responsible. The mandate of the committee has expanded significantly in recent years to include drugs for menopausal women and drugs used in the practice of andrology. The change is consistent with the growing use of this term by specialists in the field of reproductive health, which includes obstetrics, gynecology, endocrinology, andrology, epidemiology, and related specialties. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

The Fertility and Maternal Health Drugs Advisory Committee's name was changed in the charter renewal dated March 23, 1996. In this document, FDA is hereby formally changing the name and the function of the committee by revising 21 CFR 14.100(c)(9).

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely a clarifying amendment to existing regulations and when effective will reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394; 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. App. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by revising the heading of paragraph (c)(9) and paragraph (c)(9)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(9) *Advisory Committee for Reproductive Health Drugs.*

* * * * *

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

* * * * *

Dated: May 28, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–13978 Filed 6–3–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 14

Standing Advisory Committees; Change of Name and Function

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and the function of the Generic Drugs Advisory Committee to the Advisory Committee for Pharmaceutical Science. This action is being taken to more accurately describe this committee.

EFFECTIVE DATE: June 4, 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Generic Drugs Advisory Committee has been changed. After establishment of this committee, on January 22, 1990, the agency decided that the name ''Advisory Committee for Pharmaceutical Science'' would more accurately describe the committee. The Committee reviews primary scientific issues dealing with pharmaceutical science including testing, research, biopharmaceutics, pharmacology, and new chemistry. The Committee also gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases. Therefore, the agency feels the name change will more accurately describe this Committee to the public. In the Federal Register of February 21, 1996 (61 FR 6644 at 6645), FDA published a notice that indicated that the name of the Generic Drugs Advisory Committee had been changed in the charter renewal dated January 22, 1996. In this document, FDA is hereby formally changing the name and function of the committee by revising 21 CFR 14.100(c)(16).

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(3)(B) and (d) and under 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure, and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely a clarifying amendment to existing regulations and when effective will reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394; 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. App. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by revising the heading for paragraph (c)(16) and paragraph (c)(16)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(16) *Advisory Committee for Pharmaceutical Science.*

* * * * *

(ii) Function: Gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

* * * * *

Dated: May 28, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 96–13979 Filed 6–3–96; 8:45 am]
BILLING CODE 4160–01–F

21 CFR Part 177

[Docket No. 94F–0022]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of petroleum hydrocarbon resins (cyclopentadiene-type), hydrogenated, as an adjuvant in the manufacture of polypropylene homopolymer films and copolymer films of propylene and ethylene containing not less than 94 weight percent propylene for use in contact with fatty and alcoholic foods. This action responds to a petition filed by Exxon Chemical Co. The agency is also correcting a technical error in the current listing for petroleum hydrocarbon resins.

DATES: Effective June 4, 1996; written objections and requests for a hearing by July 5, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 10, 1994 (59 FR 11278), FDA announced that a petition (FAP 4B4411) had been filed by Exxon Chemical Co., P.O. Box 241, Baton Rouge, LA 70821. (The address of the petitioner has been changed to P.O. Box 5200, Baytown, TX 77522–5200.) The petition proposed to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to provide for the safe use of hydrogenated cyclodiene resins as a component of polypropylene homopolymer or a copolymer of propylene and ethylene containing not less than 94 weight percent propylene for use in contact with food.

In its evaluation of this additive, FDA has determined that the additive is more accurately described as petroleum hydrocarbon resins (cyclopentadiene-type), hydrogenated, and is approved for other food additive uses under this name in § 177.1520. Therefore, the additive will be identified with this name in the remainder of this document. The agency has also reviewed the safety of the additive and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it may contain minute amounts of polynuclear aromatic hydrocarbons (PAH's), carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants, manufacturing aids, and their constituent impurities, such as polynuclear aromatic hydrocarbons in this instance, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called ''general safety clause'' of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A), a food additive cannot be approved for a particular use unless a fair evaluation of the evidence establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The anticancer or Delaney clause of the act provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive. (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984).)

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, petroleum hydrocarbon resins (cyclopentadiene-type), hydrogenated, will result in levels of exposure to the additive no greater than 0.77 parts per million (ppm) in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data from acute toxicity and subchronic studies on the additive. No adverse effects were reported in these studies.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by polynuclear aromatic hydrocarbons that may be present as impurities in the additive. This risk evaluation of polynuclear aromatic hydrocarbons has two aspects: (1) Assessment of the worse-case exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. Polynuclear Aromatic Hydrocarbons

FDA has estimated the hypothetical worst-case exposure to polynuclear aromatic hydrocarbons (PAH's) from the petitioned uses of the additive to be 0.3 nanograms per person per day (ng/person/day), based on a PAH dietary concentration of 4.9 parts per trillion and a daily diet of 3 kilograms of food per person per day (Ref. 1).

PAH's occur as a mixture of compounds; the toxicity of these compounds varies, and some members of the family have been shown to be carcinogenic in animal studies. For this risk estimate, FDA has made the ''worst-case'' assumption that the PAH's in the additive consist entirely of benzo[a]pyrene, the member of the PAH family which current data indicate to be one of the more potent carcinogens.

Therefore, the agency used data from a carcinogenesis bioassay on benzo[a]pyrene, conducted by H. Brune et al., to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of petroleum hydrocarbon resins (cyclopentadiene-type), hydrogenated (Ref. 3). The results of the bioassay on benzo[a]pyrene demonstrated that the material was carcinogenic for Sprague-Dawley rats under the conditions of the study. The test material induced treatment-related benign forestomach tumors or esophageal tumors in male rats.

Based on a potential exposure of 0.3 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the potential exposure to PAH's from the use of the subject additive is 8.8×10^{-9}, or less than 1 in 100 million (Ref. 4). Because of

numerous conservative assumptions used in calculating the exposure estimate and the carcinogenic potency of PAH's in the additive, the actual lifetime averaged individual exposure to PAH's is expected to be substantially less than the potential exposure, and therefore, the upper-bound limit of human risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to PAH's that might result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of PAH's present as impurities in the additive. The agency finds that a specification is not necessary for the following reasons: (1) Because of the low level at which PAH's may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to the PAH's, even under worst-case assumptions, is very low, less than 1 in 100 million.

III. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed uses of the additive in polypropylene homopolymer films and propylene/ethylene copolymer films in contact with fatty and alcoholic foods are safe. The agency also concludes that the additive will have its intended technical effect. The agency is also amending the current listing for the additive to correct a technical error by changing ''cubic centimeters'' to read ''centipoise.'' Therefore, § 177.1520 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 Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

In the notice of filing for this petition that published in the Federal Register of March 10, 1994 (59 FR 11278), FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment by April 11, 1994, to the Dockets Management Branch (address above). FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch, FDA, to the Indirect Additives Branch, FDA, concerning ''FAP 4B4411 (MATS 754 M2.1): Hydrogenated Cyclodiene Resins—Use in Polypropylene Films in Contact With Fatty and Alcoholic Food—Exxon Chemical Co.—Submission of 1/3/94,'' dated June 8, 1994.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance,* edited by F. Homburger, J. K. Marquis, and S. Karger, New York, NY, pp. 24 to 33, 1985.

3. Brune, H., R. P. Deutsch-Wenzel, M. Habs, S. Ivankovis, and D. Schmahl, ''Investigation of the Tumorigenic Response to Benzo(a)pyrene in Aqueous Caffeine Solution Applied Orally to Sprague-Dawley Rats,'' *Journal of Cancer Research and Clinical Oncology,* 102:153 to 157, 1981.

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning, ''Estimation of the Upper Bound Lifetime Risk from Polynuclear Aromatic Hydrocarbons (PAH's) in Hydrogenated Cyclodiene Resin, the subject of Food Additive Petition No. 4B4411 (Exxon Chemical Co.),'' dated May 11, 1995.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 5, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection 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. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Sec. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e.)

2. Section 177.1520 is amended in the table in paragraph (b) for the item ''Petroleum hydrocarbon resins (cyclopentadiene-type) * * *'' under the heading ''Substance'' by removing the phrase ''cubic centimeters'' and replacing it with ''centipoise'' and under the heading ''Limitations'' by revising the entry to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(b) * * *

Substance	Limitations
* * *	* * * * *
Petroleum hydrocarbon resins (cyclopentadiene-type) * * *	For use only as an adjuvant at levels not to exceed 30 percent by weight in blends with: (1) Polypropylene complying with paragraph (c), item 1.1 of this section, or (2) a copolymer of propylene and ethylene containing not less than 94 weight percent propylene and complying with paragraph (c), item 3.2 of this section. The average thickness of the food-contact film is not to exceed 0.1 millimeter (0.004 inch). The finished polymer may be used in contact with (1) Food types I, II, IV–B, VI–A, VI–B, VII–B, and VIII identified in Table 1 of § 176.170(c) of this chapter and under conditions of use C through G described in Table 2 of § 176.170(c) of this chapter; and (2) food types III, IV–A, V, VI–C, VII–A, and IX identified in Table 1 of § 176.170(c) of this chapter and under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter.
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Dated: May 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13983 Filed 6–3–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0136]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous solution of hydrogen peroxide, acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethylidene-1,1-diphosphonic acid as a sanitizing solution for use on food processing equipment and utensils, including food-contact surfaces in public eating places. This action responds to a petition filed by Ecolab, Inc.

DATES: Effective June 4, 1996; written objections and requests for a hearing by July 5, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of May 17, 1993 (58 FR 28882), FDA announced that a food additive petition (FAP 3B4371) had been filed by Ecolab, Inc., 840 Sibley Memorial Hwy., St. Paul, MN 55118. The petition proposed to amend the food additive regulations in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of an aqueous solution of hydrogen peroxide, acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and hydroxyethylene diphosphonic acid as a sanitizing solution for use on food processing equipment and utensils, including food-contact surfaces in public eating places.

While the agency used the term hydroxyethylene diphosphonic acid in the notice of filing, the agency has determined that a more specific and therefore more appropriate name for the substance is 1-hydroxyethylidene-1,1-diphosphonic acid. This more specific name will be used in the remainder of this document and in the regulation.

I. Safety and Functional Effect of Petitioned Use of the Additive

Sanitizing solutions are mixtures of chemicals that function together to sanitize food-contact surfaces and are regulated as such. Each listed component in a sanitizing solution has a functional effect; however, the agency evaluates data on the antimicrobial efficacy of the entire sanitizing solution. In addition, FDA regulations require that food-contact surface sanitizing solutions be labeled in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (§ 178.1010(d)). The subject sanitizing solution is an aqueous solution of hydrogen peroxide, acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethylidene-1,1-diphosphonic acid. The functions of these components and the basis for FDA's determination of the safety of these components in the subject sanitizing solution are described below.

A. Hydrogen Peroxide

Hydrogen peroxide functions as an antimicrobial agent in the subject sanitizing solution. Hydrogen peroxide is permitted as an ingredient in sanitizing solutions under § 178.1010(b)(30) and (b)(38), and it is affirmed as generally recognized as safe (GRAS) for use in food with specific limitations under 21 CFR 184.1366. On the basis of the data submitted in support of the already-regulated uses of hydrogen peroxide and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of hydrogen peroxide in the subject sanitizing solution is safe (Refs. 1 and 2).

B. Acetic Acid

Acetic acid functions as an acidifier in the subject sanitizing solution. Acetic acid is permitted as as ingredient in sanitizing solutions under § 178.1010(b)(30) and (b)(38), and it is affirmed as GRAS for use in food under 21 CFR 184.1005. On the basis of the data submitted in support of the already-regulated uses of acetic acid and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of acetic acid in the subject sanitizing solution is safe (Refs. 1 and 2).