(within the meaning of § 133.21 of this part)'' in lieu of the present ''counterfeit American trademark'' text.

Conclusion

After analysis of the comments received and further consideration of the matter, Customs has decided to adopt the interim amendments to Part 133 of the Customs Regulations with the modification discussed above in the analysis of comments. Further, to make the text of paragraphs (a) and (b) of § 133.25 read more clearly, the phrase ''as determined by'' in paragraph (b) is replaced with the phrase ''based on'' used in paragraph (a), and the term ''domestic value'' used in paragraph (a) is inserted in paragraph (b). Lastly, the authority citation of part 133 is revised to add a specific authority citation for new § 133.25.

Inapplicability of the Regulatory Flexibility Act and Executive Order 12866

Because these regulatory amendments reflect existing statutory requirements or merely implement interpretations and policies that are already in effect under interim regulations to protect trademark owners and the public from imported merchandise bearing a counterfeit trademark, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, the regulations are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604. Further, this document does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

List of Subjects in 19 CFR Part 133

Copyrights, Counterfeit goods, Customs duties and inspection, Imports, Penalties, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures, Trademarks, Trade names, Unfair competition.

Amendments to the Regulations

For the reasons stated above, part 133 of the Customs Regulations (19 CFR part 133), is amended as set forth below:

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The general authority citation for part 133 continues, and the specific authority for § 133.52 is revised, to read as follows:

Authority: 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1624; 31 U.S.C. 9701;

* * * * *

Sections 133.25 and 133.52 also issued under 19 U.S.C. 1526;

* * * * *

2. Section 133.25 is revised to read as follows:

§ 133.25 Civil fines for those involved in the importation of counterfeit trademark goods.

In addition to any other penalty or remedy authorized by law, Customs may impose a civil fine on any person who directs, assists financially or otherwise, or aids and abets the importation of merchandise bearing a counterfeit mark (within the meaning of § 133.21 of this part) as follows:

(a) *First violation.* For the first seizure of such merchandise, the fine imposed shall not be more than the domestic value of the merchandise (*see*, § 162.43(a) of this chapter) as if it had been genuine, based on the manufacturer's suggested retail price of the merchandise at the time of seizure.

(b) *Second and subsequent violations.* For the second and each subsequent seizure of such merchandise, the fine imposed shall not be more than twice the domestic value of the merchandise as if it had been genuine, based on the manufacturer's suggested retail price of the merchandise at the time of seizure.

3. Section 133.52(c) is republished to read as follows:

§ 133.52 Disposition of forfeited merchandise.

* * * * *

(c) *Articles bearing a counterfeit trademark.* Merchandise forfeited for violation of 19 U.S.C. 1526 shall be destroyed, unless it is determined that the merchandise is not unsafe or a hazard to health and the Commissioner of Customs or his designee has the written consent of the U.S. trademark owner, in which case the Commissioner of Customs or his designee may dispose of the merchandise, after obliteration of the trademark where feasible, by:

(1) Delivery to any Federal, State, or local government agency that, in the opinion of the Commissioner or his designee, has established a need for the merchandise; or

(2) Gift to any charitable institution that, in the opinion of the Commissioner or his designee, has established a need for the merchandise; or

(3) Sale at public auction, if more than 90 days has passed since the forfeiture and Customs has determined that no need for the merchandise has been established under paragraph (c)(1) or (c)(2) of this section.

Approved: August 3, 1998.

Samuel H. Banks,

Acting Commissioner of Customs.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 98–25723 Filed 9–24–98; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 98N–0417]

Amendment to Examination and Investigation Sample Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding the collection of twice the quantity of food, drug, or cosmetic estimated to be sufficient for analysis. This action increases the dollar amount that FDA will consider to determine whether to routinely collect a reserve sample of a food, drug, or cosmetic product in addition to the quantity sufficient for analysis. Experience has demonstrated that the current dollar amount does not adequately cover the cost of most quantities sufficient for analysis plus reserve samples. This direct final rule is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and is intended to reduce the burden of unnecessary regulations on food, drugs, and cosmetics without diminishing the protection of the public health. Elsewhere in this issue of the **Federal Register,** FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws this direct final rule.

DATES: This rule is effective February 8, 1999. Comments must be received on or before December 9, 1998. If FDA receives no significant adverse comments during the specified comment period, the agency intends to publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on February 8, 1999. If the agency receives any

significant adverse comment, FDA intends to withdraw this direct final rule action by publication in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sharon M. Sheehan, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 12720 Twinbrook Pkwy., Rockville, MD 20855, 301–827–0412.

SUPPLEMENTARY INFORMATION:

I. Background

Examination and investigation samples (§ 2.10 (21 CFR 2.10)), sets out provisions related to the collection of an official sample for FDA's analysis. Routinely, the FDA investigator collects the sample and pays the owner of the regulated food, drug, or cosmetic product either the regular selling price, or, if acceptable to the owner, the dealer's invoice cost plus a nominal charge (usually 10 to 15 percent) (see Investigations Operations Manual, January 1998, ch. 4, section 416.2, at 129). The regulations require the investigator to collect an extra amount of the product beyond what is needed for analysis, known as a reserve sample, to allow for additional analysis (see section 702(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372(b) and § 2.10(c)). Under most circumstances the investigator is to collect at least ''twice the quantity estimated by him to be sufficient for analysis * * *.''

One of the few narrow exceptions to the requirement to collect at least twice the quantity estimated to be sufficient for analysis is when the cost of the quantity sufficient for analysis and the reserve sample together exceeds $50. The decision whether to collect twice the quantity sufficient for analysis if the cost of that amount exceeds the regulatory amount (currently $50) is made on a case-by-case basis.

The current regulatory amount as set forth in section 2.10(b)(2) was established in 1955 as § 1.700(b)(2) (21 CFR 1.700(b)(2)) published in the **Federal Register** of December 20, 1955 (20 FR 9539). Section 1.700 was reorganized and republished as section 2.10, and the regulatory amount was increased from $10 to $50 in 1977 (see 42 FR 15559, March 22, 1977).

A regulatory amount of $150 more accurately reflects an amount that would cover the cost of most quantities sufficient for analysis plus reserve samples. The amount of $150 is based, in part, on the Consumer Price Index (CPI) from the Bureau of Labor and Statistics, Department of Commerce. In August 1977, the CPI was 61.2; in August 1996, the CPI was 157.3. This change represents an increase of approximately 157 percent. Therefore, $50 in 1977 is equivalent to approximately $128 today. Considering that the regulatory amount has changed every 20 years, setting the amount at $150 contemplates that another increase likely will not occur for several years.

II. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how FDA will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as a noncontroversial amendment and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend the existing § 2.10(b)(2). The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment.

The FDA has provided a comment period on the direct final rule of 75 days after September 25, 1998. If the agency receives any significant adverse comment, FDA intends to withdraw this direct final rule action by publication in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If any significant adverse comment is received during the comment period, FDA will publish, within 30 days after the comment period ends, a document withdrawing the direct final rule. If FDA withdraws the direct final rule, all comments received will be considered under the proposed rule in developing a final rule under the usual Administrative Procedure Act notice-and-comment procedures.

If FDA receives no significant adverse comments during the specified comment period. FDA intends to publish a confirmation document within 30 days after the comment period ends, confirming that the direct final rule will go into effect on February 8, 1999.

III. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This direct final rule increases the dollar limit FDA uses to determine whether a quantity estimated as twice that which is sufficient for analysis will routinely be collected. The rule does not adversely affect the owners of foods, drugs, or cosmetics from which samples are collected. This direct final rule is not a significant regulatory action as defined by the Executive Order and is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that this direct final rule will not have a significant economic impact on a

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