

**SUMMARY:** Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and the public advisory committee procedures (21 CFR part 14), this document announces the establishment of one advisory committee and the termination of another. This document revises an entry in the agency's list of standing advisory committees.

**EFFECTIVE DATE:** May 26, 1978, authority for the committee will remain in effect until amended or terminated by the Commissioner of Food and Drugs.

**FOR FURTHER INFORMATION CONTACT:**

Richard L. Schmidt, Committee Management Office (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 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)), the Food and Drug Administration (FDA) announces the establishment of the Circulatory Systems Devices Panel by the Commissioner of Food and Drugs.

The Committee will review and evaluate data concerning the safety and effectiveness of circulatory systems devices currently in use and advise the Commissioner regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification of devices to recommend changes in classification as appropriate; recommend exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advise on the necessity to ban a device; and respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Concurrently with the establishment, the Commissioner approved the termination of the Cardiovascular Device Classification Panel. Under § 14.55(b) (21 CFR 14.55(b)), FDA announces the termination of this 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 (21 CFR 5.1), part 14 is

amended is § 14.100 by revising paragraph (d)(1)(ii) to read as follows:

**§ 14.100 List of standing advisory committees.**

- • • • •
- (d) • • •
- (1) • • •
- (ii) *Circulatory devices panel.* Established April 28, 1978.

Effective date: Since this is a technical conforming amendment to part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the **FEDERAL REGISTER**, May 26, 1978.

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

Dated: May 18, 1978.

WILLIAM L. RANDOLPH,  
*Acting Associate Commissioner  
for Regulatory Affairs.*

[FR Doc. 78-14451 Filed 5-25-78; 8:45 am]

**[4110-03]**

**PART 14—PUBLIC HEARING BEFORE  
A PUBLIC ADVISORY COMMITTEE**

**Advisory Committees; Establishment  
and Terminations**

**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 this document announces the establishment of one advisory committee and the termination of two others. This document adds to and deletes from the agency's list of standing advisory committees.

**EFFECTIVE DATES:** May 26, 1978. Authority for the committee will expire on May 1, 1980, unless the Secretary formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:**

Richard L. Schmidt, Committee Management Office (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 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)), the Food and Drug Administration (FDA) announces the establishment of the Anesthetic and Life Support Drugs Advisory Committee by the Secretary, Department of Health, Education, and Welfare.

The committee will review and evaluate available data concerning the safety and effectiveness of currently marketed and new prescription drug products proposed for marketing for use in anesthesiology and surgery and make recommendations to the Commissioner of Food and Drugs regarding current advances, changing concepts, and trends in the field.

Concurrently with the establishment, the Secretary approved the termination of the Anesthesiology Advisory Committee and the Surgical Drugs Advisory Committee. Under 14.55(b) (21 CFR 14.55(b)), FDA announces the termination of these committees.

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 (21 CFR 5.1), Part 14 is amended in § 14.100 by revising paragraph (c)(1) and deleting paragraph (c)(19) and marking it "reserved" as follows:

**§ 14.100 List of standing advisory committees.**

- • • • •
- (e) • • •
- (1) *Anesthetic and Life Support Drugs Advisory Committee.* (i) Date established: May 1, 1978.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in the fields of anesthesiology and surgery.

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- (19) [Reserved]
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Effective date: Since this is a technical conforming amendment to Part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the **FEDERAL REGISTER**, May 26, 1978.

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

Dated: May 18, 1978.

WILLIAM F. RANDOLPH,  
*Acting Associate Commissioner  
for Regulatory Affairs.*

[FR Doc. 78-14587 Filed 5-25-78; 8:45 am]

[4110-03]

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 77N-0110]

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Exemptions From Federal Preemption of State and Local Device Requirements; Procedures for Consideration of Applications; Correction

AGENCY: Food and Drug Administration.

ACTION: Correction.

SUMMARY: In FR Doc. 78-11719 appearing at page 18661 in the FEDERAL REGISTER of Tuesday May 2, 1978, on page 18664, amendment No. 2 is corrected by changing "§ 25.1(d)(6)" to read "§ 25.1(d)(7)" and § 25.1 *Applicability* is corrected in paragraph (d) by changing subparagraph "(6)" to read "(7)."

EFFECTIVE DATE: July 3, 1978.

FOR FURTHER INFORMATION CONTACT:

John Richards, Federal Register Writer (HFC-11), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2994.

Dated: May 22, 1978.

WILLIAM F. RANDOLPH,  
Acting Associate Commissioner  
for Regulatory Affairs.

[FR Doc. 78-14728 Filed 5-25-78; 8:45 am]

[4110-03]

SUBCHAPTER A—GENERAL

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 77N-00261]

CHEMICAL COMPOUNDS IN FOOD-PRODUCING ANIMALS

Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

AGENCY: Food and Drug Administration.

ACTION: Revocation of rule.

SUMMARY: Following an opinion and order by the United States District Court for the District of Columbia, the Commissioner of Food and Drugs is revoking the regulations establishing the procedures and criteria for evaluating the assays for carcinogenic residues in edible products of animals. The regulations will be repropounded, and interested persons given an opportunity to comment, in a future issue of the FEDERAL REGISTER.

EFFECTIVE DATE: May 26, 1978.

ADDRESS: The administrative record of this proceeding and a copy of the opinion and order of the District Court are on file with the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Edward J. Allera, Office of the General Counsel (GCF-1), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-1770.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of February 22, 1977 (42 FR 10412), the Commissioner promulgated regulations establishing criteria and procedures for evaluating the assays for carcinogenic residues in edible products of animals. Subsequently, the United States District Court for the District of Columbia issued an opinion and order (*Animal Health Institute v. Food and Drug Administration*, Civil No. 77-806 (D.D.C., February 8, 1978)) remanding the case to the Food and Drug Administration "for further findings to rectify the omissions in the current record." in accordance with the court decision, the Commissioner has concluded that republishing the regulations is the most appropriate course of action. Accordingly, this document revokes the current regulations. A notice of proposed rulemaking is being prepared and will be published in the future. Paragraph (c) of § 70.50 appearing in the revocations below is the former § 8.36(c) which was revised in the February 22, 1977, regulation and later transferred to its present designation under Part 70 in a recodification of Subchapter A published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376)) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 70—COLOR ADDITIVES

§ 70.50 [Amended]

1. In Part 70, § 70.50 is amended by revoking paragraph (c).

PART 500—GENERAL

§§ 500.80 through 500.98 [Revoked]

2. In Part 500, by revoking in its entirety Subpart E, consisting of §§ 500.80 through 500.98.

PART 514—NEW ANIMAL DRUG APPLICATIONS

§ 514.111 [Amended]

3. In Part 514, § 514.111 is amended by revoking paragraph (a)(10).

PART 571—FOOD ADDITIVE PETITIONS

§ 571.115 [Revoked]

4. In Part 571, by revoking § 571.115 *Application of the anti-cancer clause of section 409*.

Effective date: This document shall be effective May 26, 1978.

(Secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376).)

Dated: May 17, 1978.

SHERWIN GARDNER,  
Acting Commissioner  
of Food and Drugs.

[FR Doc. 78-14586 Filed 5-25-78; 8:45 am]

[4110-03]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77F-0397]

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

Subpart B—Substances for Use Only as Components of Adhesives

POLYOXYETHYLENE (20 MOLES) LANOLIN

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the food additive regulations to provide for safe use of polyoxyethylene (20 moles) lanolin as a component of adhesives intended for production of food-contact articles. This rule is based on a petition filed by ICI Americas, Inc.

DATES: Effective May 26, 1978; objections by June 26, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street, SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Notice was given in the FEDERAL REGISTER.

TER of December 23, 1977, (42 FR 64440) that a food additive petition (FAP 7B3316) had been filed by ICI Americas, Inc., Wilmington, Del. 19897, proposing that § 175.105 (21 CFR 175.105) be amended to provide for the safe use of polyoxyethylene (20 moles) lanolin as a component of adhesives in the production of food-packaging materials.

Having evaluated data in the petition and other relevant material, the Commissioner concludes that § 175.150 should be amended as set forth below to permit the use of the substance under its preferred chemical nomenclature as given below.

Therefore, under the Federal Food, and Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348 (c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1), part 175 is amended in § 175.105(c)(5) by alphabetically inserting a new item in the list of substances, to read as follows:

§ 175.105 Adhesives.

| (c) * * * | (5) * * * |  |  |  |  |
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Any person who will be adversely affected by the foregoing regulation may at any time on or before June 26, 1978, submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objections shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regula-

tion. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: May 26, 1978.  
(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348 (c)(1)).)

Dated: May 18, 1978.

WILLIAM F. RANDOLPH,  
Acting Associate Commissioner  
for Regulatory Affairs.

[FR Doc. 78-14585 Filed 5-25-78; 8:45 am]

[4110-03]

[Docket No. 78N-0095]

PART 449—GRISEOFULVIN

Griseofulvin Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the antibiotic drug regulations to provide for certification of a new dosage size of griseofulvin tablets. The manufacturer has supplied sufficient data and information to establish the safety and efficacy of the tablets.

DATES: Effective May 26, 1978; comments by June 26, 1978.

ADDRESS: Send comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Comments received may be seen at the Office of the Hearing Clerk.

FOR FURTHER INFORMATION CONTACT:

Joan M. Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs has evaluated data submitted under provisions of section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) with respect to a new dosage size (250 milligrams) of griseofulvin tablets and concludes that the manufacturer's data on that antibiotic drug product adequately establish its safety and efficacy for use as directed in the labeling; he finds that the regulations should be amended in Part 449 (21 CFR Part 449) to provide for its certification.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)) and under authority delegated to him (21 CFR 5.1), the Commissioner amends Part 449 in § 449.120d by revising the second sentence after the heading of paragraph (a)(1) to read as follows:

§ 449.120d Griseofulvin (ultramicrosize) tablets.

(a) \* \* \*

(1) *Standards of identity, strength, quality, and purity.* \* \* \* Each tablet contains either 125 or 250 milligrams of griseofulvin. \* \* \*

Because the matter is noncontroversial and meets the prerequisites for certification of this drug, the Commissioner finds for good cause that prior notice and public procedure are unnecessary and that the amendment may become effective upon the day of its publication. Interested persons may, on or before June 26, 1978, file with the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, four copies of written comments identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the office of the Hearing Clerk between the hours of 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by such comment will be the subject of a further amendment.

Effective date. This regulation shall be effective May 26, 1978.

(Sec. 508, 59 Stat. 463 as amended (21 U.S.C. 357).)

Dated: May 9, 1978.

MARY A. McENIRY,  
Assistant Director for  
Regulatory Affairs, Bureau of Drugs.  
[FR Doc. 78-14454 Filed 5-25-78; 8:45 am]

[4210-01]

Title 24—Housing and Urban Development

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

[Docket No. FI-3720]

PART 1917—APPEALS FROM FLOOD ELEVATION DETERMINATIONS AND JUDICIAL REVIEW

Final Flood Elevation Determinations for Town of Hanceville, Cullman County, Ala.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for se-