Sunshine Act Meetings

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This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

	Item
Federal Deposit Insurance Corporation	1, 2
Federal Home Loan Mortgage Corporation	3
Federal Reserve System	4
International Trade Commission	5
National Transportation Safety Board	6
Nuclear Regulatory Commission	7

1

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10:00 a.m. on Monday, August 19, 1985, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Recommendation regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of these assets:

Case No. 46,290
Continental Illinois National Bank and Trust Company of Chicago, Chicago, Illinois

Reports of committees and officers:

Minutes of actions approved by the standing committees of the Corporation pursuant to authority delegated by the Board of Directors.

Reports of the Division of Bank Supervision with respect to applications, requests, or actions involving administrative enforcement proceedings approved by the Director or an Associate Director of the Division of Bank Supervision and the various Regional Directors pursuant to authority delegated by the Board of Directors.

Discussion Agenda:
No matters scheduled.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389-4425.

Dated: August 12, 1985.
Federal Deposit Insurance Corporation.
Hoyle D. Robinson,
Executive Secretary.
[FR Doc. 85-19452 Filed 8-12-85; 3:45 pm]
BILLING CODE 6714-01-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:30 a.m. on Monday, August 19, 1985, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors, pursuant to sections 552b(c)(2), (c)(6), (c)(8), and (c)(9)(A)(ii) of Title 5, United States Code, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured banks or officers, directors, employees, agents or other persons participating in the conduct of the affairs thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda:
Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separation, removals etc.:

Names of employees authorized to be excempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389-4425.

Dated: August 12, 1985.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.
[FR Doc. 85-19453 Filed 8-12-85; 3:54 pm]
BILLING CODE 6714-01-M

3

FEDERAL HOME LOAN MORTGAGE CORPORATION

DATE AND TIME: Thursday, August 15, 1985, 1:00 p.m.

PLACE: 1776 G Street, NW., Conference Room 8-C, Washington, D.C. 20013.

STATUS: Closed.

CONTACT PERSON FOR MORE INFORMATION: Alan B. Hausman, 1776 G Street, NW., P.O. Box 37248, Washington, D.C. 20013 (202) 789-5097.

MATTERS TO BE CONSIDERED:

Closed: Minutes of May 2, 1985, Board of Directors' Meeting
Closed: President's Report
Closed: Financial Report

Date sent to **Federal Register:** August 8, 1985.

Maud Mater,
Secretary.
[FR Doc. 85-19458 Filed 8-12-85; 4:11 pm]
BILLING CODE 6720-02-M

4

FEDERAL RESERVE SYSTEM

TIME AND DATE: 12:00 noon, Monday August 19, 1985.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street

entrance between 20th and 21st Street, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: August 9, 1985.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 85-19331 Filed 8-9-85; 4:19 pm]

BILLING CODE 6210-01-M

5

INTERNATIONAL TRADE COMMISSION

[USITC SE-85-34]

TIME AND DATE: 10:00 a.m., Wednesday, August 21, 1985.

PLACE: Room 117, 701 E Street, NW., Washington, DC 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratification List.
4. Petitions and Complaints:
5. Investigations Nos. 701-TA-251/253 and 731-TA-271/274 [Preliminary] (Certain welded carbon steel pipes and tubes from India, Taiwan, Turkey, and Yugoslavia).
6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary, (202) 523-0161.

Kenneth R. Mason,

Secretary.

[FR Doc. 85-19351 Filed 8-9-85; 5:06 pm]

BILLING CODE 7020-02-M

6

NATIONAL TRANSPORTATION SAFETY BOARD

TIME AND DATE: 9 a.m., Tuesday, August 20, 1985.

PLACE: NTSB Board Room, Eighth Floor, 800 Independence Ave., SW., Washington, DC. 20594.

STATUS: The first four items on the agenda will be open to the public; the last two items will be closed under Exemption 10 of the Government in the Sunshine Act.

MATTERS TO BE CONSIDERED:

1. *Aircraft Accident Report:* Vieques Air Link, Inc., Britten-Norman BN-2A-6 Islander, N589SA, Vieques, P.R., August 2, 1984.
2. *Railroad Accident Report:* Head-on Collision of Chicago, South Shore and South Bend Railroad Trains Nos. 123 and 218, Gary, Indiana, January 21, 1985.
3. *Railroad Accident Report:* Rear-end Collision of Two Chicago Transit Authority Trains near the Montrose Avenue Station, Chicago, Illinois, August 17, 1984.
4. *Marine Summary Reports:* F/V Bonaventure, F/V Judith Lee Rose, M/V ANGELA BRILEY, and the F/V LIBERTY.
5. *Opinion and Order:* Commandant v. Mann, Docket ME-107; disposition of seaman's appeal.
6. *Opinion and Order:* Whittle v. Administrator, Docket 22 EAJA SE-60591 disposition of the Administrator's appeal from the law judge's award of fees.
7. *Opinion and Order:* Petition of Johnson, Docket SM-3322; disposition of the petitioner's request for disposition of the case on the merits.

CONTACT PERSON FOR MORE INFORMATION: Catherine T. Kaputa (202) 382-6525.

Dated: August 11, 1985.

Effie M. Upshaw,

Alternate Federal Liaison Officer.

[FR Doc. 85-19428 Filed 8-12-85; 1:01 pm]

BILLING CODE 7533-01-M

7

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of August 12, 19, 26, and September 2, 1985.

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington DC.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of August 12

Thursday, August 15

11:30 a.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of August 19—Tentative

No Commission meetings

Week of August 26—Tentative

No Commission Meetings

Week of September 2—Tentative

Tuesday, September 3

2:00 p.m.
Periodic Briefing on NTOLs (Public Meeting)

Wednesday, September 4

10:00 a.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)

2:00 p.m.
Continuation of 7/23 Discussion on Threat Level and Physical Security (Closed—Ex. 1)

Thursday, September 5

11:30 a.m.
Affirmation Meeting (Public Meeting) (if needed)

Friday, September 6

10:00 a.m.
Status of Interpretation of Appendix R—Fire Protection (Public Meeting)

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING): (202) 634-1498.

CONTACT PERSON FOR MORE INFORMATION: Julia Corrado (202) 634-1410.

Dated: August 8, 1985.

Julia Corrado,

Office of the Secretary.

[FR Doc. 85-19332 Filed 8-9-85; 4:22 pm]

BILLING CODE 7590-01-M

Federal Register

Wednesday
August 14, 1985

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 182

Sulfiting Agents; Proposal To Revoke GRAS Status for Use on Fruits and Vegetables Intended To Be Served or Sold Raw to Consumers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 182

[Docket No. 81N-0314]

Sulfiting Agents; Proposal To Revoke GRAS Status for Use on Fruits and Vegetables Intended To Be Served or Sold Raw to Consumers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that currently available information has raised significant questions about the safety of the use of sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite (collectively known as fulfiting agents or sulfites) on fruits and vegetables intended to be served raw or sold raw to consumers. As a result of these questions, FDA believes that this use of sulfites can no longer be considered to be generally recognized as safe (GRAS). Therefore, FDA is proposing to amend the regulations on the sulfiting agents in 21 CFR Part 182 to except their use on fruits and vegetables intended to be served raw or sold raw to consumers or to be presented to consumers as fresh from the uses of these substances that are GRAS.

This proposed action is based upon FDA's review of new information on sulfiting agents received in response to a proposal to affirm the GRAS status of sulfiting agents published in the **Federal Register** of July 9, 1982 (47 FR 29956); the January 31, 1985, final report of the Federation of American Societies for Experimental Biology (FASEB) on the Reexamination of the GRAS Status of Sulfiting Agents; recently published reports in the medical literature; consumer complaints received by the agency; and other relevant information.

DATE: Comments by September 13, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5676.

SUPPLEMENTARY INFORMATION:

I. Background/Regulatory History

Sulfiting agents have a long history of use as food ingredients. Since November 20, 1959 (24 FR 9368), these food ingredients have been listed as GRAS for use as chemical preservatives.

In 1976, during the course of the agency's review of the safety of GRAS Substances (Ref. 1), the Select Committee on GRAS Substances (the Select Committee) of FASEB issued a report on the health aspects of the use of sulfiting agents as food ingredients (Ref. 2). Subsequently, in the **Federal Register** of July 9, 1982 (47 FR 29956), FDA proposed to affirm, with specific use limitations, the GRAS status of certain sulfiting agents (Ref. 3).

The agency received numerous comments on the 1982 proposal. Some comments reported new uses of the sulfiting agents, significant recent expansion of some old uses, widespread use by the food-service industry, and many uses that were unlabeled. Other comments reported the possibility that a significant number of individuals may experience potentially severe allergic-type responses upon consuming foods treated with sulfiting agents. The agency is using the term "allergic-type responses" to describe the various types of symptoms that individuals have suffered after eating sulfite-treated fresh fruits and vegetables that were served or sold raw. These responses in some ways resemble responses to an allergen. However, the scientific community is unsure at this time about the actual mechanism of response elicited by the sulfite ingredient.

The agency also received a citizen petition regarding the use of sulfiting agents in food and drugs. The petition echoed many of the concerns expressed in the comments and urged the agency to take certain regulatory actions to restrict the use of sulfites in food.

A number of the comments received, as well as portions of the citizen petition, are relevant to the specific action being proposed in this document. The agency's responses to these comments are included in this document.

The new information received in response to the 1982 proposal prompted the agency to ask FASEB to reexamine the GRAS status of the use of sulfiting agents. FASEB established an ad hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents (the Panel). On July 9, 1984 (49 FR 27994), FDA announced the formation of the Panel.

The Panel evaluated recent scientific publications and new information and data submitted to FDA in response to its 1982 proposal. The Panel supplemented this information with additional materials acquired independently, and conducted an open meeting on November 29, 1984, at which individuals and organizations presented their views on sulfite-related issues. On January 31, 1985, FASEB issued its final report (Ref. 4).

In that report, although the Panel concluded that for the majority of the population "there is no evidence * * * to suspect a hazard," the Panel also concluded that for the fraction of the public that is sulfite sensitive, "there is evidence * * * that demonstrates or suggests reasonable grounds to suspect a hazard of unpredictable severity to such individuals when they are exposed to sulfiting agents in some foods at levels that are now current and in the manner now practiced" (Ref. 4, p. 60).

Upon evaluation of available information, FDA concurs with the conclusions of the Panel and is currently assessing the use of sulfiting agents on foods.

In the **Federal Register** of April 3, 1985 (50 FR 13306), FDA published a proposal to require that all packaged foods that contain 10 parts per million (ppm) or more of sulfur dioxide equivalents must be labeled to disclose the presence of a sulfiting agent. If the agency adopts that proposal, sulfite-sensitive individuals will be able to avoid packaged food products to which they might be sensitive.

The agency believes, however, that labeling is not likely to be an effective means of protecting sulfite-sensitive individuals from certain sulfited foods, including fruits and vegetables that are served raw or sold raw to consumers in food-service establishments. Ingestion of these types of foods has been associated with rare but potentially life-threatening responses in asthmatic individuals.

Because of the acute health problems that have been associated with the use of sulfites on fresh fruits and vegetables sold in food-service establishments, FDA has decided to act immediately with regard to this use, before deciding whether to affirm the GRAS status of the other uses of sulfiting agents. In addition, because of these health problems, the agency is providing only 30 days for comments on this proposal instead of the customary 60 days.

In this document, FDA is announcing its preliminary conclusion that the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw to consumers is not GRAS. To reflect this preliminary conclusion, the agency is

proposing to amend Part 182 (21 CFR Part 182).

If the agency confirms its preliminary conclusion, this use of sulfiting agents would constitute the use of an unapproved food additive. As a result, the use of sulfites on any fruit or vegetable that is intended to be served or sold raw would cause that fruit or vegetable to be adulterated and in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(2)(C)). The agency intends to address all other uses of sulfiting agents, including their use on potatoes and potato products, in the near future.

II. The use of Sulfiting Agents on Fruits and Vegetables

A. Purpose

Many raw foods, when exposed to the air, rapidly discolor or otherwise lose their natural, fresh appearance. For example, lettuce wilts and browns around the edges; cut apples become brown; avocado pulp turns black. Sulfiting agents are one type of chemical preservative that serves effectively to prevent or to delay the process of browning and deterioration of raw fruits and vegetables by acting as an antioxidant. Sulfites are used by restaurants to help maintain the fresh appearance of certain fruits and vegetables in salad bars. They are also used by some suppliers of produce that is intended for salad bar use or of vegetables that are intended for cooking. Although a number of substances such as citric acid, ascorbic acid, or sodium erythorbate could be used to maintain the freshness of raw fruits and vegetables, the primary commercial products sold for this use contain the various sulfite salts as their principal active ingredients.

Label directions for these products advise users to dissolve a specific amount of the product in water, to dip the food to be treated in this solution for a stated period of time, and to drain the food before refrigerating or cooking.

B. FDA's Concerns

FDA is concerned about the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw to consumers because of serious responses in sulfifte-sensitive individuals have been associated with this widespread use of sulfites on fresh fruits and vegetables and because such use is not commonly labeled so that sensitive individuals may avoid sulfite-treated foods. FDA's concerns extend to fruits and vegetables that may have undergone physical processing before sale, such as guacomole made from mashed avocado, and to raw fruits and vegetables that, to the consumer, appear to be fresh but that may have been processed in some way (e.g., freezing). Restaurant consumers of raw fruits and vegetables that have the appearance of freshness do not generally expect such foods to contain preservatives, and these foods are rarely labeled. Similarly, raw fruits and vegetables sold in grocery stores are not usually labeled, and consumers do not associate them with the presence of preservatives such as sulfiting agents.

FDA is also aware of a number of recent trends and practices that raise concern because they contribute to the likelihood of greater exposure to sulfites in the American diets. More Americans are eating a greater proportion of their meals away from home. One trend of considerable importance in recent years has been the increase in the presence of salad bars in restaurants and other food-service establishments. Such salad bars usually offer the consumer a wide variety of fruits and vegetables from which to choose. The popularity of these salad bars may be attributed at least in part to consumers' increasing concern about physical well-being and their desire to replace certain "processed" foods in the diet with "natural" or "fresh" foods or to reduce caloric intake.

Data indicate that sulfiting agents continued to be used on some of the foods offered for sale at many salad bars. However, their use is rarely disclosed to the consumer. In addition, the levels at which sulfiting agents are used by restaurant and food-service establishment personnel vary widely, largely as a result of the differences in the degree of care employed by such personnel. Consequently, there is a wide variation in the sulfite content of treated products.

The practices and trends described above take on added significance in light of reports received since 1982 of adverse responses associated with food allegedly treated with sulfiting agents. At present, FDA has received over 500 consumer complaints where the individuals reported suffering a variety of adverse allergic-type responses after eating food to which they believed sulfiting agents had been added.

Information currently available indicates that allergic-type responses to sulfites are most likely to occur among persons who are asthmatic. Although prevalence estimates vary, among the estimated 10 million asthmatic patients in the U.S. population, as many as 1 in 10 (or 1 million persons) may be sulfite sensitive (Ref. 4). Although there is even less certainty about the degree to which nonasthmatic persons may also be sulfite sensitive, nonasthmatics were nevertheless involved in several of the complaints reported to the agency.

C. FDA Actions

In 1983, FDA began to take steps to provide consumers with information that would help them avoid foods to which they could be sensitive because the foods were treated with sulfiting agents.

In March of that year, FDA issued an interpretation of its model food sanitation code. This interpretation was later revised in its September 1983 "Retail Food Protection Program Information Manual" (Ref. 5). The revised interpretation stated that "fresh fruits and fresh vegetables and other foods which are intended for sale in the raw state and which have received treatment with sulfiting agents at the retail establishment will be considered safe under the provisions of the model food sanitation code only if the consumers are informed that sulfiting agents have been added." By March 1985, however, 19 States had still not adopted this interpretation. Moreover, because of the great number of restaurants and other retail establishments, comprehensive enforcement is difficult to achieve.

FDA is aware that some recent information indicates that the use of sulfiting agents on salad bar items in food-service establishments, and the use of these agents by suppliers of fresh and ready-to-cook produce to such establishments, have declined in the last 2 years. For example, the National Restaurant Association, which advised its members in February 1983 to stop applying sulfites, found in a subsequent survey (reported in the June 1, 1983 letter from R. Neville to Sanford Miller) that less than 4 percent of its members were using sulfiting agents. In addition, the Produce Marketing Association reported in November 1984 that a recent survey showed that 5 percent of its members were using sulfiting agents, and that only 2 percent were using them on a regular basis (Ref. 4).

Even these relatively low percentages, however, represent a large number of retail establishments in absolute terms. Moreover, these surveys do not include the large number of retail food establishments that do not belong to the organizations conducting these surveys. Thus, the problem of sulfite-sensitive individuals unknowingly eating sulfite-treated foods still exists. This is evidenced by the fact that more than 40 percent of the consumer complaints that FDA has received have come to the

agency since the Produce Marketing Association survey was completed. Moreover, such reports have continued even in recent months.

D. Summary

In summary, FDA's concerns stem from the following facts:

1. Sulfite-sensitive asthmatics in the United States may number as many as 1 million persons.

2. Current lifestyle trends and food-processing practices point to significant exposure of individuals to sulfiting agents used on fresh fruits and fresh vegetables.

3. The potential for carelessness or misuse exists when sulfiting agents are applied to food by food-service establishment personnel.

4. Although industry data indicate a decline in the use of sulfiting agents by restaurants and produce marketers, a significant number may still be using them and FDA is still receiving reports from individuals of allergic-type responses allegedly associated with eating sulfite-treated foods.

5. Although FDA has proposed that all packaged foods that contain sulfites be so labeled, labeling in restaurants and grocery stores is not a practical alternative because labeling in those environments is not customarily used and because of the difficulty of enforcing such labeling at either the Federal or State level.

For these reasons, FDA believes that it is necessary to take action as soon as possible concerning the GRAS status of the use of sulfiting agents on fresh fruits and fresh vegetables.

III. Safety Evaluation

Consumer Complaints

Since 1982, FDA has received complaints from approximately 500 individual consumers who reported adverse responses, including 13 deaths, after eating food that the individuals either knew contained or suspected of containing sulfiting agents. Among the 500 reports of adverse responses, the largest segment (approximately 40 percent) specifically mention the occurrence of adverse responses after eating raw fruits or raw vegetables in restaurants, while 4 percent specifically mention fresh produce purchased in a grocery store. Thus, nearly half of all complaints received specifically mention fresh fruits or vegetables. By comparison, approximately 15 percent of the 500 complaints specifically mention the occurrence of adverse responses after drinking wine or beer, and 14 percent specifically mention processed, packaged food eaten at home. The remaining complaints were less specific about the type of food and the place of purchase or consumption.

The spectrum of reported responses to raw fruits and vegetables that had been treated with sulfites is broad, ranging from mild discomfort to very severe and even life-threatening. Although some reports fall into more than one clinical category, approximately 40 percent of the complaints mentioning fresh fruits or vegetables mention gastrointestinal effects, including nausea and diarrhea; about 50 percent mention various forms of respiratory distress; 10 percent mention anaphylaxis, coma, or shock; and 15 percent mention that hospitalization was required or emergency room care was sought. The remaining comments either did not mention specific symptoms or mentioned symptoms other than those described above. In approximately 30 percent of these complaints, the consumers described the responses as allergic responses.

IV. The Panels Report

As noted above, early in 1984 FDA requested that FASEB reexamine the GRAS status of sulfiting agents. In response, FASEB established the Panel, which considered all relevant available information on the use of sulfiting agents. This information included recent scientific publications; information submitted to FDA in response to its 1982 proposal; data on the levels of sulfiting agents currently used in the processing of foods and on the levels of sulfiting agents found in various foods as consumed; new toxicological information on sulfiting agents; and data regarding the ability of sulfiting agents to cause allergic-type responses in sensitive individuals. The Panel also had access to the consumer complaints (numbering approximately 300) that FDA had received by that time. In addition, the Panel conducted an open meeting on November 29, 1984, at which individuals and representatives of organizations presented data, information, and views on a range of sulfite-related issues. The Panel made its final report available to FDA on January 31, 1985.

A. Exposure

The Panel estimated that the mean dietary intake of sulfiting agents, as measured in sulfur dioxide equivalents, is about 10 milligrams per capita per day (0.17) milligram per kilogram body weight per day). It also estimated that the 99th percentile intake probably does not exceed 180 milligrams sulfur dioxide equivalents per capita per day (3 milligrams per kilogram body weight per day). The latter figure represents regular consumption of foods containing high levels of sulfites, such as wine, shrimp, "instant" potatoes, dried apricots, and "tossed salad" (Ref. 4).

B. Sulfite-Sensitivity Reactions

The Panel reviewed the evidence for the occurrence of adverse responses in certain individuals after ingesting foods containing sulfiting agents. This evidence included numerous published findings from clinical experiments involving the exposure of both asthmatic and nonasthmatic individuals to sulfiting agents. The Panel also reviewed hundreds of reports, submitted by consumers, physicians, and FDA field investigators, of adverse responses occurring after consumption of foods known to contain or suspected of containing sulfiting agents. A summary of the Panel's findings follows.

1. *Types of Responses.* The most frequently reported response following exposure to sulfites or sulfur dioxide has been bronchial hyperreactivity (bronchoconstriction and bronchospasm), although other responses such as shock, gastrointestinal disturbances, and urticaria/angioedema as well as flushing, hypotension, and tingling sensations have also been reported (Ref. 7).

2. *Clinical Studies.* Clinical investigators have attempted to document adverse responses to sulfites. Many of the studies were conducted on individuals or groups of individuals who previously reported an adverse response to a sulfite-containing food. To quantify adequately the presence and severity of adverse sulfite sensitivity responses, clinical investigators exposed individuals to measured quantities of sulfiting agents in which the amount of sulfiting agents was expressed as sulfur dioxide equivalents. The investigators then reported the extent of any adverse response in terms of a drop in what is often called the patients' "forced expiratory volume at 1 second" (FEV_1).

For example, in 1973, Kochen reported that a mildly asthmatic child experienced acute, transient asthmatic reactions following ingestion of freshly opened sulfite-containing foods (Ref. 8). Reports about this type of reaction were relatively rare until recently. However, challenge testing was not carried out to determine if sulfites were the causative agents in this case. Subsequently, Prenner and Stevens, in 1976, presented a case report of anaphylaxis occurring in a 50-year old nonasthmatic male who consumed a restaurant meal that included a green salad sprayed with a

product containing bisulfite (Ref. 9). Oral challenge with sodium bisulfite (10 milligrams total dose) resulted in erythema, itching, nausea, warmness, coughing, and bronchoconstriction for about 1 hour. Lung function measurements were not made nor was a placebo administered as a part of the challenge.

In 1977, Freedman interviewed 272 asthmatic patients and reported that 30 experienced exacerbations of asthma following ingestion of orange drinks made with sodium bisulfite (Ref. 10). Fourteen of the 30 patients allowed challenge tests with a single dose of sodium metabisulfite solution containing 25 milligrams sulfur dioxide equivalents in a weakly acidic solution (sulfur dioxide concentration 100 ppm). Within 2 to 25 minutes, 8 of the 14 patients challenged gave a positive response, defined as a drop of at least 12 percent in FEV_1.

In one case, Baker et al. reported bronchospasm in an asthmatic patient following ingestion of canned crabmeat salad with a vinegar dressing (Ref. 11). Oral challenge of this patient with sodium metabisulfite resulted in severe bronchospasm within 30 minutes. No reaction was observed after ingestion of the canned crabmeat alone when given as a clinical challenge. In a second patient whose asthma was provoked by wine, a single-blind oral challenge with a capsule containing 500 milligrams sodium metabisulfite caused a drop in peak flow rate from about 440 liters per minute before challenge to 100 liters per minute 30 minutes after challenge. Challenge with a placebo capsule did not produce a significant pulmonary change in the second patient.

In 1983, Schwartz reported the clinical presence of vague, general symptoms following oral challenge with metabisulfite in two patients who developed dizziness, weakness, nausea, chest tightness, tachycardia, and dyspnea associated with restaurant meals (Ref. 12). Pulmonary function studies during an oral metabisulfite challenge showed no changes.

Stevenson and Simon reported in 1981 on clinical investigations on four patients with histories of severe bronchoconstriction and anaphylaxis associated with consumption of restaurant meals (Ref. 13). Single-blind oral challenges were administered to these patients in the fasting state and while they were taking their usual medications. Placebo capsules were administered orally every 30 minutes on the first morning of testing, and capsules containing 1, 5, 10, 25, or 50 milligrams of potassium bisulfite were given sequentially ever 30 minutes on the second day. FEV_1 values were measured at 30-minute intervals on both days. All four patients reacted to bisulfite challenges, developing asthmatic symptoms 10 to 15 minutes after ingestion of a provocative dose (10, 25, or 50 milligrams). FEV_1 decreased 34 to 49 percent at 30 to 90 minutes after are provocation. Systemic symptoms including flushing, tingling, and faintness occurred in all subjects. Subsequent oral challenge of six sulfite-sensitive asthmatic patients with sulfite solutions produced responses equal to the responses observed after oral capsule challenge but at levels approximately one-half of the provocative capsule dose (Ref. 14). Fifteen additional asthmatic patients with a history of incrased asthmatic responses associated with consumption of food and beverages were serially challenged with capsules containing 5, 10, 25, and 50 milligrams sodium metabisulfite (Ref. 15). Only one of these patients had a significant response to the challenge. In that case, administration of 5 milligrams sodium metabisulfite produced a fall of 28 percent in FEV_1 in 2 minutes.

Capsules containing 1.4, 14, 144, or 288 milligrams potassium metabisulfite were sequentially administered to 134 patients selected from a clinic population of 1,073 patients having asthma and related allergic symptoms (Ref. 16). Decreases in FEV_1 values of at least 15 percent were reported in 50 of the 134 patients challenged. Based upon these challenges, Buckley et al. (1985) estimated that 4.6 percent of asthmatic patients respond to sulfite challenge (Ref. 16).

In another clinical study, lettuce treated with sodium bisulfite was employed as an oral challenge to evaluate pulmonary function of five stable, previously documented sulfite-sensitive asthmatic patients after consumption of food containing sulfiting agents (Refs. 17 and 18). Three-ounce portions of lettuce were dipped according to package instructions in a commercial vegetable freshener containing sodium bisulfite or in a similar commercial product that did not contain a sulfite salt. Approximately 10 milliliters of solution (80 to 90 milligrams bisulfite) adhered to the lettuce after draining. All five patients showed a significant decreased in FEV_1 (mean decrease 44 percent, range 31 to 64 percent) after consuming the sulfite-treated lettuce. None reacted to the control lettuce. Four of the patients were described as having moderate asthmatic responses, while the fifth had a life-threatening response requiring extensive emergency treatment (Ref. 18).

Not all clinical investigations reviewed by the Panel provided equally convincing and strong evidence for an association between exposure to sulfites and adverse responses. In one study performed by Sonin and Patterson in 1985, 12 patients with idiopathic anaphylaxis, 9 of whom had a history of reactions associated with restaurant meals, and 10 control subjects were challenged with increasing oral doses of sodium metabisulfite dissolved in lemonade (Ref. 19). A similar extent of mild nonspecific irritant and subjective symptoms were reported in both groups of patients. No anaphylactic responses occurred in the 12 patients with idiopathic anaphylaxis. No bronchospasm occurred, although pulmonary functions was abnormal in three of these patients.

Similarly, in a presentation made at the open meeting of the ad hoc Review Panel, Taylor reported that oral capsule challenge of 100 non-steriod-dependent asthmatic patients with potassium metabisulfite resulted in no cases of sulfite sensitivity that could be confirmed by double-blind challenge (Ref. 20). However, single-blind challenges of 69 steroid-dependent asthmatic patients resulted in a decrease in FEV_1 of at least 20 percent in 14 cases. Double-blind challenges of five of these steroid-dependent patients resulted in significant decreases in FEV_1 in only two cases.

In another study, FEV_1 values did not decline and no manifestations of sulfite sensitivity were reported following administration of bisulfite to five steriod-dependent asthmatic patients without histories of responses associated with restaurant meals (Ref. 13).

Experience with oral challenge testing of sulfites has led to differing opinions concerning the extent of sensitivity resposes to sulfiting agents. Based upon their clinical work with capsule and solution challenges of a group of asthmatic patients, Simon et al. (Ref. 21) and Simon (Ref. 18) estimate that 5 to 10 percent of the 10,000,000 asthmatic patients in the United States may be sensitive to orally ingested sulfiting agents. Buckley et al. suggest a prevalence of 4.6 percent for sulfite sensitivity based on capsule challenges of selected members of a clinic population having asthma and related unusual allergic symptoms (Ref. 16). A lower prevalence of sulfite sensitivity (1 to 2 percent of the overall asthmatic population) is estimated by Taylor (Ref. 20) whose clinical results with capsule challenge suggest that sulfite sensitivity is limited to steroid-dependent

asthmatic patients. Patterson and colleagues have yet to identify sulfite sensitivity among idiopathic anaphylactic patients selected from an extensive asthmatic population and consider that sulfite sensitivity may be a minor problem (Ref. 22). Although a number of individuals have been clinically tested for sulfite sensitivity by oral challenge, there is no compilation of data available on the distribution of asthmatic and nonasthmatic patients sensitive to sulfiting agents according to age, sex, race, genetic traits, ethnicity, and other variables.

3. Individual Case Reports. The Panel reviewed copies of all the consumer complaints that had been sent to FDA, which, at the time the Panel did its work, numbered about 300. These included reports by individual consumers who were both asthmatic and nonasthmatic. The Panel also reviewed some, more thorough, case reports submitted by physicians. Some of the consumer and physician reports included additional information from followup investigations conducted by FDA field personnel. The Panel concluded that these reports indicate an association between adverse responses and the ingestion of meals that include foods containing sulfiting agents.

C. The Panel's Conclusions and Recommendations

The Panel concluded, in part, that the available information contains sufficient evidence to demonstrate a hazard of unpredictable severity to sulfite-sensitive individuals when they are exposed to sulfiting agents in some foods at levels that are now being used.

The Panel concluded that the reported associations are sufficiently numerous, and the responses sufficiently severe, to deserve serious attention. It found that, in some cases, sulfite-sensitive individuals have had life-threatening responses following exposure to sulfite-treated foods and recommended that practical means be found to protect these individuals from the potential hazards of sulfites.

The Panel specifically noted that fresh fruits and vegetables dispensed in food-service establishments or sold in grocery stores are among the foods that have been shown to elicit adverse responses.

The Panel concluded "that additional labeling requirements alone would not assure protection."

It further concludes:

> This is particularly likely when sulfite-treated fresh fruits and vegetables and pre-cut potatoes are dispensed in food service establishments or sold in grocery stores, and consumers, service and store personnel are not adequately aware that sulfite agents are present.
>
> Information provided to the Panel indicates that the use of sulfites on fresh produce in food service establishments is being discouraged by the National Restaurant Association and the Produce Marketing Association, and that use has decreased over the past two years. Such voluntary curtailment of sulfite use on such products is an important step in reducing opportunities for unsuspecting sulfite-sensitive individuals to be exposed, and discontinuance of these uses should be encouraged by appropriate use of the regulatory process.

IV. Discussion

A. This Proposal

In this proposal, FDA is announcing that based on the data and information that have become available to it since publication of its July 9, 1982, proposal on sulfiting agents; on the conclusions that the Panel reached in its 1985 reexamination of the GRAS status of sulfites; on its evaluation of the Panel report; and on other available data, it believes that there is no longer a basis to find that the use of sulfiting agents as a preservative on fruits or vegetables intended to be served or sold raw to consumers is GRAS.

Under 21 U.S.C. 321(s), for the use of a substance to be GRAS, there must be a consensus among qualified experts that that use has been shown to be safe. Given the recent evidence of severe acute responses reported in some individuals who have eaten sulfited fruits and vegetables and the other information discussed in this document, FDA believes that a consensus that this use of sulfites is safe does not currently exist. As a result, the agency is proposing to amend Part 182 to exclude this use from those that are GRAS under the regulations on the sulfiting agents.

FDA is basing this action on a number of factors:

1. There are people within the U.S. population, whose number may be as high as 1 million, according to some estimates, who are sulfite sensitive and suffer allergic-type responses of unpredictable severity upon ingesting foods treated with sulfiting agents.

2. The use of sulfiting agents by restaurants and other food-service establishments on fruits and vegetables presented to the consumer for sale as fresh (e.g., salad bars) is cited in the largest fraction (nearly half) of the consumer complaints of adverse responses received by FDA.

3. Although sensitive individuals can possibly avoid sulfite-treated foods that are packaged and labeled, the use of signs has not proven to be effective in protecting sensitive persons in such situations as restaurant salad bars, when sulfiting agents are used on fruits and vegetables intended to be served or sold raw to consumers or presented to consumers as fresh. Adverse responses alleged to be associated with these uses have continued despite some States' efforts to require signs. Moreover, the Panel has stated that it believes that the use of signs will not be an effective means of protecting sensitive individuals. Furthermore, FDA believes, as stated earlier, that labeling in restaurants and grocery stores is not a practical alternative because labeling in those environments is not customarily used and because of the difficulty of enforcing such labeling at either the Federal or State level.

4. In addition, the levels of sulfiting agents on raw fruits and vegetables are likely to vary widely and will depend upon the care exercised by food-service personnel in following use instructions for their application. Thus, a significant potential exists for abuse or misuse of these chemical preservatives.

5. Because many restaurants now operate salad bars without using sulfites, it appears that substituting alternative preservatives or implementing revised operating procedures (e.g., refilling salad bar items more frequently) is a feasible course of action.

FDA believes that there is a pressing need for it to act with regard to the use of sulfites on raw fruits and vegetables. The response of certain individuals to sulfite-treated foods is often unpredictable, and the allergic-type responses can be extremely severe, even fatal. Consequently, the agency must act quickly to diminish the likelihood of additional severe adverse responses in unsuspecting consumers.

Therefore, the agency is allowing only 30 days for interested persons to comment on this proposal. Although 21 CFR 170.38(b)(2) states that 60 days will normally be given for comment on a proposal to find that the use of a substance is not GRAS, the procedures in § 170.38 are subject to Part 10 (21 CFR Part 10). (See 21 CFR 170.38(b)(1).) Under § 10.40(b)(2), the agency may shorten a comment period for good cause. As stated above, the agency believes that its concerns about the protection of the public health provide good cause for shortening the comment period in this instance.

FDA's concerns about the potential hazards from the use of sulfiting agents on fruits or vegetables intended to be served or sold raw extends to those fruits and vegetables that may not actually be fresh but that are presented to the consumer as fresh (e.g., thawed

frozen fruits and vegetables). Therefore, the proposed amendments to Part 182 reflect this concern.

B. Exclusions

The use of sulfiting agents on grapes is not included in this proposal. Sulfiting agents are used on grapes as a fungicide rather than as a preservative. Therefore, this use is subject to regulation by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act and not to regulation by FDA. (7 U.S.C. et seq.)

V. Other Relevant Information

A. General Comments

FDA received numerous comments on its July 9, 1982, proposal to affirm the GRAS status of certain sulfiting agents.

Three comments from the food industry related to the use of sulfiting agents on fresh fruits and fresh vegetables. One comment was from a trading association, and two were from restaurant chains. These comments simply informed FDA that they were in fact using sulfiting agents on fresh fruits and vegetables.

One comment from a private testing laboratory stated that it had tested foods for sulfite content and reported on the levels that it had measured.

B. Citizen's Petition

On October 28, 1982, the agency received a citizen petition signed by three consumers, a physician, a scientist, and representatives of the Center for Science in the Public Interest (CSPI), Washington, DC. The petitioners requested that FDA amend certain food standards and rescind certain food additive regulations, prior sanctions, and advisory opinions that permit the use of sulfiting agents at a level of more than 350 micrograms per serving. The petitioners also requested that FDA require warning labels on any food products in which sulfiting agents must be used in amounts greater than 350 micrograms per serving to perform essential public health functions.

In a supplement to this petition, which was submitted on March 15, 1983, the petitioners requested that FDA ban the use of sulfiting agents in restaurant salad bars, withdraw the prior sanction permitting the use of sodium bisulfite on potatoes, and institute appropriate enforcement action against sulfite-containing products that are labeled for use on vegetable salads because vegetable salads are a significant source of thiamine (vitamin B_1).

FDA has considered the requests made in the CSPI petition and the supplement. Because this proposed rulemaking is intended to address only the use of sulfiting agents in fruits and vegetables intended to be served raw or sold raw to consumers, the agency will respond here only to the requests that are relevant to these uses. FDA will respond to the other issues raised in the citizen petition in future **Federal Register** documents.

The petitioners submitted data to support their claim that vegetable salads are a significant source of thiamine, and that products that instruct users to apply sulfiting agents to these foods are misbranded. The petitioners suggested that FDA issue an appropriate regulatory letter to all manufacturers of such products.

FDA acknowledges that it has never authorized the use of sulfites on foods that are recognized as a significant source of thiamine. Foods that can serve as significant sources of vitamins, including thiamine, are defined in 21 CFR 101.9(c)(7)(v) as those that supply at least 10 percent of the minimum daily requirement for vitamins, which in the case of thiamine is 0.15 milligram. FDA has calculated the amount of thiamine present in a traditional serving of salad (1 cup lettuce, ½ tomato) as being less than 0.15 milligram (Ref. 6). FDA concludes, therefore, that an average serving (according to the results of the U.S. Department of Agriculture 1977–1978 Nationwide Food Consumption Survey) of a green salad does not serve as a significant source of thiamine. For this reason, FDA also concludes that it cannot grant the petitioners' request for enforcement action against products containing sulfiting agents that are labeled for use on vegetable salads.

Nonetheless, FDA has tentatively concluded that it is necessary for the agency to take action against the use of sulfiting agents on fruits and vegetables intended to be served or sold raw to consumers. It is proposing that action in this document. Moreover, should this regulation become final, products containing sulfites and labeled for use on fresh vegetable salads would be adulterated under section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)). They would be adulterated under that section because a sulfite intended to be used to preserve the freshness of raw fruits and vegetables would be an unapproved food additive and therefore unsafe under section 409(a) (21 U.S.C. 348(a)).

VI. Conclusions

This proposed rulemaking announces that currently available information has created significant questions about whether the use of sulfiting agents in fruits and vegetables intended to be served raw or sold raw to consumers is safe. As a result, FDA believes that this use of sulfites can no longer be considered to be GRAS. The agency is proposing in this document to amend Part 182 to exclude the use of sulfiting agents on fruits and vegetables intended to be served or sold raw to consumers as fresh from the uses of sulfiting agents that are GRAS. Such use of sulfiting agents would constitute the use of unapproved food additives and would, therefore, cause any food to which they have been added to be adulterated and in violation of section 402(a)(2)(C) of the Act. The comment period for this proposal is 30 days.

The agency requests comments from all interested persons on all relevant issues relating to this proposal. The agency especially seeks comments relating to the following:

1. Additional evidence concerning whether there is an association between exposure to sulfites on fresh fruits and vegetables and adverse responses in sulfite-sensitive individuals;

2. Data on the extent to which restaurants, other food-service establishments, grocery stores, and other produce handlers currently use sulfiting agents on fruits or vegetables; and

3. Practical alternatives to the use of sulfites on fresh fruits and vegetables.

VII. Economic Impact

FDA has determined that the primary cost of this proposed rule results from the substitution of other additives or procedures for sulfiting agents. In accordance with section 605(b) of the Regulatory Flexibility Act (Pub. L. 96–354), the agency has determined that no significant economic impact on a substantial number of small entities, including small businesses, will derive from this action. Further, in accordance with Executive Order 12291, FDA has analyzed the economic effects of this proposal and has determined that it is not a major rule as defined by that Order.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

VIII. Environmental Impact

The agency has considered the potential environmental effects of this action and 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 environmental assessment and finding of no significant impact may be seen in the Dockets Management Branch, between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Select Committee on GRAS substances, "Insights on Food Safety Evaluation," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223-81-2394, December 1982, and references cited therein.

2. Select Committee on GRAS Substances, "Evaluation of Health Aspects of Sulfiting Agents as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223-75-2004, 1976.

3. "Sulfiting Agents; Proposed Affirmation of GRAS Status with Specific Limitations; Removal from GRAS Status as Direct Human Food Ingredient," 47 FR 29956; July 9, 1982.

4. Select Committee on GRAS Substances, "The Reexamination of the GRAS Status of Sulfiting Agents," Life Sciences Research Office, Federation of American Societies for Experimental Biology, prepared under FDA contract 223-83-2020, January 28, 1985.

5. Retail Food Protection Program Information Manual, Part 6, Chapter 01, Number 2-101, Revised September 29, 1983.

6. Memorandum from John E. Vanderveen, Director, Division of Nutrition, to John Taylor, Director, Division of Regulatory Guidance, "Thiamine Content of Foods in Reference to Sulfiting Agents," April 10, 1985.

7. National Institute of Allergy and Infectious Diseases, American Academy of Allergy and Immunology, Committee on Adverse Reactions to Foods, "Adverse Reactions to Foods," NIH publication No. 84-2442, 1984, 220p. (available from U.S. Government Printing Office, Washington, DC).

8. Kochen, J., Sulfur Dioxide, a Respiratory Tract Irritant, Even if Ingested," *Pediatrics*, 52:145-146, 1973.

9. Prenner, B. M., and J. J. Stevens, "Anaphylaxis after Ingestion of Sodium Bisulfite," *Annals of Allergy*, 37:180-182, 1976.

10. Freedman, B. J., "Asthma Induced by Sulphur Dioxide, Benzoate and Tartrazine Contained in Orange Drinks," *Clinical Allergy*, 7:407-415, 1977.

11. Baker, G. J., P. Collett, and D. H. Allen, "Bronchospasm Induced by Metabisulfite-Containing Foods and Drugs," *Medical Journal of Australia*, 2:614-616, 1981.

12. Schwartz, H. J., "Sensitivity to Ingested Metabisulfite: Variations in Clinical Presentation," *Journal of Allergy and Clinical Immunology*, 71:487-489, 1983.

13. Stevenson, D. D., and R. A. Simon, "Sensitivity to Ingested Metabisulfites in Asthmatic Subjects," *Journal of Allergy and Clinical Immunology*, 68:26-32, 1981.

14. Goldfarb, G., and R. Simon, "Provocation of Sulfite Sensitive Asthma," *Journal of Allergy and Clinical Immunology*, 73:135, 1984 (Abstract).

15. Koepke, J. W., and J. C. Selner, "Sulfur Dioxide Sensitivity," *Annals of Allergy*, 48:258; 1982 (Abstract).

16. Buckley, C. E., III, H. A. Saltzman, and H. O. Sieker, "The Prevalence and Degree of Sensitivity to Ingested Sulfites," *Journal of Allergy and Clinical Immunology, 1985 (Abstract)*, In press.

17. Howland, W. C., and R. A. Simon, "Restaurant-Provoked Asthma: Sulfite Sensitivity," *Journal of Allergy and Clinical Immunology, 1985* (Abstract), In press.

18. Simon, R. A., Oral presentation given at the open meeting of the Ad Hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents held November 29, 1984, Bethesda, MD.

19. Sonin, L., and R. Patterson, "Metabisulfite Challenge in Patients with Idiopathic Anaphylaxis," *Journal of Allergy and Clinical Immunology*, 75:67-69, 1985.

20. Taylor, S. L., Oral presentation given at the open meeting of the Ad Hoc Review Panel on the Reexamination of the GRAS Status of Sulfiting Agents held November 29, 1984, Bethesda, MD.

21. Simon, R. A., L. Green, and D. D. Stevenson, "The Incidence of Ingested Metabisulfite Sensitivity in an Asthmatic Population," *Journal of Allergy and Clinical Immunology*, 69:118, 1982 (Abstract).

22. Patterson, R., Northwestern University, Evanston, IL., Letter plus attachments, dated July 9, 1984, to S. A. Anderson, Federation of American Societies for Experimental Biology, Bethesda, MD.

X. Miscellaneous Information

FDA is unaware of any prior sanction for the use of these ingredients in foods that covers the conditions identified in this document. Any person who intends to assert or to rely on such a sanction shall submit proof of its existence in response to this proposal. The amendments proposed above will constitute determinations that excluded prior-sanctioned uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on the sanction later.

The agency believes, however, that even if a prior sanction does exist for the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw, reliance on that sanction would likely not be a sufficient justification to continue this use of sulfiting agents. FDA believes that recent information demonstrates that this use of sulfiting agents may be injurious to a significant number of people. Furthermore, present day food-processing practices and dietary trends could not have been anticipated before 1958, when a prior sanction would have been issued. Therefore, FDA tentatively concludes that the use of sulfiting agents on fruits and vegetables intended to be served raw to consumers or sold raw to consumers would cause the food to be adulterated within the meaning of section 402 of the act (21 U.S.C. 342).

Interested persons may, on or before September 13, 1985, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 182 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for Part 182 continues to read as follows:

Authority: Secs. 201(s), 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 201(s), 348, 371).

2. In § 182.3616 by revising paragraph (c), to read as follows:

§ 182.3616 Potassium bisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

3. In § 182.3637 be revising paragraph (c), to read as follows:

§ 182.3637 Potassium metabisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to

consumers or to be presented to consumers as fresh.

4. In § 182.3739 by revising paragraph (c), to read as follows:

§ 182.3739 Sodium bisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

5. In § 182.3766 be revising paragraph (c), to read as follows:

§ 182.3766 Sodium metabisulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

6. In § 182.3798 by revising paragraph (c), to read as follows:

§ 182.3798 Sodium sulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

7. In § 182.3862 by revising paragraph (c), to read as follows:

§ 182.3862 Sulfur dioxide.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

Dated: July 24, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

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