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

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

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

* * * * *

ACE MO E5 Neosho, MO [Revised]

Neosho, Hugh Robinson Airport, MO
(lat. 36°48′39″N., long. 94°23′30″W.)
Neosho VORTAC
(lat. 36°50′33″N., long. 94°26′08″W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Neosho, Hugh Robinson Airport and within 1.8 miles each side of the Neosho VORTAC 310° radial extending from the 6.5-mile radius to 7 miles northwest of the airport.

Issued in Kansas City, MO, on February 16, 1999.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 99–5603 Filed 3–5–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50 and 812

[Docket No. 96N–0158]

RIN 0910–AA60

Protection of Human Subjects; Informed Consent; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a final rule that appeared in the **Federal Register** of October 2, 1996 (61 FR 51498) on informed consent. The document was published with some inadvertent errors in the codified section. This document corrects those errors to ensure the accuracy and consistency of the agency's regulations.

EFFECTIVE DATE: March 8, 1999.

FOR FURTHER INFORMATION CONTACT: Bonnie M. Lee, Office of the Executive Secretariat (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–4450.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, October 2, 1996 (61 FR 51498), an amendment for § 50.20 (21 CFR 50.20) was inadvertently omitted. Section 50.20 now provides for two exceptions to obtaining informed consent; one exception is contained in § 50.23 (21 CFR 50.23) and the other is contained § 50.24 (21 CFR 50.24). Accordingly this document conforms § 50.20 to the final regulations. Additionally, an amendment for § 812.47(b) (21 CFR 812.47(b)) inadvertently omitted commas which could cause confusion in understanding the meaning of the last sentence in that paragraph. Accordingly, FDA is amending the last sentence in § 812.47(b) to include two commas so that it will state ''The sponsor promptly shall provide this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.'' Also, the final rule on informed consent amended the Investigational New Drug Application (IND) regulations and the Investigational Device Exemption (IDE) regulations. In the **Federal Register** of June 16, 1997, FDA amended its IND regulations to clarify that, within 30 days after receipt of an IND for any clinical investigation involving an exception from informed consent, FDA will provide a written determination as to whether the investigation may begin. The agency inadvertently omitted a conforming amendment for the IDE regulations in § 812.20 (21 CFR 812.20). Current IDE regulations at § 812.20(a)(4)(i) require sponsors to submit a separate IDE for any clinical investigation involving an exception from informed consent under § 50.24. This requirement is to ensure that FDA has an opportunity to review the protocol and supporting information before the investigation begins. Section 812.20(a)(4)(i) also provides that the clinical investigation may not proceed without prior written authorization from FDA. The statement in § 812.20(a)(4)(i) that ''FDA shall provide such written authorization 30 days after FDA receives the IDE or earlier'' might be misread as suggesting that the agency may only grant permission for investigations to begin. To clarify the agency's intent, FDA is amending the last sentence in § 812.20(a)(4)(i) to state that ''FDA shall provide a written determination 30 days after FDA receives the IDE or earlier.''

List of Subjects

21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 50 and 812 are amended as follows:

PART 50—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 21 CFR part 50 is revised to read as follows:

Authority: 21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

2. Section 50.20 is amended by revising the first sentence to read as follows:

§ 50.20 General requirements for informed consent.

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

3. The authority citation for 21 CFR part 812 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

4. Section 812.20 is amended by revising the last sentence of paragraph (a)(4)(i) to read as follows:

§ 812.20 Application.

(a) * * *

(4)(i) * * * FDA shall provide a written determination 30 days after FDA receives the IDE or earlier.

* * * * *

5. Section 812.47 is amended by revising the last sentence of paragraph (b) to read as follows:

§ 812.47 Emergency research under § 50.24 of this chapter.

* * * * *

(b) * * * The sponsor promptly shall provide this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5522 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 97F–0412]

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 ethylene/propylene copolymers that contain up to 20 mole-percent of polymer units derived from propylene, with the remainder of the polymer consisting of ethylene, and having a minimum viscosity-average molecular weight of 95,000 and a minimum Mooney viscosity of 13, at up to 30 percent in blends with regulated polyolefins intended for contact with foods. This action responds to a petition filed by Mitsui Petrochemical Industries, Ltd.

DATES: The regulation is effective March 8, 1999; written objections and requests for a hearing by April 7, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 6, 1997 (62 FR 52136), FDA announced that a food additive petition (FAP 7B4549) had been filed by Mitsui Petrochemical Industries, Ltd., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. 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 ethylene/propylene copolymers that contain up to 20 mole-percent of polymer units derived from propylene, with the remainder of the polymer consisting of ethylene, and having a minimum viscosity-average molecular weight of 95,000 and a minimum Mooney viscosity of 13, at up to 30 percent of other regulated polymer blends intended for contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 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 § 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.

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.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before April 7, 1999, 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1520 is amended in the table in paragraph (c) by adding an item 3.7 to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(c)* * *