

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMPB

Display Date	9.24.95
Publication Date	9.25
Certifier	C. CONNOR

Food and Drug Administration

21 CFR Part 2

[Docket No. 98N-0417]

**General Administrative Rulings and Decisions; Amendment to the Examination and Investigation Sample Requirements; Companion Document to Direct Final Rule**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend 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 proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. This action is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiative, and it is intended to reduce the burden of unnecessary regulations on food, drugs, and cosmetics without diminishing the protection of the public health.

**DATES:** Comments must be received on or before (*insert date 75 days after date of publication in the Federal Register*).

**ADDRESSES:** Submit written comments 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**

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule will provide the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule. FDA is publishing the direct final rule because the rule contains a noncontroversial change, and FDA anticipates that it will receive no significant adverse comment.

A detailed rationale for the rule is set forth in the preamble to the direct final rule and in section II of this document. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends, confirming that the direct final rule will go into effect on (*insert date 135 days after date of publication in the **Federal Register***). Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If timely significant adverse comments regarding the rule are received, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA then will proceed to respond to all of the comments received regarding the rule and, if appropriate, the rule will be finalized under this proposed rule using usual notice-and-comment procedures.

This action is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiative, and it is intended to reduce the burden of unnecessary regulations on food, drugs, and cosmetics without diminishing the protection of the public health.

## II. Examination and Investigation Samples

Section 2.10 (21 CFR 2.10) regulates the examination and investigation samples and sets out provisions related to the collection of an official sample for FDA's analysis. FDA investigators routinely collect the samples and pay 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 § 2.10(b)(2) was established in 1955 as § 1.700(b)(2) (21 CFR 1.700(b)(2)) and published in the **Federal Register** of December 20, 1955 (20 FR 9525 at 9539). Section 1.700 was reorganized and republished as § 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.

### **III. 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.

### **IV. Analysis of Economic Impacts**

#### *A. Benefit-Cost Analysis*

FDA has examined the impacts of the proposed 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). FDA believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This proposed 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 proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

### *B. Regulatory Flexibility Analysis*

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 proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

### *C. Unfunded Mandates Reform Act of 1995*

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 proposed 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 proposed rule.

## **V. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed 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.

## **VI. Request for Comments**

Interested persons may, on or before (*insert date 75 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. This comment period runs concurrently with the comment period for the 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. All comments received will be considered as comments regarding the direct final rule. In the event the direct final rule is withdrawn, all comments received

regarding the direct final rule and this companion proposed rule will be considered under this proposed rule.

**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, 21 CFR part 2 is proposed to be amended as follows:

**PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS**

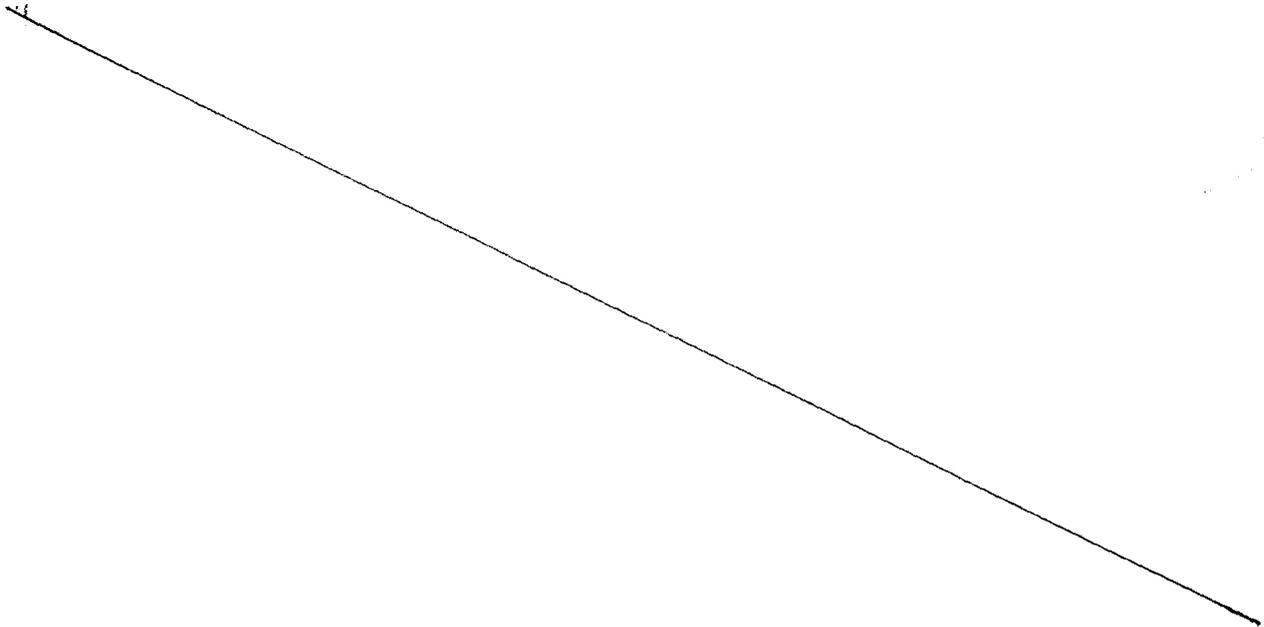
1. The authority citation for 21 CFR part 2 continues to read as follows:

**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

September 11, 1998



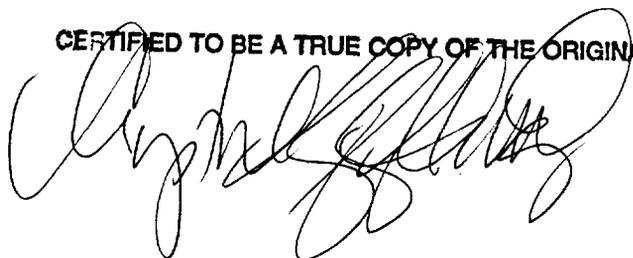
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William K. Hubbard  
Associate Commissioner for Policy Coordination

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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(b) \* \* \*

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

\* \* \* \* \*

Dated: September 11, 1998  
September 11, 1998



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William K. Hubbard  
Associate Commissioner for Policy Coordination

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