controlled substance.

* * * * *

(b) * * *

* * * * *

(2) Possession of a controlled substance, or trafficking in a controlled substance, shall, in addition to any ineligibility under paragraph (b)(1) of this section, be ineligible for any or all USDA benefits, to the extent that a court shall determine to impose such ineligibility pursuant to applicable Federal law, in which case the ineligibility shall be for such period of time as is imposed by the court, pursuant to such law, at the discretion of the court.

■ e. On page 68 FR 16176 in the first column, correct § 718.9(a) to read as follows:

§ 718.9 Signature requirements.

(a) When a program authorized by this chapter or Chapter XIV of this title requires the signature of a producer; landowner; landlord; or tenant, a husband or wife may sign all such FSA or CCC documents on behalf of the other spouse, unless such other spouse has provided written notification to FSA and CCC that such action is not authorized. The notification must be provided to FSA with respect to each farm.

* * * * *

■ 2. In the final rule FR Doc. 03–16161, published on June 26, 2003 (68 FR 37936–37952) make the following correction. On page 68 FR 37951 in the first column, correct § 1480.17(m) to read as follows:

§ 1480.17 Quantity adjustments for diminished quality for certain crops.

* * * * *

(m) Quantity adjustments for diminished quality shall also not apply under this section to: honey, maple sap, turfgrass sod, crops marketed for a use other than an intended use for which there is not an established county price or yield, or any other crop that the Deputy Administrator deems it appropriate to exclude.

* * * * *

Signed in Washington, DC, on December 23, 2003.

James R. Little,

Administrator, Farm Service Agency, and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 03–32324 Filed 12–30–03; 2:20 pm]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 300, 301, 306, 318, 320, and 381

[Docket No. 00–033F]

RIN 0583–AC78

Agency Organization

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service is amending regulations adopted under the Federal Meat Inspection Act and the Poultry Products Inspection Act by updating

and consolidating organizational provisions.

EFFECTIVE DATE: January 5, 2004.

FOR FURTHER INFORMATION CONTACT: Lynn E. Dickey, Director, Regulations and Petitions Policy Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250–3700; (202) 720–5627.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (FSIS) is responsible for carrying out various functions of the Department of Agriculture. Chief among these are the administration of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). Each of these statutes includes provisions that provide for government inspection as part of a regulatory program designed to protect the health and welfare of consumers by preventing the distribution of meat, poultry, and egg products that are unwholesome, otherwise adulterated, or misbranded (21 U.S.C. 451, 455, 602–606, 1031, and 1034).

In this rulemaking, FSIS is continuing its work to update and consolidate various regulatory provisions. This work began with the issuance of a final rule on the organization of the Agency. This rule, for which the public was given an opportunity to submit comments, was published on December 31, 1998 (the 1998 rule) (63 FR 72352). The 1998 rule amended FSIS's regulations in chapter III of title 9 of the Code of Federal Regulations (9 CFR chapter III) by establishing a new part 300 that described FSIS's mission and organization. It also transferred regulations adopted under the EPIA from part 59 of title 7 of the Code of Federal Regulations to part 590 of title 9.

The Agency received only one comment on the 1998 rule. The United Egg Association (UEA) requested that FSIS undertake a more thorough review of the regulations promulgated pursuant to the EPIA. The UEA stated that the current regulatory system was antiquated.

FSIS is conducting a comprehensive review of the EPIA regulations. The Agency anticipates that the review will result in its proposing a number of substantive changes to the EPIA regulations.

In this final rule, the Agency is consolidating and updating various provisions of the regulations issued under the FMIA (9 CFR parts 300, 301, 306, 318, and 320) and the PPIA (9 CFR part 381, subparts A, B, F, O, and Q). The Agency is also adding a section, 300.4, ''Organizational terminology; personnel'' to part 300. With the addition of this section, part 300 ''Agency Mission and Organization'', will contain a description of the part (300.1), a statement about FSIS's responsibilities (300.2), a description of FSIS's organizational structure and personnel (300.3 and 300.4), and rules on the access of government employees to regulated places of business (300.6).

In § 300.1 (Purpose), FSIS is adding a sentence to reflect the fact that part 300 includes rules on the access of government employees to regulated places of business. In paragraph (a) of § 300.2 (FSIS responsibilities), FSIS is adding a sentence that references the Department's delegation of authority regulations (7 CFR 2.7, 2.18, and 2.53). These regulations reference the statutory provisions that the Administrator of FSIS is responsible for administering on behalf of the Secretary of Agriculture.

In § 300.3 (FSIS organization), FSIS is amending paragraph (a) by adding a sentence that states that FSIS implements the inspection provisions of the FMIA, the PPIA, and the EPIA through its field structure. FSIS is also amending paragraphs (b)(1) and (2), and (c)(1) of § 300.3 to reflect the changes that the Agency has made in its headquarters and field organization since publication of the 1998 rule.

FSIS has reorganized its headquarter's offices. FSIS now has eight principal components or offices instead of four. These offices are under the direction of an Assistant Administrator. The Assistant Administrators, along with their staffs and the Office of the Administrator, are still located at the U.S. Department of Agriculture Headquarters in Washington, DC.

FSIS has renamed one of the program offices listed in paragraph (b)(1) of § 300.3. The Office of Policy, Program Development, and Evaluation is now the Office of Policy and Program Development. The functions for this office have also changed. The Office of Policy and Program Development is charged with developing and articulating the Agency's policies regarding food safety and other consumer protections.

FSIS has added four program offices. These offices are the Office of Food Security and Emergency Preparedness (OFSEP), the Office of Program Evaluation, Enforcement, and Review (OPEER), the Office of Public Affairs, Education, and Outreach (OPAEO), and the Office of International Affairs (OIA).

The OFSEP's mission is to prevent or, if necessary, coordinate a response to an intentional attack on the food supply.

The OPEER's primary function is to perform as the Agency's quality assurance program. This staff continually acts as the Agency's eyes and ears to ensure that Agency programs are functioning in an efficient and effective manner.

The OPAEO is responsible for communicating with three main audiences: Congress, constituents, and the media. The OPAEO communications with Congress include everything from preparing testimony for hearings on Capitol Hill to briefing congressional staff on regulatory proposals affecting FSIS. The OPAEO also shares information with, and gathers feedback from, constituents of the Agency and provides newspaper, television and radio reporters accurate and timely information about FSIS's crucial role in protecting public health. The Staff Offices that are currently listed in paragraph (b)(2) of § 300.3 have been reorganized and incorporated into the new Office of Public Affairs, Education, and Outreach.

The OIA is responsible for developing policy and procedures to assure that meat, poultry, and egg products imported into the U.S. are safe, wholesome, unadulterated, properly labeled and packaged, and for facilitating the certification of U.S. meat, poultry, and egg products intended for export.

In addition to the four new program offices described above, the Administrator has created a position titled Special Assistant for Civil Rights. This individual reports directly to the Administrator. The Administrator also has an Executive Assistant and a Codex Manager.

As anticipated in the 1998 rule (63 FR 72352, footnote 1), FSIS has closed its district office in Boston, Massachusetts. The Agency has also reassigned the program responsibilities for the States of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont to the district office located in Albany, New York, and has reassigned the program responsibilities for Puerto Rico and the Virgin Islands to the district office located in Atlanta, Georgia.

In May 2002, FSIS realigned its district office structure. The realignment resulted in a reduction from 17 districts to 15 districts with 2 satellite offices. The Pickerington, Ohio district office will now be a satellite office and will be serviced by the Chicago, Illinois district office. The State of Kentucky will now be serviced by the Raleigh, North

Carolina district office and the State of West Virginia will be serviced by the Beltsville, Maryland district office.

The Salem, Oregon district office will become a satellite office and will be serviced by the Boulder, Colorado district office. The States and areas affected are Alaska, American Samoa, Guam, Hawaii, Idaho, Oregon, and Washington. The State of New Jersey, which was serviced by the Albany, New York district office will now be serviced by the Philadelphia, Pennsylvania district office. FSIS is amending paragraph (c)(1) of § 300.3 to reflect this fact and to correct the address listed for the district office in Maryland which is located in Beltsville, not Greenbelt.

FSIS is including, in paragraph (a) of § 300.4 (Organizational terminology; personnel), updated terminology that combines and replaces the current definitions in § 301.2 of Administrator, Circuit Supervisor, Inspector, Inspector in charge, Program, Program employee, and Secretary; and the current definitions in § 381.1(b) of Administrator, Circuit Supervisor, Inspection Service, Inspection Service employee, Inspection Service supervisor, Inspector, Inspector in Charge, and Secretary.

FSIS also is removing obsolete and unnecessary organizational information and terminology. Provisions that the Agency is deleting include: § 306.1 (Designation of circuit supervisors and assistants); the definitions in § 301.2 of Area, Area Supervisor, Circuit, the Department, Food Safety and Inspection Service, Import Field Office, Import Supervisor, and Regional Director; and the definitions in § 381.1(b) of Department, Import Field Office, and Import Supervisor.

FSIS is addressing several changes in the Agency's organization and the administration of its regulatory functions in paragraph (b) of § 300.4. Section 300.4(b) indicates that the Agency has replaced its regional office and import field office structure with a district office structure, that the authority previously delegated to Regional Directors now is delegated to district managers, and that the authority previously delegated to area supervisors and import supervisors now is delegated to inspection program supervisors in the successor district offices.

In paragraph (b) of § 300.6, FSIS is addressing access to places of business regulated under the FMIA or the PPIA. Paragraph (b)(1) addresses access to establishments that slaughter livestock or otherwise prepare meat products or slaughter poultry or otherwise process poultry products. It replaces the first sentence of § 306.2 and all of § 381.32. Paragraph (b)(2) addresses access to and examinations of facilities, inventories, and records authorized by section 202 of the FMIA and section 11(b) of the PPIA (21 U.S.C. 460(b) and 642). It replaces the first sentences of § 320.4 and § 381.178 (Access to and inspection of records, facilities and inventory; copying and sampling).

FSIS is updating its regulations on the accreditation of chemistry laboratories (§ 318.21 and § 381.53), a function performed by FSIS's Office of Public Health and Science (OPHS). An erroneous street address for the Accredited Laboratory Program is being removed and the OPHS Assistant Administrator is referred to instead of a former OPHS organizational unit.

In § 320.5 (Registration) and § 381.179 (Registration), FSIS is amending paragraph (a) in both sections by changing the office name from where registration forms are obtained and also providing another option for obtaining registration forms. The office name will be changed from Compliance Programs, Regulatory Programs, to Evaluation and Enforcement Division, Office of Program Evaluation, Enforcement and Review. The other option added for obtaining an application is to call the District Office.

FSIS has determined that the notice and comment and delayed effective date requirements of the Administrative Procedure Act (5 U.S.C. 553(b) and (d)) do not apply to this rule. The amendments made by this rule reflect the Agency's current responsibilities, the organization through which it carries out those responsibilities, and technical and minor changes in the organization of the Agency's regulations and organizational terminology. Therefore, FSIS has, for good cause, found that notice and public procedure thereon are unnecessary, and it is issuing these amendments as a final rule, effective upon publication.

Executive Order 12866 and Effect on Small Entities

The changes in this rule are organizational and technical. Their adoption will not affect the costs of regulated establishments or of FSIS, except to the extent that providing the public with current information on how the Agency operates should increase the Agency's efficiency and improve the delivery of inspection services to members of the regulated industries. Therefore, FSIS has determined that this rule is not a significant regulatory action under the criteria set forth in Executive Order 12866.

For the same reasons, FSIS certifies that this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, as provided in section 605 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), sections 603 and 604 do not apply.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. No retroactive effect will be given to the rule and no administrative proceedings will be required before parties may file suit in court challenging the rule. States and local jurisdictions may not impose inconsistent requirements on federally inspected premises, facilities, or operations.

Paperwork Reduction Act

No collections of information will be affected by the adoption of this rule.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and make copies of this **Federal Register** publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the FSIS Web page located at *http://www.fsis.usda.gov*. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information contact the Congressional and Public Affairs Office, at (202) 720–9113. To be added to the free e-mail subscription service (Listserv) go to the ''Constituent Update'' page on the FSIS Web site at *http://www.fsis.usda.gov/oa/update/update.htm*. Click on the ''Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

List of Subjects in 9 CFR Chapter III

Part 300

Meat and meat products, Poultry and poultry products.

Part 301

Meat and meat products, Poultry and poultry products.

Part 306

Government employees, Meat inspection.

Part 318

Laboratories, Meat inspection, Reporting and recordkeeping requirements.

Part 320

Meat inspection, Reporting and recordkeeping requirements.

Part 381

Laboratories, Poultry and poultry products, Reporting and recordkeeping requirements.

■ For the reasons set forth above, the Food Safety and Inspection Service is amending 9 CFR Chapter III as follows:

PART 300—AGENCY MISSION AND ORGANIZATION

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 21 U.S.C. 451–470, 601–695, 1031–1056; 7 U.S.C. 138–138i, 450, 1621–1627, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

§ 300.1 [Amended]

■ 2. Section 300.1 is amended by adding, at the end, ''It also includes rules on the access of government employees to regulated places of business.''

■ 3. Paragraph (a) of § 300.2 is revised to read as follows:

§ 300.2 FSIS responsibilities.

(a) *Delegations of authority.* The Secretary of Agriculture and Under Secretary for Food Safety have delegated to the Administrator of the Food Safety and Inspection Service the responsibility for exercising the functions of the Secretary of Agriculture under various statutes (see 7 CFR 2.7, 2.18, and 2.53).

* * * * *

■ 4. Section 300.3 is amended as follows:

■ a. Paragraph (a) of § 300.3 is amended by adding, at the end, ''FSIS implements the inspection provisions of the FMIA, the PPIA, and the EPIA through its field structure.''

■ b. The introductory text of paragraph (b) of § 300.3 is amended by removing ''four'' in the first sentence of the introductory text and adding, in its place, ''eight''.

■ c. Paragraph (b)(1) of § 300.3 is amended and the table of district office locations and geographic boundaries in paragraph (c)(1) is revised to read as follows:

§ 300.3 FSIS organization.

* * * * *

(b) *Headquarters.* * * *

(1) *Program Offices.* FSIS's headquarters offices are the Office of Public Health and Science, which provides scientific analysis, advice, data, and recommendations on matters involving public health and science; the Office of Management, which provides centralized administrative and support services; the Office of Policy and Program Development, which develops and articulates the Agency's policies regarding food safety and other consumer protections; the Office of Field Operations, which manages regulatory oversight and inspection (see paragraph (c) of this section); the Office of Food Security and Emergency Preparedness, which works to prevent or, if necessary, coordinate a response to an intentional attack on the food supply; the Office of Program Evaluation, Enforcement, and Review, which acts to ensure that Agency programs are functioning in an efficient and effective manner; the Office of Public Affairs, Education, and Outreach, which is responsible for facilitating communications between FSIS and Congress, the Agency's constituents, and the media; and the Office of International Affairs, which is responsible for recommending and developing international policy activities.

(2) [Reserved]

(c) *Field.* * * *

(1) *District offices.* * * *

Alameda, CA	California.
Boulder, CO	Arizona, Colorado, Nevada, New Mexico, Utah, Alaska, American Samoa, Guam, Hawaii, Idaho, Northern Mariana Islands, Oregon, and Washington.
Salem, OR (satellite office)	
Minneapolis, MN	Minnesota, Montana, North Dakota, South Dakota, and Wyoming.
Des Moines, IA	Iowa and Nebraska.
Lawrence, KS	Kansas and Missouri.
Springdale, AR	Arkansas, Louisiana, and Oklahoma.
Dallas, TX	Texas.
Madison, WI	Michigan and Wisconsin.
Chicago, IL	Illinois, Ohio, and Indiana.
Pickering, OH, (satellite office)	
Philadelphia, PA	Pennsylvania and New Jersey.
Albany, NY	Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont.
Beltsville, MD	Delaware, District of Columbia, Maryland, Virginia, and West Virginia.
Raleigh, NC	North Carolina, South Carolina, and Kentucky.
Atlanta, GA	Florida, Georgia, Puerto Rico, and the Virgin Islands.
Jackson, MS	Alabama, Mississippi, and Tennessee.

* * * * *

■ d. Paragraph (b)(2) of § 300.3 is removed and reserved.

■ 5. Part 300 is further amended by adding § 300.4 to read as follows:

§ 300.4 Organizational terminology; personnel.

(a) Unless otherwise specifically provided or required in the context of a particular part of the regulations:

Administrator means the Administrator of the Food Safety and Inspection Service or any other officer or employee of the Department to whom authority has been or may in the future be delegated to act in his or her stead.

Circuit Supervisor means the official of the Inspection Service who is assigned responsibility for supervising the conduct of inspection at a specific group of official establishments.

Inspection program, inspection service, or *program* means the organizational unit within the Department with responsibility for carrying out the FMIA, the PPIA, and the EPIA.

Inspection program employee, inspection service employee, or *program employee* means an inspector or other government employee who is authorized to conduct any inspection or perform any other duty in connection with the inspection program, inspection service, or program.

Inspection service supervisor or *Inspection program supervisor* means an inspection program or service employee

or program employee who is delegated authority to exercise supervision over one or more phases of the inspection program.

Inspector means an inspector of the inspection program, inspection service, and program. (''Inspector'' includes an employee or official of the Federal government or the government of a State or territory or the District of Columbia who is authorized by the Administrator to inspect meat and meat products or poultry and poultry products under the authority of the FMIA or the PPIA, respectively, under an agreement entered into between the Administrator and the appropriate State or other agency.)

Inspector in charge or *IIC* means an inspection program employee, inspection service employee, or program employee who has primary responsibility for inspection program functions at a particular official establishment.

Secretary means the Secretary of Agriculture of the United States or his or her delegate.

(b) FSIS has replaced the regional office and import field office structure referenced in some parts of subchapter A of this chapter. Authority previously delegated to Regional Directors now is delegated to district managers; authority previously delegated to area supervisors and import supervisors now is delegated to inspection program supervisors in the successor district offices.

■ 6. Section 300.6 is amended by adding paragraph (b) to read as follows:

§ 300.6 Access to establishments and other places of business.

* * * * *

(b) *Meat and poultry establishments and related industries.*

(1) At all times, by day or night, whether the establishment is being operated or not, inspection program employees must have access to the premises and to every part of an establishment that slaughters livestock or otherwise prepares meat products or slaughters poultry or otherwise processes poultry products that are subject to inspection for the purpose of conducting an inspection or performing any other inspection program duty. The numbered official badge of an inspection program employee is sufficient identification to entitle him or her to admittance to all parts of such an establishment and its premises.

(2) At all ordinary business hours, upon presentation of credentials by a representative of the Secretary, any person (including any firm or corporation or other business unit) subject to recordkeeping requirements under section 202 of the FMIA or section 11(b) of the PPIA must permit such representative to enter his or her place of business to examine the facilities and inventory and to examine and copy the records specified in § 320.1 and § 381.175, respectively, of this chapter and, upon payment of the fair market value therefor, take reasonable samples of the inventory.

PART 301—TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

■ 7. The name for part 301 is revised as forth above.

■ 7a. The authority citation for part 301 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 U.S.C. 138–138i, 450, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

■ 8. Section 301.1 is revised to read as follows:

§ 301.1 General.

For purposes of this chapter and unless otherwise specifically provided by regulation or required in the context of particular regulations:

(a) Terms have the meanings set forth in this part;

(b) The singular form also imports the plural, and the masculine form also imports the feminine and vice versa.

■ 9. In § 301.2, the undesignated paragraphs that define the terms *Administrator, Area, Area Supervisor, Circuit, Circuit supervisor, The Department, Food Safety and Inspection Service, Import Field Office (IFO), Import Supervisor, Inspector, Inspector in charge, Program, Program employee, Regional Director,* and *Secretary* are removed.

PART 306—ASSIGNMENT AND AUTHORITIES OF PROGRAM EMPLOYEES

■ 10. The authority citation for part 306 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

■ 11. Section 306.1 is revised to read as follows:

§ 306.1 Designation of circuit supervisor and assistants. [See §§ 300.3 and 300.4 of this chapter regarding FSIS' organization and inspection program supervisors.]

■ 12. Section 306.2 is revised to read as follows:

§ 306.2 Program employees to have access to establishments. [See § 300.6 of this chapter regarding access to establishments and other places of business.]

§ 306.3 [Amended]

■ 13. The last sentence of § 306.3 is removed.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 14. The authority citation for part 318 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 U.S.C. 138f, 450, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

§ 318.21 [Amended]

■ 15. Section 318.21 is amended to read as follows:

■ a. Paragraphs (b)(1), (b)(3)(vi), (c)(1), and (c)(3)(vi) are amended by removing ''room 516–A, Annex Building,'' and ''300 12th Street SW.,''.

■ b. Paragraphs (b)(3)(i), (b)(3)(xi), and (c)(3)(xi) are amended by removing ''Quality Systems Branch, FSIS Chemistry Division'' and adding, in its place, ''Assistant Administrator, Office of Public Health and Science''.

PART 320—RECORDS, REGISTRATION, AND REPORTS

■ 16. The authority citation for part 320 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

■ 17. Section 320.4 is revised to read as follows:

§ 320.4 Access to and inspection of records, facilities and inventory; copying and sampling.

Representatives of the Secretary afforded access to a business specified in § 320.1 of this part (see § 300.6(b)(2) of this chapter) also must be afforded any necessary facilities (other than reproduction equipment) for the examination and copying of records and for the examination and sampling of inventory.

■ 18. Paragraph (a) of § 320.5 is amended by removing the phrase ''the Compliance Programs, Regulatory Programs,'' in the last sentence and adding in its place ''Evaluation and Enforcement Division, Office of Program Evaluation, Enforcement, and Review'' and adding to the end of the sentence ''or by calling the District Office.''

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 19. The authority citation for part 381 is revised to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

Subpart A—Definitions

■ 20. In § 381.1(b), the undesignated subordinate paragraphs that define the terms *Administrator, Circuit supervisor, Department, Import Field Office (IFO), Import Supervisor, Inspection Service, Inspection Service employee, Inspection Service supervisor, Inspector, Inspector in Charge,* and *Secretary* are removed.

Subpart B—Administration; Application of Inspection and Other Authorities

§ 381.3 [Amended]

■ 21. Section 381.3 is amended by removing and reserving paragraph (a).

Subpart F—Assignment and Authorities of Program Employees; Appeals

■ 22. Section 381.32 is revised to read as follows:

§ 381.32 Access to establishments. [See § 300.6 of this chapter regarding access to establishments and other places of business.]

§ 381.33 [Amended]

■ 23. The last sentence of § 381.33 is removed.

Subpart O—Entry of Articles into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements

§ 381.153 [Amended]

■ 24. Section 381.153 is amended to read as follows:

■ a. Paragraphs (b)(1), (b)(3)(vi), (c)(1), and (c)(3)(vi) are amended by removing ''room 516–A, Annex Building,'' and ''300 12th Street SW.,''.

■ b. Paragraphs (b)(3)(i), (b)(3)(xi), and (c)(3)(xi) are amended by removing ''Quality Systems Branch, FSIS Chemistry Division'' and adding, in its place, ''Assistant Administrator, Office of Public Health and Science''.

Subpart Q—Records, Registration, and Reports

■ 25. Section 381.178 is revised to read as follows:

§ 381.178 Access to and inspection of records, facilities and inventory; copying and sampling.

Representatives of the Secretary afforded access to a business specified in § 381.175 of this part (see § 300.6(b)(2) of this chapter) also must be afforded any necessary facilities (other than reproduction equipment) for the examination and copying of records and the examination and sampling of inventory.

■ 26. Section 381.179 is amended to read as follows:

§ 381.179 Registration.

■ Paragraph (a) is amended by removing the phrase ''the Compliance Programs, Regulatory Programs,'' in the last sentence and adding in its place ''District Enforcement Operations, Field Operations'' and adding to the end of the sentence ''or by calling the District Office.''

Done at Washington, DC, on December 24, 2003.

Garry L. McKee,

Administrator.

[FR Doc. 04–175 Filed 1–2–04; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 610

[Docket No. 1980N–0208]

Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and final order.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations in response to the report and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids with Standards of Potency (the Panel). The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids that have standards of potency, bacterial antitoxins, and immune globulins. On the basis of the Panel's findings and recommendations, FDA is classifying these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category IIIB (off the market pending completion of studies permitting a determination of effectiveness).

DATES: This rule is effective January 4, 2003. The final order on categorization of products is effective January 5, 2004.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

The purposes of this document are:

1. To categorize those bacterial vaccines and toxoids licensed before July 1972 according to the evidence of their safety and effectiveness, thereby determining whether they may remain licensed and on the market;

2. To issue a final response to recommendations made in the Panel's report. These recommendations concern conditions relating to active components, labeling, tests required before release of product lots, product standards, or other conditions considered by the Panel to be necessary or appropriate for assuring the safety and effectiveness of the reviewed products;

3. To revise the standard for potency of Tetanus Immune Globulin in § 610.21 (21 CFR 610.21); and

4. To apply the labeling requirements in §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) to bacterial vaccines and toxoids by amending the implementation dates in § 201.59 (21 CFR 201.59).

II. History of the Review

In the **Federal Register** of February 13, 1973 (38 FR 4319), FDA issued procedures for the review by independent advisory review panels of the safety, effectiveness, and labeling of biological products licensed before July 1, 1972. This process was eventually codified in § 601.25 (21 CFR 601.25) (38 FR 32048 at 32052, November 20, 1973). Under the panel assignments published in the **Federal Register** of June 19, 1974 (39 FR 21176), FDA assigned the biological product review to one of the following groups: (1) Bacterial vaccines and bacterial antigens with ''no U.S. standard of potency,'' (2) bacterial vaccines and toxoids with standards of potency, (3) viral vaccines and rickettsial vaccines, (4) allergenic extracts, (5) skin test antigens, and (6) blood and blood derivatives.

Under § 601.25, FDA assigned responsibility for the initial review of each of the biological product categories to a separate independent advisory panel consisting of qualified experts to ensure objectivity of the review and public confidence in the use of these products. Each panel was charged with preparing an advisory report to the Commissioner of Food and Drugs which was to: (1) Evaluate the safety and effectiveness of the biological products for which a license had been issued, (2) review their labeling, and (3) identify the biological products that are safe, effective, and not misbranded. Each advisory panel report was also to