1981 Comp., p. 173, and E.O. 12518, 3 CFR, 1985 Comp., p. 348.

2. Section 801.9 is amended by adding paragraph (b)(7) to read as follows:

§ 801.9 Reports required.

* * * * *

(b) *Annual surveys.* * * *

(7) BE–82, Annual Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons:

(i) A BE–82, Annual Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons, will be conducted covering companies' 1995 fiscal year and every year thereafter except when a BE–80, Benchmark Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons, is conducted (see § 801.11). All legal authorities, provisions, definitions, and requirements contained in § 801.1 through § 801.8 are applicable to this survey. Additional rules and regulations for the BE–82 survey are given in paragraphs (b)(7)(i)(A) through (D) of this section. More detailed instructions are given on the report form itself.

(A) *Who must report.*—(*1*) *Mandatory reporting.* Reports are required from each U.S. person who is a financial services provider or intermediary, or whose consolidated U.S. enterprise includes a separately organized subsidiary or part that is a financial services provider or intermediary, *and* who had transactions (either sales or purchases) directly with unaffiliated foreign persons in all financial services combined in excess of $5,000,000 during its fiscal year covered by the survey. The $5,000,000 threshold should be applied to financial services transactions with unaffiliated foreign persons by all parts of the consolidated U.S. enterprise combined that are financial services providers or intermediaries. Because the $5,000,000 threshold applies separately to sales and purchases, the mandatory reporting requirement may apply only to sales, only to purchases, or to both sales and purchases.

(i) The determination of whether a U.S. financial services provider or intermediary is subject to this mandatory reporting requirement may be judgmental, that is, based on the judgment of knowledgeable persons in a company who can identify reportable transactions on a recall basis, with a reasonable degree of certainty, without conducting a detailed manual records search.

(ii) Reporters who file pursuant to this mandatory reporting requirement must provide data on total sales and/or purchases of each of the covered types of financial services transactions and must disaggregate the totals by country.

(*2*) *Voluntary reporting.* If, during the fiscal year covered, sales or purchases of financial services by a firm that is a financial services provider or intermediary, or by a firm's subsidiaries or parts combined that are financial services providers or intermediaries, are $5,000,000 or less, the U.S. person is *requested* to provide an estimate of the total for each type of service. Provision of this information is voluntary. Because the $5,000,000 threshold applies separately to sales and purchases, this voluntary reporting option may apply only to sales, only to purchases, or to both sales and purchases.

(B) *BE–82 definition of financial services provider.* The definition of a financial services provider used for this survey is the same as that used for the BE–80 benchmark survey, as defined in § 801.11(b).

(C) *Covered types of services.* The BE–82 survey covers the same types of financial services transactions that are covered by the BE–80 benchmark survey, as listed in § 801.11(c).

(D) *What to file.* (*1*) The BE–82 survey consists of Forms BE–82(A) and BE–82(B). Before completing a Form BE–82(B), a consolidated U.S. enterprise (including the top parent and all of its subsidiaries and parts combined) must complete Form BE–82(A) to determine its reporting status. If the enterprise is subject to the mandatory reporting requirement, or if it is exempt from the mandatory reporting requirement but chooses to report data voluntarily, either a separate Form BE–82(B) may be filed for each separately organized financial services subsidiary or part of the consolidated U.S. enterprise, or a single BE–82(B) may be filed, representing the sum of covered transactions by all financial services subsidiaries or parts of the enterprise combined.

(*2*) Reporters that receive the BE–82 survey from BEA, but that are not reporting data in either the mandatory or voluntary section of any Form BE–82(B), must return the Exemption Claim, attached to Form BE–82(A), to BEA.

(ii) [Reserved]

[FR Doc. 95–28229 Filed 11–14–95; 8:45 am]

BILLING CODE 3510–EA–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to the list of FDA officials in the Center for Drug Evaluation and Research (CDER) with authority to perform all the functions of the Commissioner of Food and Drugs with respect to approval of new drug applications and supplements thereto on drugs for human use. This action is being taken to realign approval points for division-level authorities to a more reasonable and manageable number.

EFFECTIVE DATE: November 15, 1995.

FOR FURTHER INFORMATION CONTACT:

Rixie L. Scott, Center for Drug Evaluation and Research (HFD–057), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0530; or

Ellen R. Rawlings, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: FDA is amending the regulations in § 5.80 *Approval of new drug applications and their supplements* (21 CFR 5.80) by revising § 5.80(a)(1)(iii) and removing paragraph (a)(1)(iv) with the titles therein to delegate to the Director, Office of Over-the-Counter Drugs, authority to approve new drug applications and supplements thereto on drugs for human use, except for those drugs listed in 21 CFR 314.440(b). These changes are being made to realign approval points for division-level authorities to a more reasonable and manageable number.

Further redelegation of the authority delegated is not authorized at this time. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701–1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.80 is amended by revising paragraph (a)(1)(iii) and by removing paragraph (a)(1)(iv) to read as follows:

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) * * *

(iii) The Director, Office of Over-the-Counter Drug Evaluation, CDER, for drugs under the Director's jurisdiction.

* * * * *

Dated: November 2, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–28149 Filed 11–14–95; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 175

[Docket No. 95F–0064]

Indirect Food Additives: Adhesives and Components of Coatings

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 silver chloride-coated titanium dioxide as a preservative in polymer latex emulsions in resinous and polymeric coatings intended for use in contact with food. This action is in response to a petition filed by Johnson Matthey Chemicals.

DATES: Effective November 15, 1995; written objections and requests for a hearing by December 15, 1995.

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

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of April 13, 1995 (60 FR 18845), FDA announced that a food additive petition (FAP 5B4453) had been filed by Johnson Matthey Chemicals, c/o 1000 Potomac St. NW., Washington, DC 20007. The petition proposed that the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) be amended to provide for the safe use of silver chloride-coated titanium dioxide as a preservative in polymer latex emulsions used in resinous and polymeric coatings intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed use of the additive in resinous and polymeric coatings intended for use in contact with food is safe and that the regulations in § 175.300 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.

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.

Any person who will be adversely affected by this regulation may at any time on or before December 15, 1995, 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 175

Adhesives, 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 175 is amended as follows:

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

1. The authority citation for 21 CFR part 175 continues to read as follows:

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

2. Section 175.300 is amended in paragraph (b)(3)(xxxiii) by alphabetically adding a new entry to read as follows: