List of Subjects

19 CFR Part 123

Administrative practice and procedure, Aliens, Canada, Customs duties and inspection, Fees, Forms, Immigration, Imports, Mexico, Reporting and recordkeeping requirements, Test programs.

Amendments to the Regulations

For the reasons stated above, it is proposed to amend part 123 of the Customs Regulations (19 CFR part 123), as set forth below:

PART 123—CUSTOMS RELATIONS WITH CANADA AND MEXICO

1. The authority citation for part 123 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1431, 1433, 1624.

* * * * *

2. In § 123.1, it is proposed to amend the first sentence in paragraph (a) by adding the words ‘‘, unless excepted by voluntary enrollment in and compliance with PORTPASS—a joint Customs Service/Immigration and Naturalization Service facilitated entry program (See, Immigration and Naturalization Regulations at 8 CFR 235.13),’’ after the words ‘‘Individuals arriving in the United States’’; and, to amend paragraph (b) by removing the second and third sentences and adding, in their place, the sentence that reads as follows:

§ 123.1 Report of arrival from Canada or Mexico and permission to proceed.

* * * * *

(b) *Vehicles.* * * *. Upon arrival of the vehicle in the U.S., the driver shall, unless he or she and all of the vehicle’s occupants are excepted by enrollment in, and in compliance with, PORTPASS—a joint Customs Service/Immigration and Naturalization Service facilitated entry program (See, Immigration and Naturalization Regulations at 8 CFR 235.1 and 286.8), immediately report such arrival to Customs, and shall not depart or discharge any passenger or merchandise (including baggage) without authorization by the appropriate Customs officer.

* * * * *

Approved: July 29, 1996.

George J. Weise,

Commissioner of Customs.

Dennis M. O’Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–23361 Filed 9–11–96; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 70, 71, 80, 101, 107, 170, 172, 173, 174, 175, 177, 178, 184, and 1250

[Docket No. 96N–0149]

RIN 0910–AA69

Reinvention of Regulations Needing Revisions; Request for Comments on Certain Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period on the advance notice of proposed rulemaking to reinvent certain regulations; the advance notice appeared in the Federal Register of June 12, 1996 (61 FR 29701). The agency is taking this action in response to several requests for an extension of the comment period. This extension is intended to allow interested persons additional time to submit comments to FDA on the proposed reinvention of certain regulations.

DATES: Written comments by October 10, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corinne L. Howley, Center for Food Safety and Applied Nutrition (HFS–24), 200 C St., SW, Washington, DC 20204, 202–205–4272.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 12, 1996 (61 FR 29701), FDA issued an advance notice of proposed rulemaking to reinvent certain regulations that appear to need revision. These regulations were identified by FDA as candidates for revocation following a page-by-page review of its regulations that the agency conducted in response to the Administration’s ‘‘Reinventing Government’’ initiative. Interested person were given until September 10, 1996, to comment on the advance notice.

FDA received several requests for an extension of the comment period on its advance notice of proposed rulemaking to reinvent certain regulations. After careful consideration, FDA has decided to extend the comment period to October 10, 1996, to allow additional time for the submission of comments on whether the regulations discussed in the advance notice should be revised.

Interested persons may, on or before October 10, 1996, submit to 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.

Dated: September 9, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–23481 Filed 9–10–96; 11:02 am]

BILLING CODE 4160–01–F

21 CFR Part 101

[Docket No. 96N–0244]

Food Labeling; Declaration of Free Glutamate in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is considering establishing requirements for label information about the free glutamate content of foods. The recent finding of the Federation of American Societies for Experimental Biology (FASEB) that oral ingestion of 3 or more grams (g) of monosodium glutamate (MSG) without food can cause adverse reactions in certain otherwise healthy individuals has prompted the agency to consider what action is necessary to protect consumers from inadvertently ingesting levels of MSG or other forms of free glutamate that could cause an adverse reaction. Thus, the agency seeks public comment on whether additional labeling requirements are necessary to protect glutamate-intolerant consumers from adverse reactions, and, if so, how such labeling requirements should be implemented. The agency also solicits comment on establishing formal criteria for the use of claims about the absence of MSG to ensure that labels bearing such claims are not misleading. The agency solicits comment on whether such criteria should be based on a defined threshold level of free glutamate in a finished food, on the ingredients used in the food, or both.

DATES: Written comments by November 12, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Felicia B. Satchell, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Glutamic acid, one of the amino acids found in nature, is a building block of virtually all proteins and is a normal component of the human body. In the human body and in most foods, glutamic acid exists primarily in its salt form, glutamate. Glutamate is a naturally occurring component of many foods, including tomatoes, cheese, meat, mushrooms, and milk. ''Free'' glutamate is glutamate that is not incorporated into a protein; ''bound'' glutamate is glutamate that is a component of an intact protein. Meat and milk contain primarily bound glutamate, while tomatoes, mushrooms, and certain cheeses contain, in addition to bound glutamate, relatively high levels of free glutamate.

It is the free form of glutamate that has been shown to have flavor-enhancing properties in food. As noted previously, some foods contain relatively high levels of naturally occurring free glutamate. Free glutamate may be introduced into foods as a component of various food ingredients, such as tomato sauce and hydrolyzed protein products, or it may be added in one of its various salt forms, such as MSG.

MSG is the most commonly used form of free glutamate added to food for flavor-enhancing purposes. It is a white, practically odorless, free-flowing crystalline powder (Ref. 1), similar in appearance to salt or sugar. MSG has been used for many years as a flavor enhancer for a variety of foods prepared in homes and restaurants and by food processors. MSG is manufactured commercially by a fermentation process using starch, beet sugar, cane sugar, or molasses. The American food processing industry has used MSG widely since the late 1940's (Ref. 2), and consumption in the United States is estimated to be 28,000 tons per year. As a food ingredient, MSG is used to enhance the flavor of meat, poultry, vegetables, and many processed foods. MSG is described in 21 CFR 182.1 as an example of a common food ingredient that is generally recognized as safe (GRAS) under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)). When used as an ingredient in a food, MSG must be declared in the ingredient statement by its common or usual name, in accordance with section 403(i) of the act (21 U.S.C. 343(i)) and 21 CFR part 101. Thus, ''monosodium glutamate'' must appear in the ingredient list of any food to which MSG has been added (21 CFR 101.22(h)(5)). This is true even when MSG has been added indirectly as part of another ingredient to which MSG has been added (e.g., a spice blend that includes MSG).

While MSG is the most well-known and widely used form of free glutamate used to enhance the flavor of foods, other salts of free glutamate, such as monopotassium glutamate and monoammonium glutamate also have flavor-enhancing properties. GRAS uses of glutamic acid, glutamic acid hydrochloride, monoammonium glutamate, and monopotassium glutamate are codified in 21 CFR 182.1045, 182.1047, 182.1500, and 182.1516, respectively. Like MSG, these substances must be declared in the ingredient statement of any food to which they are added.

Free glutamate occurs naturally in various foods and in food substances that are used as ingredients in finished foods, or it can be produced by hydrolysis of proteins; in such cases, the presence of free glutamate in the food is not required to be declared on the label under existing regulations. Naturally occurring free glutamate is not required to be declared in the ingredient statement because it is not an added ingredient; rather, it is a natural constituent of the food, like protein or a vitamin. Similarly, when a food that contains naturally occurring free glutamate is used as an ingredient in another food, the free glutamate is not required to be declared in the ingredient statement of the finished food. Rather, the ingredient containing the free glutamate is declared in the ingredient statement by its common or usual name. The principle that it is the ingredients and not the constituents of a food that must be declared also applies when a food that contains free glutamate produced by protein hydrolysis is used as an ingredient in another food. In that situation too, the glutamate-containing ingredient must be declared in the ingredient statement of the finished food, but free glutamate need not be declared as an ingredient. Because the average consumer is not aware that ingredients like hydrolyzed soy protein, autolyzed yeast extract, tomato paste, and parmesan cheese contain free glutamate or that free glutamate is essentially equivalent to MSG, declaration of these ingredients by their common or usual names does not indicate to the consumer that an MSG-like substance is present in the food.

A number of consumers, particularly consumers who report adverse reactions to MSG, have stated to FDA (Ref. 3) their belief that manufacturers use ingredients such as hydrolyzed proteins and autolyzed yeast extracts for the express purpose of adding free glutamate to a food while hiding its presence. These consumers report the same types of adverse reactions to foods containing hydrolyzed proteins, autolyzed yeast extracts, and forms of ''manufactured'' glutamate (other than MSG) that they experience when they inadvertently consume foods that have MSG declared in the ingredient list. Consequently, FDA has received numerous requests that labels of all foods containing these ingredients be required to declare the presence of free glutamate in the finished food, on the ground that free glutamate presents a health concern to consumers. Some consumers have also requested that FDA require that the amount of free glutamate be declared on the label. Until recently, the agency's response has been that the scientific literature does not provide a public health basis on which to impose special labeling requirements for such ingredients or for foods that contain free glutamate. However, in light of the recent findings of the Life Sciences Research Office (LSRO) of FASEB, the agency is reconsidering the need for labeling to inform individuals who experience adverse reactions to glutamate about its presence in a food. (The agency notes that in the Federal Register of January 6, 1993 (58 FR 2950), it proposed to require the term ''(contains glutamate)'' as part of the common or usual name for autolyzed yeast extracts and highly hydrolyzed proteins. That proposal was not based on any health concern regarding the use of these ingredients in food; therefore, the comments to that proposal and the agency's decision with respect to those comments will not be addressed in this document.)

B. Previous Safety Reviews

Until the recent findings of the FASEB report (discussed in section I.C. of this document) that a subgroup of otherwise healthy individuals experiences a complex of symptoms following ingestion of 3 or more (g) of MSG without food, FDA relied on

previous safety review studies in deciding that special labeling for free-glutamate-containing (hereinafter referred to as ''glutamate-containing'') foods was not warranted. These studies indicated that while anecdotal reports of adverse reactions to MSG and other glutamate-containing ingredients existed, there were no verifiable scientific data establishing that the levels of these ingredients used in the food supply could cause adverse reactions in the general population. Historically, the agency has not issued labeling requirements on the basis of anecdotal reports alone because such reports do not by themselves establish a cause-and-effect relationship between the suspected substance and the occurrence of an adverse reaction.

MSG and other glutamate-containing ingredients have been the subject of numerous safety reviews during the past decade. In 1969, largely as a result of a recommendation by the White House Conference on Food, Nutrition and Health, FDA proceeded to reevaluate the safety of all GRAS substances for food use. The Select Committee on GRAS Substances (SCOGS), convened by FASEB in 1972 under a contract with FDA, independently reviewed the health aspects of MSG and of glutamate-containing protein hydrolysates in 1978 and 1980 (Refs. 4, 5, 6, and 7). Although protein hydrolysates are not listed as GRAS food ingredients by regulation, they are described as GRAS in a number of FDA opinion letters (Refs. 8, 9, 10, and 11). SCOGS concluded that MSG and hydrolyzed proteins were safe for the general population at then-current levels of use but recommended additional evaluation to determine their safety at significantly higher levels of consumption.

In 1986, FDA's Advisory Committee on Hypersensitivity to Food Constituents (Ref. 12) concluded that MSG posed no threat to the general public but that reactions of brief duration might occur in some people. Other reports gave similar findings. A 1991 report by the European Community's (EC) Scientific Committee for Foods (Ref. 13) reaffirmed the safety of MSG and other forms of free glutamate and classified the ''acceptable daily intake'' for MSG as ''not specified,'' the most favorable designation for a food ingredient. In addition, the EC committee said, ''infants, including prematures, have been shown to metabolize glutamate as efficiently as adults and, therefore, do not display any special susceptibility to elevated oral intakes of glutamate.''

A 1992 report from the Council on Scientific Affairs of the American Medical Association (Ref. 14) stated that glutamate in any form has not been shown to be a ''significant health hazard.'' Also, the 1987 Joint Expert Committee on Food Additives of the United Nations Food and Agriculture Organization and the World Health Organization (Ref. 15) placed MSG and other glutamate salts in the safest category of food ingredients.

Although the general consensus of the many safety reviews that have been done on the use of MSG and other glutamate-containing ingredients in foods is that they are safe for the general population, the use of these ingredients has been very controversial. FDA has received many anecdotal reports of adverse reactions following ingestion of glutamate-containing foods. Between 1980 and 1995, the Adverse Reaction Monitoring System in FDA's Center for Food Safety and Applied Nutrition received 661 reports of complaints about adverse reactions to MSG (Ref. 16). Headache was the most frequently reported symptom. However, other symptoms, such as a ''burning sensation'' on the back of the neck, forearms, and chest, facial pressure or tightness, neck and chest pain, palpitations, numbness, nausea, and vomiting, were also reported. These symptoms were transient, typically beginning within 25 minutes after consumption of MSG or of a glutamate-containing food and subsiding within about 2 hours. Initially many of these symptoms became known popularly as ''Chinese Restaurant Syndrome.'' As discussed in section I.C. of this document, FASEB refers to these symptoms collectively as the ''MSG symptom complex.''

C. The FASEB Report

Because of the agency's concern regarding the continued reports of adverse reactions to MSG and other glutamate-containing ingredients and because of the expanding base of scientific knowledge on the role of glutamate in brain function, FDA decided that an up-to-date review of the safety of MSG and other glutamate-containing ingredients was warranted. Thus, as part of its ongoing evaluation of GRAS ingredients and in response to the concerns raised by consumers, FDA contracted with FASEB in 1992 to do an up-to-date scientific safety review of the effects of the use of MSG and hydrolyzed protein products as food ingredients. The agency announced the study in the Federal Register of December 4, 1992 (57 FR 57467). As discussed in that document, the objectives of the review were to: (1) Determine whether MSG and hydrolyzed protein products, as used in the American food supply, contribute to the presentation of a complex of symptoms (initially described as the Chinese Restaurant Syndrome) after oral ingestion of levels up to or beyond 5 g per eating occasion (i.e., a meal or snack), and/or the elicitation of other reactions, including more serious adverse reactions that have been reported to occur following ingestion of 25 to 100 milligrams per eating occasion; (2) to determine whether MSG and hydrolyzed protein products, as used in the American food supply, have the potential to contribute to brain lesions in neonatal or adult nonhuman primates and whether there is any risk to humans ingesting dietary MSG; (3) to assess whether hormones are released from the pituitary of nonhuman primates following ingestion of MSG or hydrolyzed protein products and whether any comparable risk to humans ingesting food containing these substances exists; and (4) to define the metabolic basis that might underlie any adverse reactions to MSG and hydrolyzed protein products.

FASEB convened an ad hoc expert panel to perform a comprehensive review of the scientific literature and adverse report submissions to both FDA and LSRO. The expert panel also considered oral and written testimony received at a 2-day open meeting held in 1993. The expert panel used a weight of evidence approach in reaching its conclusions about the evidence of adverse effects of MSG. In other words, the expert panel analyzed the data by considering the totality of the scientific evidence in a given area rather than weighing one interpretation against another.

The expert panel reported its findings to FASEB, which reviewed the expert panel's work and prepared a report entitled ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG)'' (Ref. 17). The FASEB report was submitted to FDA on July 31, 1995. While FASEB found no scientifically verifiable evidence of adverse effects in most individuals exposed to high levels of MSG, it concluded that there is sufficient documentation to define an acute, temporary, and self-limiting ''MSG symptom complex'' in a subgroup of the population. The symptoms characteristic of the complex include: (1) A burning sensation of the back of the neck, forearms, and chest; (2) facial pressure or tightness; (3) chest pain; (4) headache; (5) nausea; (6) upper body tingling and weakness; (7) palpitation; (8) numbness in the back of neck, arms and back; (9) bronchospasm, i.e., constriction of the bronchial tubes

resulting in difficulty in breathing (observed in asthmatics only); and (10) drowsiness. These symptoms were judged to be related to the amount of MSG consumed and whether the MSG was consumed with or without food. FASEB identified this group of symptoms as the ''MSG symptom complex,'' stating that the previously used term, ''Chinese restaurant syndrome,'' was pejorative and did not reflect the extent or nature of the symptoms that have been associated with the myriad of exposure scenarios. FASEB concluded that ''Based on scientifically verifiable evidence, there is a subgroup of presumably healthy individuals within the general population that responds, generally within one hour of exposure, with manifestations of the MSG Symptom Complex to an oral bolus [dose] of MSG ≥ 3 g in the absence of food.''

FASEB also identified a subgroup of asthmatics reported to respond to oral doses of MSG with bronchospasm. The study conducted by Allen, Delohery, and Baker (Ref. 18) described severe bronchospasm in individuals with unstable asthmatic conditions in conjunction with symptoms of the MSG symptom complex following an oral dose of MSG. In addition, the study reported that some asthmatic subject experienced a 6 to 12 hour delayed bronchospasm without other MSG-related symptoms. While FASEB recognized and described limitations in the study design used by Allen, et al., it concluded that the study was a reasonably well-designed scientific oral dose study in asthmatic subjects, and that the study provided evidence to support the existence of a subgroup of asthmatic responders to MSG.

With regard to hydrolyzed proteins, FASEB identified no scientific reports of glutamate-related adverse effects of ingesting protein hydrolysates, whether microbial, vegetable, or animal in origin. Protein hydrolysates are used at very low levels, typically constituting only a small percentage (less than 1 percent) of a finished food.

Because of glutamate's role as a stimulatory neurotransmitter in the brain, the scientific community has speculated about the potential influence of dietary glutamate on brain glutamate metabolism and the potential role of dietary glutamate in provoking or exacerbating long-term illnesses. At FDA's request, FASEB reviewed the scientific literature on these issues. Although FASEB acknowledged the neurotoxic potential of glutamate produced in the body (as opposed to glutamate consumed in food), it found no studies or corroborating evidence linking adverse effects associated with consuming free glutamate in food to changes in brain function or to levels of glutamate in the bloodstream. Consequently, FASEB concluded that no evidence exists to support a role for dietary MSG or other forms of free glutamate consumed in food in causing or exacerbating serious, long-term medical problems resulting from degenerative nerve cell damage, such as Alzheimer's disease, Huntington's chorea, or amyotrophic lateral sclerosis, or to any other long-term or chronic illness. However, FASEB recommended that future efforts to explain reported adverse effects from ingested MSG be designed to test potential relationships between dietary glutamate and the physiological functions of the central nervous system.

FASEB also reviewed the chemical characteristics of various forms of free glutamate to determine if there was some structural or chemical difference in free glutamate occurring in the form of MSG or hydrolyzed protein products, as compared to free glutamate that naturally occurs in foods. FDA asked FASEB to include this issue in its review because of the contention by some consumers that manufactured forms of glutamate, such as MSG and hydrolyzed protein products, are in some way different from naturally occurring glutamates, and that the manufactured forms of glutamate are the only forms that trigger adverse reactions.

Free glutamate can exist in two possible stereoisomeric forms: D-glutamate and L-glutamate. L-glutamate is the predominant natural form and the only form with flavor-enhancing activity. FASEB concluded that MSG symptom complex reactions are related to L-glutamate exposure and that the chemical nature of L-glutamate is the same regardless of the source, i.e., whether manufactured or naturally occurring in the food. Thus, FASEB found no evidence to support the contention that adverse reactions occur with manufactured but not naturally occurring glutamate.

FASEB further concluded that with regard to determining glutamate levels and assessing risk from consumption of specific foods, a clear distinction must be made between free glutamate and glutamate as a component of protein (i.e., bound glutamate). Free glutamate is readily available for use in the body, whereas bound glutamate becomes available to body tissues more slowly, as the intestines chemically break down foodstuffs. FASEB also noted that the presence of food, as when MSG is consumed as part of a meal, attenuates the rise in blood glutamate levels and perhaps the effect, at least with regard to the potential for any direct central nervous system effect. However, FASEB was unable to identify any studies that have effectively compared blood glutamate levels between responders (i.e., persons who experience adverse reactions following exposure to MSG) and nonresponders, or any studies in which responders have been given a dose of MSG with a meal or 20 to 30 minutes before a meal.

FDA has reviewed the findings and conclusions contained in the FASEB report (Ref. 19). Based on FASEB's findings, FDA has tentatively concluded that requirements for label information about glutamate content may be warranted under certain conditions.

II. The Agency's Response

FASEB's conclusion that oral ingestion of 3 or more grams of MSG without food can cause adverse reactions in certain otherwise healthy individuals has prompted the agency to consider what action is necessary to protect these consumers from inadvertently ingesting levels of free glutamate that could trigger an adverse reaction. The agency believes that it may be appropriate to establish labeling requirements to alert free-glutamate-intolerant (hereinafter referred to as ''glutamate-intolerant'') consumers to the presence of free glutamate in a food.

The agency has carefully evaluated FASEB's findings and has reached several tentative conclusions regarding the basis on which any labeling policy to alert glutamate-intolerant consumers should be established.

A. Total Free Glutamate

Based on FASEB's findings that it is the free glutamate component of MSG that appears to be linked to the occurrence of the MSG symptom complex, that free glutamate is the same chemically in both its natural and manufactured forms, and that free glutamate has the same function regardless of source, i.e., free glutamate in MSG functions the same as free glutamate in hydrolyzed proteins or tomato products, the agency tentatively finds that any labeling policy it establishes should be based on the total amount of free glutamate in a serving of food, rather than on the number or kind of glutamate-containing ingredients in the food.

FDA has received correspondence suggesting that adverse reactions result only from exposure to manufactured free glutamate in food (Ref. 3). Based on FASEB's findings, the agency rejects this view. As previously discussed,

FASEB reported that all free glutamate found in food is the same regardless of the source. Further, in examining the scientific reports relating to physiological mechanisms of action, FASEB found no evidence indicating that manufactured free glutamate functions differently in the body than free glutamate naturally occurring in foods. The agency agrees with FASEB that all forms of free glutamate are chemically and functionally the same. Moreover, the agency notes that the available analytical methodology measures the total amount of free glutamate in a finished food and does not distinguish among free glutamate occurring in the form of MSG, as a constituent of ingredients such as hydrolyzed proteins, or as a natural constituent of food such as cheese, mushrooms, or meat. Accordingly, the agency tentatively finds that any labeling requirement for glutamate-containing foods should apply to foods that contain free glutamate from any source.

B. Food Matrix

Although FASEB noted that the presence of food may attenuate the rise of blood glutamate levels, the FASEB report cited no scientific evidence establishing a relationship between the occurrence of MSG symptom complex reactions and metabolic responses to ingestion of MSG, such as changes in blood glutamate levels. The agency requests data describing the effect of the food matrix (i.e., the food in which free glutamate is present or with which it is eaten) on the occurrence of the MSG symptom complex. If the food matrix does have an effect, does the effect vary depending on the type of food?

In the absence of sound scientific data demonstrating that the food matrix reduces the risk or severity of adverse effects following ingestion of free glutamate, the agency's likely approach would be to assume that the food matrix has no predictable mitigating effect on the occurrence of the MSG symptom complex and to develop a labeling policy based on the level of free glutamate reported to cause reactions when consumed without food. Because the agency does not yet have such data, this assumption is adopted for purposes of the preliminary discussion in this document.

C. Materiality

Section 403(a) of the act (21 U.S.C. 343(a)) states that a food is misbranded if its labeling is false or misleading in any particular. Under section 201(n) of the act, labeling is misleading if it ''fails to reveal facts material * * * with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling * * * or under such conditions of use as are customary or usual.'' Thus, a food label is misleading if it does not disclose consequences that may result from consumption of the food.

The agency believes that information on the presence of free glutamate in a food becomes a material fact for the glutamate-intolerant consumer in the decision to purchase a food (and in the subsequent use of the food) when free glutamate is present at a level such that a glutamate-intolerant person who consumes the food alone or as part of a meal that includes other glutamate-containing foods may suffer an adverse reaction. The presence of free glutamate below this level is not material because it would not cause a reaction or contribute significantly toward a total intake of free glutamate that might cause a reaction. Moreover, special glutamate labeling on products that contain levels of free glutamate below the material level could cause the label statement to lose its significance for glutamate-intolerant consumers, especially if such labeling appeared on products previously consumed by such consumers without subsequent occurrence of any adverse reaction.

The level shown to elicit adverse reactions in glutamate-intolerant individuals is 3 g of MSG, according to the FASEB report. Based on this data, the agency tentatively finds that the presence of free glutamate in a serving of the food in an amount such that consumption of the food as part of a meal may expose the consumer to the equivalent of 3 g of MSG is a material fact under section 201(n) of the act. Using a conversion factor of 0.787 to correct for the inactive portion of the MSG molecule (MSG consists of free glutamate plus sodium and water), 3 g of MSG converts to approximately 2.4 g of free glutamate. Accordingly, an effective labeling policy should assist glutamate-intolerant consumers in restricting their consumption of free glutamate during a meal or snack to levels below 2.4 g.

As discussed in section I. of this document, FASEB identified a subgroup of asthmatics reported to respond to oral doses of MSG at levels of 0.5 to 2.5 g. The agency believes that the limitations of the Allen study cited by FASEB in reaching this conclusion are considerable, however (Ref. 19). For example, the study design included: (1) A 5-day pretest diet excluding chemicals known to provoke asthma (not otherwise defined), but lacked data with regard to patient compliance with the pretest diet; (2) ingestion of unidentified substances other than MSG; (3) limited placebo-control testing; and, most importantly, (4) the withdrawal of asthma medication that could have prevented or delayed an asthmatic response. Because of the questions raised by the study design and the limited data in this area, FDA's current view is that a cause-and-effect relationship has not been established between exposure to MSG at levels of 0.5 to 2.5 g and adverse reactions in this subgroup of asthmatics. The agency requests comments on this aspect of the FASEB report, as well as any new data demonstrating a relationship between exposure to free glutamate at levels below 2.4 g (3 g of MSG) and adverse reactions in asthmatics. If such data are received, FDA will be better able to evaluate the need for a labeling policy to enable glutamate-intolerant asthmatics to protect themselves from adverse reactions.

FDA's preliminary view is that a policy requiring glutamate labeling should be based on the amount of free glutamate in a serving of a food. Foods are labeled individually to reflect the nutrient content and other characteristics of the particular food. Because a food's contribution to the diet is based on an individual serving of the food, current regulations require foods to be labeled with nutrition information on a per-serving basis. Since the regulations implementing the Nutrition Labeling and Education Act (Pub. L. 101–445) became effective in 1994, consumers have become adept at using label information to monitor their intake of certain nutrients (Ref. 20). A glutamate labeling policy based on the amount of free glutamate in a serving of a food would be consistent with current labeling regulations, and FDA tentatively finds that such a policy would be useful to consumers who wish to avoid intake of free glutamate at levels that may cause an adverse reaction.

D. Labeling Threshold Approach

Applying these principles, the question then becomes how to calculate an appropriate labeling threshold, i.e., the level of free glutamate in a serving of an individual food that should trigger a labeling requirement because consumption of the food as part of a meal that may include other glutamate-containing foods could result in overall intake of free glutamate at levels that have been demonstrated to cause an adverse reaction. That is, what is the appropriate mechanism to relate a total

intake of 2.4 g of free glutamate (from all servings of foods consumed at the meal) to the contribution of an individual food?

One possible approach is to assume that the average daily consumption of a U.S. consumer is 20 servings per day, spread over approximately 3 meals and a snack. A snack is considered roughly two servings and a meal five to six servings. (The agency used a similar approach in determining disclosure levels for nutrient content claims and disqualifying levels for health claims. (56 FR 60426, 56 FR 60543–60544, 58 FR 2492, and 59 FR 24239)). Assuming that a meal consists of approximately six servings, the glutamate-intolerant consumer would be at risk if the total amount of free glutamate from all six servings in the meal were equal to or greater than 2.4 g. Spreading this amount equally over each of the six servings would suggest that each serving of food should contain no more than 0.4 g of free glutamate. Thus, one approach could be to require any food containing 0.4 g or more free glutamate per serving to bear a label statement about its free glutamate content. Such labeling would alert the glutamate-intolerant consumer to foods that contribute significant levels of free glutamate to a meal. With such information, the consumer could avoid foods with significant levels of free glutamate or, as an alternative, include limited quantities of a labeled food in the meal while being careful not to eat other glutamate-containing foods. Using 0.4 g as a labeling threshold would require foods like tomato juice and some soup mixes and canned soups to bear glutamate labeling (Ref. 21).

Although a labeling threshold or ''trigger'' of 0.4 g per serving based on average consumption estimates would adequately protect most glutamate-intolerant consumers, it might not be sufficient to protect those whose food intake is in the high range, that is, at or above the 90th percentile. According to food consumption and food frequency surveys (Refs. 22 and 23) conducted in the United States, intake at the 90th percentile for most commonly consumed foods is roughly 2 times the mean intake for that food (Ref. 24). Thus, a high-intake consumer could be exposed to levels close to 0.8 g from a single food if a regular-size serving of the food contained just under 0.4 g of free glutamate. In such a case, the food would not be required to bear a glutamate content statement, yet the amount eaten by high-intake consumers would contain a significant level of free glutamate. Taking into consideration the number of products that may contain free glutamate and the acute nature of the effects of free glutamate exposure for certain individuals, the agency is concerned that a label trigger of 0.4 g would not sufficiently protect high-intake consumers. The agency believes, therefore, that it is prudent to build in a safety factor to ensure that high-intake consumers are adequately informed of any potential risk.

Allowing for intakes up to twice the mean intake, to provide an additional margin of safety, would result in a labeling threshold of 0.2 g free glutamate (0.4 divided by 2) per serving of food. If the agency were to take this approach and require a glutamate label statement for foods that contain 0.2 or more grams free glutamate per serving, additional foods such as blue cheese, spaghetti sauce, and some brands of soy sauce and tomato paste would be required to bear a label statement about free glutamate content (Ref. 21).

FDA notes that the use of labeling thresholds is not new. Existing regulations establish labeling thresholds for certain ingredients that have been identified as causing adverse reactions either in sensitive individuals or in the general population. These regulations require special labeling for foods that exceed the labeling threshold. For example, the statement ''Excess consumption may have a laxative effect'' is required on foods that contain sorbitol when ''reasonably foreseeable'' consumption of the food could result in a daily sorbitol intake of 50 g or more (21 CFR 184.1835). To cite another example, the label statement ''Sensitive individuals may experience a laxative effect from excessive consumption of this product'' is required when a single serving of a food contains more than 15 grams of polydextrose (21 CFR 172.841). To the best of the agency's knowledge, the use of a labeling threshold has worked well in protecting consumers from adverse reactions caused by excessive consumption of sorbitol and polydextrose.

E. Request for Comments

FDA is soliciting comments on all aspects of this advance notice of proposed rulemaking (ANPRM), and specifically requests comments on the following:

1. The agency invites comments on whether additional labeling requirements should be established to protect glutamate-intolerant consumers from adverse reactions. The agency also solicits comments on the effectiveness of the regulatory approach described previously, as well as suggestions for other approaches that would adequately inform and assist glutamate-intolerant consumers to avoid exposure to levels of free glutamate that might cause a reaction. Suggestions for other approaches should include data or other information to substantiate the effectiveness of the approach. In particular, the agency solicits comments on whether the labeling threshold should be set higher or lower than 0.2 g free glutamate per serving, and on the costs and benefits of labeling policies using different possible labeling thresholds. The agency notes that regulations based on this ANPRM may have a significant impact on a substantial number of small entities. Therefore, the agency particularly requests information on the costs to small businesses of alternative MSG labeling policies and on policy options that would reduce the burden on small businesses while meeting the objectives of MSG labeling. Recognizing that foods would have to be chemically analyzed to determine the free glutamate content and that labels would have to be changed for some foods, the agency solicits data and comments on the economic impact associated with various labeling policies.

2. The agency solicits data on the levels of glutamate in foods to assist it in determining how many and what kinds of foods would be affected by various regulatory approaches.

3. The agency also solicits comments on the advantages or disadvantages of a simple label statement that the food contains free glutamate, as compared to a quantitative statement of the amount of free glutamate in a serving of the food either in absolute terms (i.e., g) or as a percentage of the intake level that might lead to adverse reactions in some consumers. As a preliminary matter, FDA's view is that quantitative labeling is not necessarily any more useful than a general label statement alerting the glutamate-intolerant consumer to the presence of free glutamate in the food when the level is significant. The agency notes that because almost all foods contain trace levels of free glutamate, quantitative labeling for all foods with detectable levels of free glutamate might cause confusion among glutamate-intolerant consumers about which foods could be consumed without risking a reaction. Consumers might unnecessarily limit their food choices by assuming that they should not eat any food labeled to contain any amount of free glutamate, however small. FDA's preliminary view is that, if quantitative labeling is required, a labeling threshold should be established to prevent this problem. The agency solicits comments on this view and on whether the optimal threshold for quantitative free glutamate labeling

would be the same as the optimal threshold for a label statement that the food contains free glutamate.

4. Finally, the agency solicits comments on the following questions regarding the content, wording, and placement of labeling for glutamate-containing foods, and on any other aspects of such labeling:

(a) What information should be included in labeling for glutamate-containing foods? How should any required label statement be worded? Should the scientifically accurate term ''free glutamate'' be used in such labeling, or should the term ''MSG'' be used for all forms of free glutamate because consumers are more familiar with it?

(b) Should a label statement such as ''contains free glutamate'' be included in the ingredient list because consumers traditionally use the ingredient list to determine if the food contains ingredients they wish to avoid? Alternatively, should such a label statement be placed adjacent to the ingredient list or elsewhere on the information panel, or should the label statement be placed on the principal display panel? Suggestions for placement of the label statement should include the comment's rationale for choosing one location over another.

(c) Is a separate label statement about free glutamate content necessary when MSG is an ingredient in the food and is therefore declared in the ingredient list? Current information in the agency's possession suggests that glutamate-intolerant consumers already identify and avoid foods that declare MSG as an ingredient, although they often fail to recognize the presence of free glutamate when it occurs in forms other than MSG (Ref. 3). Thus, the agency solicits comments on the need for a statement about free glutamate content in foods that contain MSG as a declared ingredient.

III. The ''No MSG'' Labeling Policy

A. Current Label Claims

The controversy over the use and safety of MSG in foods has prompted some food manufacturers to make label claims such as ''No MSG'' or ''No added MSG'' when MSG is not used as an ingredient in the food. Several manufacturers have opted to reformulate their products to remove MSG as an ingredient, or to substitute for MSG other ingredients that have similar flavor-enhancing properties. Many of these reformulated foods bear label claims about the absence of MSG. In some cases manufacturers replace MSG with ingredients like hydrolyzed proteins, autolyzed yeast extracts, or other flavor-enhancing ingredients that contain substantial amounts of free glutamate.

Based on correspondence submitted to the agency and arguments raised in a citizen petition submitted on behalf of Jack L. Samuels, Adrienne Samuels, John Olney, et al., (Docket No. 94P–0444), FDA recognizes that many consumers, especially those who report having adverse reactions to MSG, refer to all forms of manufactured glutamate as MSG. As previously discussed, the scientific evidence does not support the assertion that manufactured free glutamate functions differently in the body than naturally occurring free glutamate. Moreover, even though FDA has attempted to clarify the distinction between the ingredient monosodium glutamate (MSG) and other ingredients that contain free glutamate in correspondence and other FDA documents, such as FDA's Backgrounder on MSG (Ref. 25), consumers either do not fully understand or do not acknowledge this distinction. Consequently, consumers continue to use the term ''MSG'' to mean all forms of free glutamate that are added to food. For example, FDA has received numerous written and oral complaints (Ref. 3) charging manufacturers with hiding the presence of ''MSG'' by declaring the substance under other names such as ''flavorings,'' ''hydrolyzed protein,'' ''autolyzed yeast extract,'' and similar terms.

FDA tentatively finds that consumers are likely to perceive a ''No MSG'' or ''No added MSG'' claim on a label as indicating the absence of all forms of free glutamate in the food. Such claims encourage consumers wishing to avoid free glutamate to purchase a food by representing the food as free of MSG. Moreover, manufacturers of hydrolyzed proteins and other glutamate-containing ingredients often promote them to manufacturers of finished foods as functional substitutes for MSG that permit a ''clean'' ingredient statement and a ''No MSG'' claim on the label of the finished food. In this context, ''clean'' means an ingredient list that does not include ''monosodium glutamate.'' Thus, while technically such foods bearing a claim about the absence of MSG do not contain the ingredient monosodium glutamate, they frequently contain levels of free glutamate that cause claims like ''No MSG'' and ''No added MSG'' to be misleading. Some manufacturers attempt to evade the ingredient declaration requirement for MSG by reformulating their products with MSG-containing ingredients (for example, certain spice blends) that are added to the product in lieu of MSG itself. They then modify the ingredient list on the product label to delete MSG and replace it with a generic term such as ''spices.'' (As noted in section I. of this document, this practice violates existing ingredient labeling requirements; when MSG is added to a food as an ingredient of a spice blend, MSG must still be declared in the ingredient statement by its common or usual name, monosodium glutamate.) In some cases, these manufacturers also add a ''No MSG'' claim to the label.

A related problem is the use of claims such as ''No MSG'' and ''No added MSG'' on foods that contain substantial amounts of naturally occurring free glutamate, such as tomato paste and certain cheeses. Although such foods do not contain MSG itself, they contain ingredients with concentrations of free glutamate that function as flavor enhancers like MSG. Because of their free glutamate content, these foods are as likely to cause or contribute to an MSG symptom complex reaction as a food that contains a comparable amount of MSG. A claim such as ''No MSG'' is misleading because it implies that the food may be consumed by glutamate-intolerant consumers without risk of a reaction.

A food that bears a false or misleading claim about the absence of MSG is misbranded under section 403(a) of the act. FDA has repeatedly advised consumers and industry that it considers such claims as ''No MSG'' and ''No added MSG'' to be misleading when they are used on the labels of foods made with ingredients that contain substantial levels of free glutamate (Refs. 25, 26, and 27). FDA has authority to take action against such misbranded foods under existing law, but because of the proliferation of such claims on products made with ingredients that contain substantial levels of free glutamate, the agency believes that formal criteria would be useful to define more precisely the circumstances under which labels bearing claims about the absence of MSG are misleading. While such criteria are being developed, however, FDA will continue to take regulatory action as appropriate against false or patently misleading claims about the absence of MSG, such as ''No MSG'' claims on products made with MSG-containing ingredients, hydrolyzed proteins, or autolyzed yeast extracts.

B. Approaches Under Consideration

The agency is considering a variety of approaches to address misleading claims about the absence of MSG. As a

starting point, a food that contains MSG, or ingredients to which MSG has been added, is misbranded if it bears a ''No MSG'' or similar claim. Such claims are false and, therefore, their regulatory status needs no further clarification. The discussion below concerns the development of criteria to prevent misbranding because of misleading ''No MSG'' and ''No added MSG'' claims on foods that contain free glutamate but to which MSG itself has not been added, directly or indirectly.

1. Cutoff levels

One strategy the agency is considering involves establishing a ''cutoff level'' for claims about the absence of free glutamate. If the finished food contains free glutamate above the cutoff level, a ''No MSG'' or similar label statement would be prohibited. There are several ways in which such a level could be defined:

a. Quantitation limit for free glutamate. One approach would be to use the analytical limit of quantitation (LOQ) for free glutamate as the cutoff level. The enzymatic procedure of Hattula and Wallin (Ref. 28), a commonly used, collaboratively studied analytical method for determining free glutamate content, has an estimated quantitation limit of 100 parts per million (ppm) (Ref. 29). Under this approach, any food with a level of free glutamate above the LOQ, i.e., a level above 100 ppm using the Hattula and Wallin method, would be disqualified from bearing a ''No MSG'' claim. However, because glutamate is ubiquitous in the food supply and low levels of free glutamate typically occur in many raw or minimally processed foods, using the LOQ as the cutoff level would disqualify almost all foods from bearing a ''No MSG'' claim. For example, typical levels of free glutamate in canned peas and canned corn are 320 ppm (.032 g) and 470 ppm (.047 g) respectively (Ref. 30). Although these levels are lower than the level generally associated with flavor-enhancing function (500 ppm) and lower than the amount of free glutamate found in most foods containing monosodium glutamate, hydrolyzed proteins, or yeast extracts, they are above the LOQ of 100 ppm. Consequently, relying on a ''limit of quantitation'' criterion would disqualify foods like canned peas and canned corn from bearing a ''No MSG'' claim.

b. Functional level. According to the scientific literature (Ref. 31), free glutamate has a flavor-enhancing effect at levels as low as 500 ppm. Using 500 ppm as the cutoff level for claims about the absence of MSG would allow a ''No MSG'' label statement on most raw or minimally processed foods that naturally contain free glutamate, while prohibiting such claims on MSG substitutes like protein hydrolysates and autolyzed yeast extracts. Under this approach, foods such as canned peas and canned corn would be permitted to bear a ''No MSG'' claim. However, tomato sauce and fresh tomatoes, because of their relatively high natural free glutamate content, would be prohibited from bearing such a claim, as would parmesan cheese.

c. Labeling threshold. As discussed in section II. of this document, the agency is considering whether to require a label statement about free glutamate content on foods that contain 0.2 g or more free glutamate per serving. For consistency, the cutoff for claims about the absence of MSG could be set at the same level. Under this approach, a ''No MSG'' claim would be permitted on foods like canned peas and canned corn. However, bacon flavored toppings made from hydrolyzed vegetable protein would also qualify to bear a ''No MSG'' claim because the serving size for toppings is so small. Claims about the absence of MSG would be prohibited on any food required to bear a label statement about the presence of free glutamate.

The agency solicits comment on whether an approach based on a cutoff level of free glutamate in the finished food should be adopted to determine whether a food may bear a ''No MSG'' or ''No added MSG'' claim. Further, the agency solicits comment on whether such a cutoff level should be: (a) The analytical limit of quantitation for free glutamate; (b) the level at which free glutamate functions as a flavor enhancer; (c) the level of free glutamate that would trigger a label statement about the food's glutamate content; or (d) some other level.

2. Ingredients

The second approach the agency is considering would prohibit ''No MSG'' and similar claims on foods made from ingredients that contain substantial amounts of free glutamate. In the agency's opinion, ingredients like hydrolyzed vegetable proteins, autolyzed yeast extracts, soy sauce, parmesan cheese, and tomato paste contain enough free glutamate to cause a ''No MSG'' label claim to be misleading. To adopt this approach, the agency would have to define what constitutes a ''substantial'' amount of free glutamate in an ingredient. Should a ''substantial'' amount of free glutamate be defined as the amount reported to have flavor-enhancing properties, i.e., 500 ppm (Ref. 31), or in some other way?

Further, is an approach that prohibits a ''No MSG'' claim if an ingredient in a food contains a ''substantial'' amount of free glutamate equitable in all cases, or should the amount of an ingredient added to a food also be considered in determining whether a claim is misleading? For example, could ingredients like tomato paste or soy protein isolate be added to a food in trace amounts without rendering a ''No MSG'' claim misleading?

3. Combination or Other Approaches

The agency also invites comments on possibilities for combining any of the approaches described in this section to develop a comprehensive labeling policy to ensure that ''No MSG'' claims are truthful and not misleading. For example, would a labeling policy that allowed a ''No MSG'' or similar claim only on foods that: (1) Contain no ingredients that have a ''substantial'' amount of free glutamate, and (2) contain levels of total free glutamate per serving below a cutoff level of 0.2 g, be more desirable than a policy that relied on one criterion alone? This approach would permit claims about the absence of MSG on foods like canned peas and canned corn, but prohibit such claims on foods like bacon flavored toppings made with hydrolyzed protein and on foods that have a relatively high natural free glutamate content, including tomato sauce and parmesan cheese. Alternatively, is there another combination of approaches that would be more effective in ensuring that label claims about the absence of MSG are not misleading? Suggestions for other approaches or combinations of approaches should include data or other information to substantiate the effectiveness of the approach.

IV. References

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

1. National Academy of Science, ''Food Chemicals Codex,'' 4 ed., 1996, p. 260.

2. Taliaferro, P. T., ''Monosodium Glutamate and the Chinese Restaurant Syndrome: A Review of Food Additive Safety,'' *Journal of Environmental Health*, vol. 57, No. 10, pp. 8–12, 1995.

3. Satchell, F. B., Division of Programs and Enforcement Policy (HFS–158), Center for Food Safety and Applied Nutrition, memorandum to file: ''Consumer Correspondence to FDA Regarding the Use and Labeling of MSG in Foods,'' July 3, 1996.

4. Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, ''Evaluation of the Health Aspects of Certain Glutamates as Food Ingredients-Report 37a,'' (PB 283–475/AS), 1978.

5. Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, ''Evaluation of the Health Aspects of Protein Hydrolysates as Food Ingredients- Report 37b,'' (PB 283–440/AS), 1978.

6. Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, ''Evaluation of the Health Aspects of Certain Glutamates as Food Ingredients, Supplemental Review and Evaluation-Report 37a-Suppl.,'' (PB 178635), 1980.

7. Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, ''Evaluation of the Health Aspects of Protein Hydrolysates as Food Ingredients, Supplemental Review and Evaluation-Report 37b-Suppl.,'' (PB80–178643), 1980.

8. FDA opinion letter from Einar T. Wulfsberg, Food and Drug Officer to Mr. Ratton B. Rogers, the Nestle Co., November 12, 1959.

9. FDA opinion letter from Einar T. Wulfsberg, Food and Drug Officer to Mr. J. Ter Marsch, August 25, 1961.

10. FDA opinion letter from D. R. Kleber, Jr., Division of Advisory Opinions Bureau of Enforcement to Yeast Products, Inc., January 22, 1962.

11. FDA opinion letter from Virgil O. Wodicka, Director, Bureau of Foods to Mr. William H. Honstead, The ESU Research Foundation, Kansas State University, 1972.

12. Advisory Committee on Hypersensitivity to Food Constituents—Proceedings Ad Hoc, May 8, 1986, pp. 13–28.

13. Reports of the Scientific Committee for Food on a First Series of Food Additives of Various Technological Functions, Commission of the European Communities, Reports of the Scientific Committee for Food, 25th series, 1991.

14. Report of the Council on Scientific Affairs, American Medical Association, ''Food and Drug Administration Regulations Regarding the Inclusion of Added L-Glutamic Acid Content on Food Labels,'' Report: D (A–92), 1992.

15. The Joint Food Agriculture Organization/World Health Organization Expert Committee on Food Additives, ''L-Glutamic Acid and its Ammonium, Calcium, Monosodium and Potassium Salts-Toxicological Evaluation of Certain Food Additives,'' WHO Food Additive Series, No. 22, pp. 97–161, 1988.

16. Gray, D., FDA memorandum, May 23, 1996.

17. Life Sciences Research Office, Federation of American Societies for Experimental Biology, ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG),'' Report, 1995.

18. Allen, D. H., J. Delohery, and G. Baker, ''Monosodium L-Glutamate-Induced Asthma,'' *Journal of Allergy and Clinical Immunology*, vol. 80, pp. 530–537, 1987.

19. FDA memorandum concerning evaluation of the Federation of American Societies for Experimental Biology (FASEB) (July 1995 Report) from the Director, Division of Health Effects Evaluation to Lawrence Lin, ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG),'' August 30, 1996.

20. Levy, A. S., B. M. Derby, Consumer Studies Branch, Center for Food Safety and Applied Nutrition, FDA, ''The Impact of the NLEA on Consumers: Recent Findings From FDA's Food Label and Nutrition Tracking System,'' 1996.

21. Warner, C., and D. Daniels, FDA memorandum, August 14, 1996.

22. United States Department of Agriculture, ''Continuing Survey of Food Intake by Individuals'' (1989–90, 1990–91, 1991–92), Nationwide Food Consumption Survey, 1987.

23. Market Research Corporation of America (1992), 5-Year Menu Census, 1982–87, FDA Contract No. 223–87–2088.

24. DiNovi, M., FDA memorandum, ''Basis for High-Intake Estimates,'' July 1, 1996.

25. FDA Backgrounder (BG95–16), ''Monosodium Glutamate (MSG),'' August 31, 1995.

26. FDA Warning Letter from Elaine C. Messa, District Director, Irvine, CA to Patricia Bragg, President, Live Food Products, May 29, 1996.

27. FDA correspondence from John E. Thomas to Sonja L. Valiulis, October 14, 1992.

28. Hattula, M. T., and H. C. Wallin, ''Enzymatic Determination of Free Glutamic Acid in Dried Soups and in Minced Sausages: NMKL1 Collaborative Study,'' *Journal of the Association of Official Analytical Chemists*, vol. 74, No. 6, pp. 921–925, 1991.

29. Facsimile from H. C. Wallin to C. Warner, May 6, 1996.

30. Daniels, D. H., F. L. Joe, and G. W. Diachenko, ''Determination of Free Glutamic Acid in a Variety of Foods by High-Performance Liquid Chromatography,'' *Food Additives and Contaminants*, vol. 12, No. 1, pp. 21–29, 1995.

31. Yamaguchi, S., and A. Kimizuka, ''Psychometric Studies on the Taste of Monosodium Glutamate,'' Glutamic Acid: Advances in Biochemistry and Physiology, Raven Press, New York, pp. 35–54, 1979.

V. Comments

Interested persons may, on or before November 12, 1996, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. 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 Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This advance notice of proposed rulemaking is issued under sections 5 and 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1454, 1455), sections 201, 301, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 343, 371), and under the authority of the Commissioner of Food and Drugs.

Dated: August 29, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–23159 Filed 9–5–96; 4:43 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 946

[VA–106–FOR]

Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; notice of opportunity for hearing or public meeting.

SUMMARY: OSM is announcing a hearing (or public meeting if only one person requests a hearing) on a portion of a proposed amendment to the Virginia regulatory program (hereinafter referred to as the Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment for which the hearing is being announced concerns the proposed use of a 28-degree angle of draw with the rebuttable presumption of causation by subsidence provision. The amendment is intended to revise the State program to be consistent with the Federal regulations as amended on March 31, 1995 (60 FR 16772).

DATES: The hearing is scheduled for Wednesday, September 18, 1996, at 7:00 p.m. at the Big Stone Gap Field Office. Requests to speak at the hearing must be received by 4:00 p.m., on September 16, 1996. If a public meeting is held instead of a hearing, it will be held on Wednesday, September 18, 1996, at the Big Stone Gap Field Office at a time to be determined.

ADDRESSES: Request to offer testimony at the hearing should be mailed or hand delivered to Mr. Robert A. Penn, Director, Big Stone Gap Field Office at the first address listed below.

Copies of the Virginia program, the proposed amendment, a listing of the scheduled public hearing (or public meeting if only one person wishes to provide testimony), and all written comments received in response to the