with, but not part of, the decisional record of the proceeding.

(2) *Public notice requirement.* The Secretary shall periodically issue a public notice listing any prohibited off-the-record communications or summaries thereof received by his or her office relating to a proceeding. Such notice shall identify the author of the communication, the date the communication was received, and the docket number to which it relates.

(3) *Responses to prohibited off-the-record communications.* Any party may file a response to a communication placed in the non-decisional public record under paragraph (f)(1) of this section. A party may also file a written request for an opportunity to respond, on-the-record, to any facts or contentions made in an off-the-record communication placed in the non-decisional public file. The Commission will grant such request only where it determines that the dictates of fairness so require. When the request is granted, a copy of both the off-the-record communication, and the permitted response, will be made a part of the decisional record.

(g) *Handling of permitted off-the-record communications.*—(1) *Disclosure requirement.* (i) Any written information, and a summary of the substance of any significant oral information, not already in the record, obtained through a permitted communication in response to an emergency covered by paragraph (d)(2) of this section, will be submitted to the Secretary and placed in the decisional record of the underlying Commission proceeding.

(ii) Any permitted written information obtained through a permitted communication with a non-party elected public official under paragraph (d)(6) of this section will be submitted to the Secretary and placed in the decisional record of the proceeding.

(iii) Except for information of which official notice may be taken, any written information, and a summary of the substance of any significant oral information, not already in the record, obtained through a permitted communication with a Federal, state, or local agency under paragraph (d)(8) of this section, will be submitted to the Secretary and placed in the decisional record of the Commission proceeding.

(iv) Any written information, and a summary of the substance of any significant oral information, not already in the environmental documentation of a proceeding, obtained through a permitted communication to or from any person under paragraph (d)(9) of this section, will be submitted to the Secretary, placed in the public record of the proceeding, and addressed in the final environmental document issued by the Commission.

(v) Any written information, and a summary of the substance of any significant oral information, not already in the record, obtained through a permitted communication involving an individual non-party landowner under paragraph (d)(10) of this section will be submitted to the Secretary, and placed in the decisional record of the Commission proceeding.

(2) *Public notice requirement and response.* For each communication required to be disclosed under paragraph (g)(1) of this section, the Secretary shall periodically issue a public notice listing any permitted off-the-record communications or summaries thereof received by his or her office relating to a proceeding. Any party may file a response on the record.

(h) *Sanctions.* (1) If a person knowingly makes or causes to be made a communication in violation of paragraph (b) of this section, the Commission may disqualify and deny the person, temporarily or permanently, the privilege of practicing or appearing before it, in accordance with Rule 2101 (appearances); and

(2) If a party or its agent or representative knowingly makes or causes to be made a communication in violation of paragraph (b) of this section, the Commission may require the party, agent, or representative to show cause why the party's claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected because of the prohibited off-the-record communication.

(i) *Section not exclusive.* (1) The Commission may, by rule or order, modify any provision of this section as it applies to all or part of a proceeding, to the extent permitted by law.

(2) The provisions of this section are not intended to limit the authority of a decisional employee to decline to engage in permitted off-the-record communication, or where not required by the rule, to make a public disclosure of a permitted off-the-record communication, in circumstances where the employee determines that such action is appropriate.

7. The heading of § 385.2202 is revised to read as follows:

§ 385.2202 Separaton of functions (Rule 2202).

[FR Doc. 98–25373 Filed 9–24–98; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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.

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 December 9, 1998.

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 February 8, 1998. 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 December 9, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed 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.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25359 Filed 9–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA–122–FOR]

Pennsylvania Regulatory Program

AGENCY: OSM, Interior.

ACTION: Proposed rule; notice of hearing and extension of comment period.

SUMMARY: In a letter dated July 29, 1998 (Administrative Record No. PA–841.07), the Pennsylvania Department of Environmental Protection submitted to OSM proposed regulatory amendments to the Pennsylvania regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment proposes changes to the Pennsylvania program with regard to the mine subsidence control, subsidence damage repair or replacement, and water supply replacement provisions of SMCRA. The amendment submission included Act 54 and implementing regulations. OSM announced receipt of the amendment in the August 25, 1998, **Federal Register** (63 FR 45199) and solicited public comments on the proposed regulatory changes. The August 25, 1998, notice stated that the public comment period would end on September 24, 1998, and if a hearing on the amendment is requested, that the hearing would be held on September 21, 1998.

Several individuals requested that a public hearing be held in Washington, Pennsylvania. These individuals also requested additional time to prepare for the hearing. OSM is honoring this request in order to give interested parties ample notification of the hearing location, and ample time to prepare their comments for the hearing. As a result, the deadline for submitting public comments has been extended.

This notice sets forth the times and location of the pending public hearing, and the extended deadline that public comments can be submitted to OSM regarding the adequacy of the proposed amendment.

DATES: Written comments must be received on or before 4:00 p.m. on October 19, 1998, to ensure consideration in the rulemaking process. The public hearing will be held at 6:30 p.m. on October 13, 1998.

ADDRESSES: Written comments and requests to testify at the hearing should be mailed or hand-delivered to Mr. Robert J. Biggi, Director, Harrisburg Field Office at the first address listed below.

Copies of the Pennsylvania program, the proposed amendment, a listing of any scheduled public meetings or hearing, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Harrisburg Field Office, Third Floor, Suite 3C, Harrisburg Transportation Center, 415 Market Street, Harrisburg, Pennsylvania 17101, Telephone: (717) 782–4036.

Pennsylvania Department of Environmental Protection, Bureau of Mining and Reclamation, Rachel Carson State Office Building, P.O. Box 8461, Harrisburg, Pennsylvania 17105–8461, Telephone: (717) 787–5103.

Each requester may receive, free of charge, one copy of the proposed amendment by contacting the OSM Harrisburg Field Office.

The public hearing will be held at the Ramada Inn, 1170 West Chestnut Street, Washington, Pennsylvania 15301–4631.

FOR FURTHER INFORMATION CONTACT: Robert J. Biggi, Director, Harrisburg Field Office, Telephone (717) 782–4036.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

In accordance with the provisions of 30 CFR 884.15, OSM is seeking comment on whether the amendment proposed by Pennsylvania satisfies the applicable requirements for the approval of State program amendments. If the amendment is deemed adequate, it will become part of the Pennsylvania program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Harrisburg Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by close of business on October 6, 1998. Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons who desire to comment have been heard.

II. Procedural Determinations

Executive Order 12866

This proposed rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by