Rules and Regulations

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 238

Contracts With Transportation Lines; Addition of Guy-America Airways, Inc.

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule adds Guy-America Airways, Inc. to the list of carriers which have entered into agreements with the Service to guarantee the passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

EFFECTIVE DATE: February 4, 1982.

FOR FURTHER INFORMATION CONTACT: Stanley J. Kieszkiel, Acting Instructions Officer, Immigration and Naturalization Service, 425 Eye Street, NW., Washington, DC 20536; Telephone: (202) 633–3048.

SUPPLEMENTARY INFORMATION: This amendment to 8 CFR 238.3 is published pursuant to 5 U.S.C. 552. The Commissioner of Immigration and Naturalization Service entered into an agreement with Guy-America Airways, Inc. on February 4, 1982 to guarantee passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

The agreement provides for the waiver of certain documentary requirements and facilitates the air travel passengers on international flights while passing throught the United States.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is unnecessary because the amendment merely makes an editorial change to the listing of transportational lines.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that the rule will not have a significant impact on a substantial number of small entities.

This order constitutes a notice to the public under 5 U.S.C. 552 and is not a rule within the definition of section 1(a) of E.O. 12291.

PART 238—CONTRACTS WITH TRANSPORTATION LINES

Accordingly, 8 CFR Part 238 is amended as follows:

§ 238.3 [Amended]

In § 238.3 *Aliens in immediate and continuous transit*, the listing of transportation lines in paragraph (b) *Signatory lines* is amended by adding in alphabetical sequence, "Guy-America Airways, Inc."

(Secs. 103, 66 Stat. 173 (8 U.S.C. 1103); 238, 66 Stat. 202 (8 U.S.C. 1228))

Dated: February 24, 1982.

Alan C. Nelson,
Commissioner of Immigration and Naturalization.

[FR Doc. 82-5464 Filed 3-1-82; 8:45 am]
BILLING CODE 4410-10-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 112

Viruses, Serums, Toxins, and Analogous Products; Revision of Packaging Biological Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This amendment revises the packaging requirement formerly entitled *Packaging desiccated products*. The amendment makes packaging standards applicable to all biological products rather than just desiccated products. The amendment also deletes the 1,000 dose limit for final containers of mass administration products for poultry.

As amended, this section now specifies the allowable number of doses in a final container of poultry products for administration to individual birds, the allowable number of final containers of biological product in a carton, when and to what extent containers of diluent must be included in a carton with final containers of desiccated product, when final containers of product must be packaged in a carton, and a poultry product labeling requirement for multiple container cartons reflecting the continuance of current labeling requirements.

Average poultry flock size has increased 5 to 10 times since the 1,000 dose per container limit was established for poultry products. The deletion of specified maximal doses per container for mass administration products makes these products more convenient and economical to use in larger flocks than the 1,000 dose containers.

Broadening the scope of the section to include all biological products makes a place in the regulations for current and future standards for packaging products other than desiccated ones.

EFFECTIVE DATE: This amendment becomes effective March 2, 1982.

FOR FURTHER INFORMATION CONTACT: Dr. R. J. Price, Senior Staff Veterinarian, Veterinary Biologics Staff, USDA, APHIS, VS, Room 827, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–8245.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under USDA procedures established in Secretary's Memorandum No. 1512–1 to implement Executive Order 12291 and has been classified as a "non-major" rule.

This final rule may have a significant economic effect primarily on producers and consumers of mass administration poultry vaccines. Eighty percent of the total doses of such vaccines produced annually are either Newcastle Disease Vaccines, Bronchitis Vaccines, or Newcastle Disease-Bronchitis Vaccines. Available data suggest that production costs for these three types of products might be reduced 10 percent or more by packaging in 5,000 to 10,000 dose containers rather than the present limit of 1,000 doses per container. It is also estimated that these larger vials of vaccines might be sold 10 percent cheaper per dose. Based upon an estimated annual production of 6 billion doses of Newcastle and Bronchitis Vaccines, currently selling for approximately $1 per 1,000 doses, the annual reduction in cost to consumers

could be approximately $600,000. No estimate on economic impact is available for the other mass administered poultry products which include Laryngotracheitis Vaccine, Avian Encephalomyelitis Vaccine, Pasteurella Multocida Vaccine, and Bursal Disease Vaccine.

The economic effect of the packaging standards for nondesiccated products will be minimal, because the present revision merely codifies current licensee practices.

Additionally, Dr. Harry C. Mussman, Administrator of the Animal and Plant Health Inspection Service, has determined that this action will not have a significant economic impact on a substantial number of small entities.

There are currently 11 USDA licensed establishments producing one or more of these mass administration poultry vaccines. Only three of these are considered small entities; i.e., a business which is independently owned and operated and which is not dominant in the field of veterinary biologics manufacturing. Two of these businesses responded in favor of this proposed rule. There is currently insufficient information to project the specific effect on the third small business entity concerned. However, a general production cost decrease is expected.

The limitation of 1,000 doses of desiccated poultry product per final container was intended to insure that all of the vaccine in a container would be used within a short time after reconstitution to prevent significant loss of potency. At the time this standard was enacted in 1961, the 1,000 dose container was convenient for the size of flocks grown. Presently, the average flock is 5 to 10 times larger, and houses have been expanded to accommodate up to 50,000 birds. The 1,000 dose container no longer meets the need of the poultry industry.

This final rule represents a relaxation of the regulations by removing the 1,000 dose per container limit for all mass administration poultry vaccines; i.e., vaccines administered by aerosol or in drinking water. Larger dose vials will enable producers to vaccinate the currently larger flocks of birds more conveniently and with some labor savings in vaccine preparation. As shown above, it is suggested that the larger dose vials could result in a 10 percent or more cost saving to the consumers of these vaccines. The 1,000 dose limit for poultry products for administration to individual birds has been retained, because the time involved in individual administration still poses a threat of loss of potency if larger, multiple-dose final containers are used. This regulation shall become effective immediately upon publication as authorized by the Administrative Procedure Act (5 U.S.C. 553(d)(1), (d)(3)). The major, substantive change in the rule herein amended relieves the packaging restrictions under which desiccated vaccine manufacturers are currently operating. By making the rule effective immediately Veterinary Services (VS) is enabling these manufacturers to market larger-dose vials of vaccine without undue delay to give the poultry industry the practical and economic benefits of larger-dose vaccines as soon as possible.

Presently this section only refers to desiccated products. Packaging standards and a place for future standards are needed for other products. Since the time § 112.6 was enacted, changes in the industry have warranted administrative interpretations of the applicability of the section and amendments to the section such as the one for packaging Marek's Disease Vaccine. Cumulative changes in the industry have brought to the attention of the agency the need to revise the entire section to develop a comprehensive, integrated, regulatory program with respect to packaging biological products. The latest change in the industry has been the development of a large, multiple-dose, mass administration poultry biological product which is not manufactured in desiccated form as previous products have been. As there were no standards in the regulations to cover the situation, the entire section has been revised to keep the regulations responsive to developments in the industry which the agency is charged with regulating. Therefore, to broaden the scope of the section, the heading has been revised to refer to packaging biological products instead of packaging desiccated products. The body of the section has been changed to refer to nondesiccated as well as desiccated biological products to increase the applicability of the standards to a broader range of products. Changes in language are intended to clarify the broader scope of this section.

On September 14, 1981, a notice of proposed rulemaking was published in the **Federal Register** at 46 FR 45616 discussing this revision and soliciting comments. Three poultry producers and a poultry producers' trade association responded favorably to the deletion of the 1,000 dose limit for final containers of mass administration products for poultry. None of them commented upon other items in the proposed rule. Eight vaccine manufacturers and a vaccine manufacturers' trade association responded. Five of the manufacturers favored or had no objection to deleting the 1,000 dose per vial limit for mass administration poultry products, but the other three manufacturers and the trade association were opposed to this change. Three manufacturers recommended specifying a maximum of 5,000 or 10,000 doses per vial for mass administration poultry products. The agency is charged with the responsibility of regulating the veterinary biologics industry to insure that only pure, safe, potent, and efficacious products, when used according to label directions, are permitted in interstate commerce. Frozen mass administration poultry products in 5,000 and 10,000 dose vials have met these criteria and been licensed. It is probable that desiccated or other forms of these products could also meet the above criteria. No purity, safety, potency, or efficacy data were submitted to indicate there is a need to specify a maximal number of doses per container. Therefore, the final rule is adopted as proposed deleting the 1,000 dose per vial limit for mass administration poultry products. The maximal container size is left unspecified to keep the regulation responsive to future developments which may affect the industry. Each manufacturer of desiccated mass administration poultry biologics must decide based upon its own technical and economic evaluation whether or not to produce these products and what dosage sizes to market. Two of the manufacturers questioned the source of economic data and accuracy of the estimated production cost and selling price reductions resulting from the deletion of the 1,000 doses per vial limit for mass administration poultry products. The estimates were derived from confidential data for both frozen and desiccated products supplied by members of the manufacturing industry. The estimates were based upon the limited available data. Veterinary Services intended to indicate that vaccine production cost and selling price changes are likely to vary from these estimates as more products are licensed and become subject to market pressures. Two of those opposed to the action predicted a long term increase in vaccine prices resulting from elimination of manufacturers from this market with subsequent diminution of competitive forces. This evaluation was unsupported by data. Therefore, VS considered this opinion highly speculative and an insufficient reason to change the proposed rule. Some of the manufacturers and the manufacturers' trade association recommended in

addition to the VS proposals that the regulations be amended to delete the existing 10 final containers per carton limit for poultry products and to delete any requirement that diluent for poultry products be packaged with the final container(s) of the product. They also recommended that the proposal be changed to include the use of automatic vaccinating equipment in the definition of mass administration products for poultry. These recommendations have been favorably considered by the agency and will be published in the **Federal Register** later as a separate proposed rule. This is necessary to give the entire industry and all other interested parties an opportunity to comment upon these proposals before publication as a final rule. One manufacturer expressed concern that no exception was provided in paragraph (b) to permit the packaging of the USDA contract Brucella Abortus Vaccine and diluent used in the Brucellosis Eradication Program. Adequate exception for this vaccine is already provided for in 9 CFR 106.1.

After due consideration of all relevant matters, including the proposal set forth in the above notice, and under authority in the Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151–158), the amendment of Part 112, Subchapter E, Chapter I, Title 9 of the Code of Federal Regulations, as published in the above notice, is hereby adopted as follows:

PART 112—PACKING AND LABELING

Section 112.6 is revised to read:

§ 112.6 Packaging biological products.

(a) Each multiple-dose final container of a biological product which requires a diluent for administration shall be packaged in an individual carton with a container of the proper volume of diluent for that dose as specified in the filed Outline of Production. Each multiple-dose final container of a product which does not require a diluent for administration need not be packaged in an individual carton unless the final container labeling does not contain all information required by the regulations. Such information must be included in or on a carton. Exceptions are provided in paragraphs (c) and (d) of this section and § 112.8.

(b) Single-dose final containers of a product need not be packaged one per carton. For single-dose products which require a diluent for administration, the number of containers of the proper amount of diluent specified in the filed Outline of Production for the number of doses contained in the carton shall be included in each carton.

(c) Poultry products for mass administration (including, but not limited to such means as drinking water and aerosol sprays) may be packaged in multiple-dose final containers as specified in the filed Outline of Production. Poultry products for administration to individual birds shall not exceed 1,000 doses in each final container. One to ten poultry product final containers may be packaged in a single carton. For products which require a diluent for administration, the number of containers of the proper amount of diluent specified in the filed Outline of Production for the number of multiple-dose final containers contained in the carton shall be included in each carton, except as specified in paragraph (d) of this section. The following requirements apply to cartons containing more than one final container of poultry product or of diluent:

(1) They shall be sealed prior to leaving the licensed establishment;

(2) The contents may not be repackaged after the seal is applied to the carton;

(3) The contents of such cartons may not be sold in fractional units; and

(4) The following statement must appear in a prominent place on the label of the carton: "Federal regulations prohibit the repackaging or sale of the contents of this carton in fractional units. Do not accept if seal is broken."

(d) Diluent for the following products need not be packaged with the final container(s) of the product, but the licensee shall provide the consumer with the required number of containers of the proper amount of diluent as specified in the filed Outline of Production:

(1) Marek's Disease Vaccine.

(2) Poultry vaccines administered to individual birds using automatic vaccinating equipment.

Done at Washington, D.C., this 24th day of February 1982.

K. R. Hook,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 82-5489 Filed 2-25-82; 12:41 pm]

BILLING CODE 3410-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Revised Organization

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the regulations setting forth its organization structure. Several reorganizations have occurred since the structure was last issued. These revised regulations will present FDA's latest organization structure and give the latest addresses for the field organization.

EFFECTIVE DATE: March 2, 1982.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Office of Management and Operations (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly § 5.1; see 46 FR 26052; May 11, 1981)), Part 5 is amended by revising §§ 5.100 and 5.115 to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

§ 5.100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

Office of the Commissioner [1]

Commissioner of Food and Drugs.
Deputy Commissioner.
Office of Regulatory Affairs.
Office of Health Affairs.
Office of Policy Coordination.
Office of Management and Operations.
Office of Planning and Evaluation.
Office of Legislative Affairs.
Office of Public Affairs.
Office of Consumer Affairs.

Bureau of Biologics [2]

Office of the Director.
Division of Compliance (Biologics).
Division of Virology.
Division of Blood and Blood Products.
Division of Product Quality Control.
Division of Biochemistry and Biophysics.
Division of Bacterial Products.
Division of Biologics Evaluation.

Bureau of Drugs [1]

Office of the Director.
Office of Planning, Evaluation, and Management.
Associate Director for Drug Monographs.
Division of OTC Drug Evaluation.
Division of Biopharmaceutics.
Division of Generic Drug Monographs.
Associate Director for Biometrics and Epidemiology.
Division of Biometrics.
Division of Poison Control.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857

[2] Mailing address: 8800 Rockville Pike, Bethesda, MD 20014.

Division of Drug Experience.
Associate Director for Compliance.
Division of Methadone Monitoring.
Division of Drug Quality Evaluation.
Division of Drug Labeling Compliance.
Division of Drug Quality Compliance.
Associate Director for Pharmaceutical Research and Testing.
Division of Drug Biology.
Division of Drug Chemistry.
National Center for Antibiotics Analysis.
National Center for Drug Analysis.
Associate Director for New Drug Evaluation.
Division of Anti-Infective Drug Products.
Division of Cardio-Renal Drug Products.
Division of Surgical-Dental Drug Products.
Division of Metabolism and Endocrine Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology and Radiopharmaceutical Drug Products.
Division of Drug Advertising and Labeling.
Division of Scientific Investigations.
Associate Director for Information Systems.
Division of Drug Information Resources.
Division of Information Systems Design.
Medical Library.

Bureau of Foods [3]

Office of the Director.
Associate Director for Compliance.
Division of Compliance and Industry Programs.
Division of Food and Color Additives.
Division of Food Animal Additives.
Division of Regulatory Guidance.
Division of Cooperative Programs.
Associate Director for Nutrition and Food Sciences.
Division of Consumer Studies.
Division of Nutrition.
Division of Microbiology.
Division of Food Technology.
Associate Director for Toxicology.
Division of Mathematics.
Division of Pathology.
Division of Toxicology.
Associate Director for Physical Sciences.
Division of Chemical Technology.
Division of Color Technology.
Division of Cosmetics Technology.
Division of Chemistry and Physics.

Bureau of Medical Devices [4]

Office of the Director.
Assistant Director for Consumer and Industry Programs.
Office of Small Manufacturers Assistance.
Assistant Director for Program Operations.
Associate Director for Health Affairs.
Associate Director for Standards.
Division of General Medical Device Standards.
Division of In Vitro Diagnostic Device Standards.
Associate Director for Compliance.
Division of Compliance Programs.
Division of Compliance Operations.
Division of Product Surveillance.
Associate Director for Device Evaluation.
Division of Cardiovascular Devices.
Division of Gastroenterology/Urology and General Use Devices.
Division of Anesthesiology and Neurology Devices.
Division of Obstetrics/Gynecology and Radiology Devices.
Division of Surgical and Rehabilitation Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic, Ear, Nose, Throat, and Dental Devices.

Bureau of Radiological Health [4]

Office of the Director.
Associate Director for Management and Systems.
Associate Director for Health Affairs.
Division of Compliance.
Division of Biological Effects.
Division of Electronic Products.
Division of Training and Medical Applications.

Bureau of Veterinary Medicine [3]

Office of the Director.
Associate Director for Human Food Safety.
Associate Director for Research.
Division of Veterinary Medical Research.
Associate Director for Scientific Evaluation.
Division of Drugs for Avian Species.
Division of Drugs for Ruminant Species.
Division of Drugs for Swine and Minor Species.
Division of Drugs for Non-Food Animals.
Associate Director for Surveillance and Compliance.
Division of Compliance.
Division of Surveillance.
Division of Animal Feeds.

Executive Director of Regional Operations [1]

Office of the Executive Director.[1]
Associate Director for Administration.
Associate Director for Field Support.
Office of Resource Planning and Management.
Division of Field Science.
Division of Field Investigations.
Division of Field Regulatory Guidance.
Associate Director for Federal-State Relations.
Division of Federal-State Relations.

National Center for Toxicological Research [5]

Office of the Director.
Office of Scientific Intelligence.
Associate Director for Research Operations and Planning.
Office of Management.
Division of Management Services.
Division of Toxicological Data Management Systems.
Division of Facilities Engineering and Maintenance.
Associate Director for Research.
Division of Teratogenesis Research.
Division of Mutagenesis Research.
Division of Carcinogenesis Research.
Division of Molecular Biology.
Division of Biometry.
Division of Chemistry.
Associate Director for Chemical Evaluation.
Division of Chemical Toxicology.
Division of Pathology.
Division of Animal Husbandry.
Division of Microbiological Services.

[3] Mailing address: 200 C St. SW., Washington, DC 20204.

[4] Mailing address: 8757 Georgia Ave., Silver Spring, MD 20910.

[5] Mailing address: Jefferson, AR 72079.

§ 5.115 Field structure.

Region I

Regional Field Office: 585 Commercial St., Boston, MA 02109.
District Office: 585 Commercial St., Boston, MA 02109.
Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890.

Region II

Regional Field Office: 830 Third Ave., Brooklyn, NY 11232.
District Office: 830 Third Ave., Brooklyn, NY 11232.
District Office: 599 Delaware Ave., Buffalo, NY 14202.
District Office: 20 Evergreen Place, East Orange, NJ 07018.
District Office: P.O. Box S–4427, San Juan Station, San Juan, PR 00905.
Import District Office: 830 Third Ave., Brooklyn, NY 11232.

Region III

Regional Field Office: Rm. 1204, 2nd and Chestnut Sts., Philadelphia, PA 19106.
District Office: Rm. 1204, 2nd and Chestnut Sts., Philadelphia, PA 19106.
District Office: 900 Madison Ave., Baltimore, MD 21201.

Region IV

Regional Field Office: 8800 W. Peachtree St., Atlanta, GA 30309.
District Office: 8800 W. Peachtree St., Atlanta, GA 30309.
District Office: 297 Plus Park Blvd., Nashville, TN 37217.
District Office: P.O. Box 118, Orlando, FL 32802.

Region V

Regional Field Office: Rm. A–1945, 175 W. Jackson Blvd, Chicago, IL 60604.
District Office: Rm. 1222, 433 W. Van Buren St., Chicago, IL 60607.
District Office: 1141 Central Parkway, Cincinnati, OH 45202.
District Office: 1560 E. Jefferson Ave., Detroit, MI 48207.
District Office: 240 Hennepin Ave., Minneapolis, MN 55401.
Minneapolis Center for Microbiological Investigations: 240 Hennepin Ave., Minneapolis, MN 55401.

Region VI

Regional Field Office: 3032 Bryan St., Dallas, TX 75204.
District Office: 3032 Bryan St., Dallas, TX 75204.
District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.
Houston Station Office: Suite 250, 1440 North Loop, Houston, TX 77009.

Region VII

Regional Field Office: 1009 Cherry St., Kansas City, MO 64106.
District Office: 1009 Cherry St., Kansas City, MO 64106.
St. Louis Station Office: Rm. 755, 1114 Market St., St. Louis, MO 63101.

Region VIII

Regional Field Office: Rm. 500, 721 19th St., U.S. Customhouse, Denver, CO 80202.
District Office: Rm. 500, 721 19th St., U.S. Customhouse, Denver, CO 80202.

Region IX

Regional Field Office: Rm. 518, U.N. Plaza Federal Office Bldg., San Francisco, CA 94102.
District Office: Rm. 518, U.N. Plaza Federal Office Bldg., San Francisco, CA 94102.
District Office: 1521 W. Pico Blvd., Los Angeles, CA 90015.

Region X

Regional Field Office: Rm. 5003, 909 First Ave., Seattle, WA 98174.
District Office: Rm. 5003, 909 First Ave., Seattle, WA 98174.

Effective date. This regulation shall become effective March 2, 1982.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: February 24, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-4692 Filed 3-1-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 14

Advisory Committees; Reestablishment

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972, and the public advisory committee procedures (21 CFR Part 14), the Food and Drug Administration (FDA) announces the reestablishment of the Panel on Review of Allergenic Extracts. This document adds to the agency's list of standing advisory committees. In a notice published elsewhere in this issue of the **Federal Register**, FDA asks for nominations for membership on this committee.

DATES: Effective March 2, 1982; authority for the committee being reestablished will end on December 31, 1983, unless the Secretary formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Richard L. Schmidt, Committee Management Office (HFA-306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and § 14.40(b) (21 CFR 14.40(b)), FDA announces the reestablishment of the Panel on Review of Allergenic Extracts.

The Panel on Review of Allergenic Extracts reviews and evaluates available data on the safety, effectiveness, and adequacy of labeling of currently marketed biological products for the diagnosis, prevention, or treatment of allergies and allergic diseases and advises the Commissioner of Food and Drugs on the affirmation or revocation of biological product licenses based on a current evaluation of the safety, effectiveness, and labeling of the products.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 14 is amended in § 14.100 by adding new paragraph (b)(1)(i), to read as follows:

§ 14.100 List of standing advisory committees.

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(b) *Bureau of Biologics*—(1) * * *

(i) *Allergenic Extracts Panel.* (*a*) Date reestablished: January 18, 1982.

(*b*) Function: Reviews and evaluates available data on the safety, effectiveness, and adequacy of labeling of currently marketed biological products intended for the diagnosis, prevention, or treatment of allergies and allergic diseases.

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Effective date. Because this is a technical conforming amendment to Part 14, the Commissioner of Food and Drugs finds that there is good cause for the rule to be published without notice and comment and to be effective immediately upon publication in the **Federal Register**, March 2, 1982.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: February 12, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-5460 Filed 3-1-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 172

[Docket No. 81F-0024]

Food Additives Permitted for Direct Addition to Food for Human Consumption; White Mineral Oil

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of white mineral oil as a dust control agent for wheat being stored in grain elevators. This action responds to a food additive petition filed by Witco Chemical Corp.

DATES: Effective March 2, 1982; objections by April 1, 1982.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204; 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 20, 1981 (46 FR 13378), FDA announced that a petition (FAP 0A3505) had been filed by Witco Chemical Corp., 277 Park Ave., New York, NY 10017, proposing to amend § 172.878 (21 CFR 172.878) to provide for the safe use of white mineral oil as a dust control agent for commodity seeds stored in grain elevators.

FDA has evaluated data in the petition and other relevant material and concludes that white mineral oil is safe for use as a dust control agent for wheat under the prescribed conditions of use, and that § 172.878 should be amended as set forth below. In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the potential environmental effects of this regulation as announced in the notice of filing published in the **Federal**