



3. **Takeoff Power.** Notwithstanding the definition of "takeoff power" in Part 1 of the FAR, "takeoff power" means the horsepower obtained from each initial power setting approved for takeoff under these special conditions.

C. **Performance Requirements.** The applicant must comply with the following performance and reliability requirements.

1. An ATPCS system failure during the critical time interval must be shown to be improbable.

2. The concurrent existence of an ATPCS failure and an engine failure during the critical time interval must be shown to be extremely improbable.

3. All applicable performance requirements of Part 25 must be met with an engine failure occurring at the most critical point during takeoff with the ATPCS system functioning.

D. **Power Setting.** The initial takeoff power set on each engine at the beginning of the takeoff roll may not be less than:

1. Ninety percent (90%) of the power level set by the ATPCS (the maximum takeoff power approved for the airplane under existing conditions);

2. That required to permit normal operation of all safety related systems

and equipment dependent upon engine power or power lever position; or

3. That shown to be free of hazardous engine response characteristics when power is advanced from the initial takeoff power level to the maximum approved takeoff power.

E. **Powerplant Controls.** 1. In addition to the requirements of § 25.1141, no single failure or malfunction, or probable combination thereof, of the ATPCS system, including associated systems, may cause the failure of any powerplant function necessary for safety.

2. The ATPCS must be designed to:

a. Apply power on the operating engine, following an engine failure during takeoff, to achieve the selected takeoff power without exceeding engine operating limits;

b. Permit manual decrease or increase in power up to the maximum takeoff power approved for the airplane under existing conditions through the use of the power lever. For aircraft equipped with limiters that automatically prevent engine operating limits from being exceeded under existing conditions, other means may be used to increase the maximum level of power controlled by

the power levers in the event of an ATPCS failure, provided the means:

(1) Is located on or forward of the power levers;

(2) Is easily identified and operated under all operating conditions by a single action of either pilot with the hand that is normally used to actuate the power levers; and

(3) Meets the requirements of § 25.777, paragraphs (a), (b), and (c);

c. Provide a means to verify to the flightcrew prior to takeoff that the ATPCS is in a condition to operate; and

d. Provide a means for the flightcrew to deactivate the automatic function. This means must be designed to prevent inadvertent deactivation

F. **Powerplant Instruments.** In addition to the requirements of § 25.1305:

1. A means must be provided to indicate when the ATPCS is in the armed or ready condition; and

2. If the inherent flight characteristics of the airplane do not provide adequate warning that an engine has failed, a warning system that is independent of the ATPCS must be provided to give the pilot a clear warning of any engine failure during takeoff.

Issued in Seattle, Washington, on May 19, 1986.

Wayne J. Barlow,

Director, Northwest Mountain Region.

[FR Doc. 86-11935 Filed 5-29-86; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 385

[Docket No. 60463-6063]

Soviet Oil and Gas; Technical Data License Applications

AGENCY: Export Administration, International Trade Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Departments of Commerce and State have agreed to an adjustment in the existing licensing policies for exports of oil and gas exploration and production data to the Union of Soviet Socialist Republics. Current policy to deny export license applications for oil and gas exploration and production-related technical data is being changed to reflect consideration of such applications on a case-by-case basis. This implements a revision in foreign policy export controls that was contained in the Secretary's Annual Report to Congress on Foreign Policy

Controls of January 17, 1986. Accordingly, the Export Administration Regulations (15 CFR Parts 368-399) are being amended to reflect the new policy.

EFFECTIVE DATE: May 30, 1986.

FOR FURTHER INFORMATION CONTACT: Robert Spruell, Country Policy, Strategic Planning and Policy Division, Export Administration, Department of Commerce, Washington, DC 20230 (Telephone (202) 377-3205).

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. Because this rule concerns a foreign affairs function of the United States, it is not a rule or regulation within the meaning of section 1(a) of Executive Order 12291, and it is not subject to the requirements of that Order. Accordingly, no preliminary or final Regulatory Impact Analysis has to be or will be prepared.

2. Section 13(a) of the Export Administration Act of 1979, as amended (50 U.S.C. App. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule is also exempt from these APA requirements because it involves a foreign affairs function of the United States. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Accordingly, as is being issued in final form. However, as with other Department of Commerce rules, comments from the public are always welcome. Written comments (six copies) should be submitted to: Betty Ferrell, Regulations Branch, Export Administration, U.S. Department of Commerce, P.O. Box 273, Washington, DC 20044.

3. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

4. This rule mentions a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Applicants for the validated export license required by this rule must complete and submit Form ITA-622P. This collection of information has been approved by the Office of

Management and Budget under control number 0625-0001.

List of Subjects in 15 CFR Part 385

Communist countries, Exports, Union of Soviet Socialist Republics.

PART 385 - [AMENDED]

Accordingly, Part 385 of the Export Administration Regulations (15 CFR Parts 368-399) is amended as follows:

1. The authority citation for 15 CFR Part 385 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503, 50 U.S.C. App. 2401 *et seq.*, as amended by Pub. L. 97-145 of December 29, 1981, and by Pub. L. 99-64 of July 12, 1985; E.O. 12525 of July 12, 1985 (50 FR 28757), July 16, 1985; Pub. L. 95-223, 50 U.S.C. 1701 *et seq.*; E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985).

2. Section 385.2 is amended by revising the last sentence in paragraph (c) to read as follows:

§ 385.2 Country Group Q, W, and Y: U.S.S.R., other Warsaw Pact Countries, Albania, Mongolian People's Republic, and Laos.

(c) * * * License applications for technical data for oil and gas exploration and production will be reviewed on a case-by-case basis.

Dated: May 27, 1986.

Walter J. Olson,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 86-12199 Filed 5-29-86; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 83C-0051]

Listing of Color Additive for Coloring Contact Lenses; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of May 6, 1986, for the final rule that amended the color additive regulations to provide for the safe use of an orange dye, 6-ethoxy-2-(6-ethoxy-3-oxobenzobenzothien-2-[3H]-ylidene)benzothiophen-3(2H)-one, for coloring contact lenses. This action

responds to a petition filed by Custom Tint Laboratories, Inc.

DATE: Effective date confirmed: May 6, 1986.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a final rule published in the Federal Register of April 3, 1986 (51 FR 11435), FDA amended the color additive regulations to provide for the safe use of an orange dye for coloring contact lenses.

In the final rule, FDA gave interested parties until May 5, 1986, to file objections. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA has concluded that the final rule published in the Federal Register of April 3, 1986, for the safe use of an orange dye, 6-ethoxy-2-(6-ethoxy-3-oxobenzobenzothien-2-[3H]-ylidene)benzothiophen-3(2H)-one for coloring contact lenses should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the April 3, 1986, final rule. Accordingly, the amendments promulgated thereby became effective May 6, 1986.

Dated: May 23, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-12089 Filed 5-29-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 172 and 178

[Docket No. 85F-0430]

Food Additives; Petroleum Wax

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 polyalkyl (C_{16} - C_{22}) acrylate polymer as a processing aid in the manufacture of petroleum wax used in food and in nonfood articles in contact with food. This action responds to a petition filed by Shell Oil Co.

DATES: Effective May 30, 1986; objections by June 30, 1986. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 172.886 effective May 30, 1986.

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

FOR FURTHER INFORMATION CONTACT: Lester Borodinsky, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of October 8, 1985 (50 FR 41026), FDA announced that a petition (FAP 5A3885) has been filed by Shell Oil Co., Suite 200, 1025 Connecticut Ave. NW., Washington, DC 20036, proposing that the food additive regulations be amended to provide for the safe use of polyalkyl (C_{16} - C_{22}) acrylate polymer as a processing aid in the manufacture of petroleum wax used in food and in nonfood articles in contact with food. This processing aid is currently regulated under § 172.886(c)(2) for use in the manufacture of petroleum wax used in chewing gum base only.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed uses of the food additive are safe, and that the regulations 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 (address above) 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.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the *Federal Register* of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an environmental assessment under 21 CFR 25.31a(a).

Any person who will be adversely affected by this regulation may at any time on or before June 30, 1986 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

21 CFR Part 172

Food additives, Incorporation by reference.

21 CFR Part 178

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, Parts 172 and 178 are amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 172.886 by revising paragraph (c)(2) to read as follows:

§ 172.886 Petroleum wax.

(c) * * *

(2) Poly(alkylacrylate) (CAS Reg. No. 27029-57-8), made from long chain (C_{16} - C_{22}) alcohols and acrylic acid, having: (i) A number average molecular weight between 40,000 and 100,000; (ii) a weight average molecular weight (MW_w) to number average molecular weight (MW_n) ratio (MW_w/MW_n) of not less than 3; and (iii) unreacted alkylacrylate monomer content not in excess of 14 percent, as determined by a method entitled, "Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax," which is incorporated by reference (copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408). Petroleum wax shall contain not more than 1,050 parts per million of poly(alkylacrylate) residues as determined by a method entitled, "Method for Determining Residual Level of Poly(alkylacrylate) in Petroleum Wax," which is incorporated by reference. Copies are available from the address cited in this paragraph (c)(2).

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

3. The authority citation for 21 CFR Part 178 is revised to read as follows and the authority citations following the sections in Part 178 are removed:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 340); 21 CFR 5.10 and 5.61.

4. In § 178.3710 by adding new paragraph (f) to read as follows:

§ 178.3710 Petroleum wax.

* * * * *

(f) Petroleum wax may contain poly(alkylacrylate) (CAS Reg. No. 27029-57-8), as described in § 172.886(c)(2) of this chapter, as a processing aid in the manufacture of petroleum wax.

Dated: May 22, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-12091 Filed 5-29-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 175

[Docket No. 85F-0165]

Indirect Food Additives: Adhesives and Components of Coatings

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 2-bromo-2-nitro-1,3-propanediol as a preservative in adhesives for food-packaging applications. This action responds to a petition filed by the Boots Co. PLC.

DATES: Effective May 30, 1986; objections by June 30, 1986.

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: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFA-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of May 22, 1985 (50 FR 21141), FDA announced that a petition (FAP 5B3836) had been filed by the Boots Co. PLC, 1 Thane Rd., Bldg. D6 Beeston, Nottingham NG2 3AA, England, proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of 2-bromo-2-nitropropane-1,3-diol as a preservative in adhesives for food-packaging applications.

Following publication of the filing notice in the Federal Register, FDA determined that the more precise chemical name for the additive is 2-bromo-2-nitro-1,3-propanediol. This name identifies the additive in the regulation set forth below.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the

regulations 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 (address above) 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.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the Federal Register of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(1).

Any person who will be adversely affected by this regulation may at any time on or before June 30, 1986, 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 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 175

Adhesive, 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, Part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 is revised to read as follows and the authority citations following the sections in Part 175 are removed:

Authority: Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. 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) * * *

Substances	Limitations
2-Bromo-2-nitro-1, 3-propanediol (CAS Reg. No. 52-51-7).	For use only as an antibacterial preservative.

Dated: May 22, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-12090 Filed 5-29-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 522

Implantation or Injectible Dosage Form New Animal Drugs Not Subject to Certification; Gentamicin Sulfate Injection

Correction

In FR Doc. 86-9267, appearing on page 15606, in the issue of Friday, April 25, 1986, make the following corrections:

1. In the first column, in the second line of the subject heading of this document, "From" should read "Form" as corrected above.

2. In the second column, in the second line of the Part 522 heading, "From" should read "Form".

BILLING CODE 1505-01-M