substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further regulatory flexibility analysis is required.

The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). This direct final rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act. Industry will incur no net costs as a result of this direct final rule.

IV. Paperwork Reduction Act of 1995

This direct 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.

V. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Request for Comments

Interested persons may, on or before December 9, 1998, submit to the Dockets Management Branch (address above) written comments regarding this direct final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 24 CFR part 2 is amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 357, 360b, 361, 371, 372, 374; 15 U.S.C. 402, 409.

2. Section 2.10 is amended by revising paragraph (b)(2) to read as follows:

§ 2.10 Examination and investigation samples.

* * * * *

(b) * * *

(2) The cost of twice the quantity so estimated exceeds $150.

* * * * *

Dated: September 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination

[FR Doc. 98–25358 Filed 9–24–98; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of authority and Organization

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 1 to 99, revised as of Apr. 1, 1998, page 42, § 5.33(c) was inadvertently removed and is reinstated to read as follows:

5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug.

* * * * *

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 93C–0248]

Listing of Color Additives Exempt from Certification; Canthaxanthin; Confirmation of Effective Date; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date; correction.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of April 28, 1998, for the final rule that appeared in the **Federal Register** of March 27, 1998 (63 FR 14814), and amended the color additive regulations to provide for the safe use of canthaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. FDA also is correcting an inadvertent error in the final rule.

DATES: Effective date confirmed: April 28, 1998.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3078.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 27, 1998 (63 FR 14814), FDA amended 21 CFR part 73 to provide for the safe use of canthaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh.

FDA gave interested persons until April 27, 1998, to file objections and requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the final rule published in the **Federal Register** of March 27, 1998, should be confirmed.

In addition, in the final rule appearing on page 14814 in the **Federal Register** of Friday, March 27, 1998, the following correction is made:

On page 14815, in the first column, in the first complete paragraph, in line 17, the number ''264'' is corrected to read ''26.4''.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, notice is given that no objections or requests for a hearing were filed in response to the March 27, 1998, final rule. Accordingly, the amendments promulgated thereby became effective April 28, 1998.

Dated: September 17, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25640 Filed 9–24–98; 8:45 am]

BILLING CODE 4160–01–F