Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5676.

SUPPLEMENTARY INFORMATION: FDA established the current closing date of December 5, 1986, for the provisional listing of FD&C Yellow No. 6, D&C Red No. 8, and D&C Red No. 9 by regulation published in the **Federal Register** of October 6, 1986 (51 FR 35511). FDA extended the closing date for these color additives until December 5, 1986, to provide time for the preparation and publication of appropriate **Federal Register** documents. The regulation set forth below will postpone the December 5, 1986, closing date for the provisional listing of these color additives until February 3, 1987.

In the **Federal Register** of June 6, 1986 (51 FR 20786), FDA announced that the agency had essentially completed its review and evaluation of available information relevant to the use of these color additives in food, drugs, and cosmetics. The agency concluded that the drug and cosmetic uses of D&C Red No. 8 and D&C Red No. 9, and the food, drug, and cosmetic uses of FD&C Yellow No. 6 are safe. Thus, the agency has permanently listed the color additives for these uses.

The two final rules referred to above provide 30 days for any person who will be adversely affected by these final rules to file written objections. The postponement of the closing date for 60 days will provide time for receipt and evaluation of objections or requests for a hearing submitted in response to these final rules.

FDA believes that it is reasonable to postpone the closing date for these color additives until February 3, 1987, to provide time for the receipt and evaluation of any objections. FDA concludes that this extension is consistent with the public health and the standards set forth for continuation of provisional listing in *McIlwain* v. *Hayes*, 690 F.2d 1041 (D.C. Cir. 1982).

Because of the shortness of time until the December 5, 1986, closing date, FDA concludes that notice and public procedure on this regulation are impracticable and that good cause exists for issuing the postponement as a final rule and for an effective date of December 5, 1986. This regulation will permit the uninterrupted use of these color additives until further action is taken. In accordance with 5 U.S.C. 553 (b) and (d) (1) and (3), this postponement is issued as a final regulation, effective on December 5, 1986.

List of Subjects in 21 CFR Part 81

Color additives, Cosmetics, Drugs.

Therefore, under the Transitional Provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 81 is amended as follows:

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

1. The authority citation for 21 CFR Part 81 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1058 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); Title II, Pub. L. 86–618; sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note); 21 CFR 5.10.

§ 81.1 [Amended]

2. In § 81.1 *Provisional lists of color additives* by revising the closing dates for "FD&C Yellow No. 6" in paragraph (a) and for "D&C Red No. 8" and "D&C Red No. 9" in paragraph (b) to read "February 3, 1987."

§ 81.27 [Amended]

3. In § 81.27 *Conditions of provisional listing* by revising the closing dates for "FD&C Yellow No. 6," "D&C Red No. 8," and "D&C Red No. 9," in paragraph (d) to read "February 3, 1987."

Dated: November 29, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86–27249 Filed 12–4–86; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 201

[Docket No. 84N–0113]

Sulfiting Agents; Labeling in Drugs for Human Use; Warning Statement

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its drug labeling regulations to require that a warning statement be included in the labeling of all prescription drugs for human use to which sulfites have been added to the final dosage form. FDA believes that this action is necessary because of the evidence that adverse reactions to sulfites may occur in certain persons, especially asthmatics. This warning statement is intended to aid health care professionals in patient management by providing them with the information necessary to avoid prescribing sulfite-containing drugs to patients known to be sulfite sensitive.

EFFECTIVE DATE: June 3, 1987 for all affected products initially introduced or initially delivered for introduction into interstate commerce. For additional information concerning the effective date see "**EFFECTIVE DATE**" heading appearing in the preamble of this document.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Drugs and Biologics (HFN–362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8046.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of November 19, 1985 (50 FR 47558), FDA proposed to require that a warning statement be included in the labeling of all prescription drug products intended for human use that contain sulfites. FDA proposed this rule in response to reports that certain people, especially asthmatics, experience serious allergic-type reactions after exposure to drug products that contain sulfites. The required warning statement would provide health care professionals with the information necessary to avoid prescribing such drug products to people known to be sulfite sensitive.

In the preamble to the proposed rule, the agency discussed: (1) The widespread use of sulfites as antioxidants in a variety of prescription drug products; (2) the petition from the Center for Science in the Public Interest (CSPI) requesting that the agency ban the use of sulfites in drug products or require a warning label on drug products containing sulfites; and (3) the adverse reports submitted to the agency and adverse reactions cited in the medical literature indicating that sulfites can precipitate mild to life-threatening hypersensitivity reactions.

The agency acknowledged that people who want to avoid sulfite-containing drug products should be given sufficient information to do so, but disagreed with the petitioner that a complete prohibition against their use was justified. The proposed rule stated that because sulfites serve a necessary public health function by maintaining the potency of certain medications, some of which may be life saving, any prohibition against their use could be justified only if acceptable alternatives were available. The agency is not aware of a generally suitable substitute for sulfites at this time.

FDA also described in the proposal several initiatives begun by the drug industry relating to inactive ingredients, such as sulfites, in drug products. Both

the Proprietary Association, representing manufacturers of nonprescription drug products, and the Pharmaceutical Manufacturers Association (PMA), representing prescription drug product manufacturers, initiated voluntary inactive ingredient labeling programs. These programs called for the labeling of drug products produced after December 1985 to declare the presence of inactive ingredients such as sulfites. As stated in the proposal, these initiatives should result in inactive ingredient labeling for the majority of drug products sold in the United States. Because of these voluntary efforts, the agency concluded that Federal regulation to require the listing of sulfites on the label of over-the-counter (OTC) or prescription drug products would not be needed at this time. In regard to prescription drugs, however, the proposal contended that the label declaration of sulfite alone was not sufficient and that a warning label should be placed on sulfite-containing prescription drug products to help ensure that health care professionals are alerted to the problem. Therefore, in addition to the voluntary listing of sulfites in the product label, FDA proposed that a specific statement on the possibility of adverse reactions associated with use be included in the "Warning" section of prescription drug product labeling to bring this fact to the attention of the physician. The preamble to the proposed rule stated that the regulation would apply to any prescription drug product to which sulfites are added as an inactive ingredient, regardless of the amount added.

Highlights of the Final Rule

As discussed below, most of the comments received supported the proposed warning statement for prescription drug products, although many of these comments urged the agency to include a warning on OTC drug products as well. Several of the comments favoring the proposal asked for clarification of statements in the preamble or suggested minor modifications to the proposed warning statement. About one-fourth of the comments received, however, thought that the agency's proposed action was not sufficient in view of the dangers posed by sulfites and stressed that sulfites should be banned from drug products altogether.

As explained in the preamble to the proposed rule, the agency believes that adverse reactions associated with sulfites warrants inclusion of a "warning" statement in professional labeling. However, the agency also believes that sulfites serve a necessary public health function, and that a complete prohibition against their use cannot now be justified. Therefore, the final regulation closely parallels the proposal.

The final rule requires the following statement in prescription drug product labeling, "Contains (*insert the name of the sulfite, e.g., sodium metabisulfite*), a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people." The agency has deleted the words "hives," "itching," and "wheezing" from the codified language of the final rule because these reactions are included in the terms above.

In response to comments received on the proposal, this final rule and preamble contain the following additional changes: (a) Clarification that the regulation is intended to apply to all prescription drug products to which sulfites are added as an inactive ingredient, and (b) inclusion of a separate warning statement for epinephrine products containing sulfites when the products are indicated for treating certain emergency situations.

Comments

The agency received 208 comments on the proposed rule from industry, trade associations, State and local agencies, consumer groups, health professional organizations, individual health professionals and individual consumers, and an FDA Ad Hoc Advisory Committee. On the basis of the information in the proposal and a review of the comments and other information available to the agency on sulfites, the agency believes that encouraging voluntary labeling programs for OTC drug products designed to provide sulfite-sensitive individuals with the necessary information to avoid sulfite-containing drug products is preferable to a mandated Federal program with the same purpose. For prescription drug products, however, the agency continues to believe that a warning statement is needed in the labeling of all prescription drug products containing sulfites to aid physicians in treating known sulfite-sensitive patients with the most appropriate therapies. Comments received are discussed and responded to below.

1. Several comments, while agreeing with the agency's proposed action, suggested that the agency clarify whether the intent of the proposal was to require a warning on all prescription drug products containing sulfites even in trace amounts, or only on those products to which the sulfites are added directly as inactive ingredients. Some of these comments further suggested that the agency establish a threshold level for sulfites in prescription drugs and that the warning label requirement would become applicable only if this level were exceeded. The comments argued that without appropriate clarification most prescription drug products would bear the proposed warning statement thereby diluting its effectiveness and benefits.

The agency's intent in the proposed rule was to require the sulfite warning labeling on all prescription drug products to which sulfites were added as an inactive ingredient, regardless of the amount. The agency did not attempt to establish a threshold level for sulfites that would require the warning because biological threshold levels in sensitive individuals are unknown. As several comments pointed out, many drug products contain low levels of sulfites because one or more of the raw materials used in the production of the drug product contain sulfites. For example, the gelatins used in the manufacture of hard gelatin capsules often contain sulfites, as do the starches used in the manufacture of tablets. The result is that many drug products that have not had sulfites added as inactive ingredients may nevertheless contain some level of sulfite from indirect sources. As described below, the agency's proposal, and thus this final rule, would not apply to such products.

The requirement for the warning labeling applies only to prescription drug products to which sulfites have been directly added as an inactive ingredient. The agency does not believe that it has enough information on indirect sources of sulfites in prescription drug products to warrant extending the warning to those products. To provide the agency with sufficient information to examine this issue further as may be necessary, FDA is requesting that industry, trade associations, consumer groups, health professionals, and other interested persons make available to the agency any information that they have relating to indirect sources of sulfites in prescription drug products, including the number of drug products that would be involved, the levels of sulfites that are present from indirect sources, and methods for

detecting sulfites in drugs. The information should be submitted, under Docket No. 84N-0113, to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

2. Several comments from consumer groups and State agencies, while supporting the proposal, stated that the warning statement should be on the prescription package that is given to the consumer at the time of purchase.

The agency disagrees with the comments that FDA should require a sulfite warning on the package dispensed by the pharmacist. The primary purpose of the sulfite warning is to aid physicians in patient management by providing physicians with information necessary to avoid prescribing sulfite-containing drugs to known sulfite-sensitive persons. In the past, FDA has not normally required this type of information to be placed by pharmacists on individually prescribed products (e.g., FD&C Yellow No. 5; 21 CFR 201.20). However, the agency would not object to pharmacists attaching a warning statement to sulfite-containing drug products.

3. One comment from industry questioned whether a prescription drug product may be labeled "sulfite free" if no detectable level of sulfite is found in the product by current assay methods.

FDA will not object to prescription drug product labeling bearing a truthful statement informing the physician that there is no sulfite in the product, so long as the statement is informational and accurate. The agency acknowledges that labeling a product "sulfite free" could be helpful to persons who wish to avoid sulfites. However, the burden of proof for the accuracy of the label statement rests on the manufacturer. The agency, therefore, cautions manufacturers who decide to label their products as "sulfite free" to be certain that their products do not contain either directly added sulfite or detectable levels of sulfites from indirect sources when tested by current state-of-the-art methods. The presence of sulfites in a product labeled as "sulfite free" would cause the product to be misbranded.

4. One comment argued that because no adverse reactions have been reported in the medical literature for oral prescription drug products, these products should not be required to contain the warning statement.

The agency disagrees with this comment. Although the agency is not aware of any adverse reaction reports involving oral prescription drug products, the potential for reaction from sulfites administered orally has been amply demonstrated in a number of studies. For example, numerous patients, when challenged with metabisulfite in a capsule form, showed a significant fall in pulmonary function and severe symptoms requiring treatment (50 FR 47559; November 19, 1985). The agency believes that it can be concluded from these studies that oral drug products containing sulfites may cause allergic reactions. On the basis of this accumulated evidence, the agency is requiring that this warning statement be included in the labeling of all dosage forms of prescription drug products that contain added sulfites.

5. One comment suggested that the sulfite warning should be "boxed" or "highlighted" for prominence on the prescription drug package. The comment stated that the sulfite warning could be easily overlooked by health care professionals if the warning is not highlighted.

Under § 201.57(e) (21 CFR 201.57(e)), which lists specific requirements on content and format of labeling for human prescription drugs, the agency has the authority to require a "boxed" warning on prescription drug packages for special problems, particularly those that may lead to death or serious injury. The intent of the box is to draw special attention to the warning to assure that it will be noted by the physician. The agency's policy is to use restraint in requiring warnings to be boxed because overuse of the box will ultimately lead to reducing its effect. In the case of sulfites, the agency has taken steps, in addition to the warning in the labeling, to publicize the problem. FDA has published several articles in the *FDA Drug Bulletin*, which were mailed to health care professionals to increase their overall awareness of adverse reactions to sulfite-containing drugs administered to sulfite-sensitive persons. The agency is considering updating these articles in future issues of the *FDA Drug Bulletin*. Articles in the lay press and various professional journals have covered the subject to some extent. Therefore, there is a general awareness of the fact that sulfites can cause severe reactions in sulfite-sensitive persons. Having taken all of these factors into consideration, the agency has concluded that boxing the warning in the labeling of prescription drug products is not necessary to assure that physicians or other health care professionals will note the warning. Therefore, the suggestion in the comment is rejected.

6. One comment suggested that the required sulfite warning be revised to read "may contain" rather than "contains" sulfites. This wording change would allow prescription drug manufacturers flexibility in switching from one supplier of raw materials to another that may or may not contain sulfite.

The requirement for the warning statement applies only to drug products that contain sulfites that have been added to the product as an inactive ingredient. The warning is not required when the sulfite is from an indirect source as described in the comment.

7. Two comments stated that the amount of sulfite in a prescription drug product should be listed in the labeling because some patients demonstrate a dose-dependent relationship to sulfites. One comment further stated that knowledge of sulfite levels would permit both physicians and consumers to make more informed choices of medications that could be critical for sulfite-sensitive patients.

The agency does not believe there are sufficient data to demonstrate the usefulness of listing the quantity of directly added sulfites in prescription drug products. Although there are individual cases in which a dose-dependent response can be demonstrated, patients have been known to react differently to a specific dose of sulfite on different occasions. Consequently, an individual patient's tolerance may not necessarily be well established. The agency emphasizes that the intent of the warning statement is to alert the physician to the presence of sulfites so that the physician can avoid prescribing the drug product to sulfite-sensitive patients. In many instances alternative medications are available that do not contain sulfites. For these reasons, the agency is not requiring that the quantity of sulfites be listed in the labeling, although manufacturers are of course free to include the information.

8. One comment asked that epinephrine for injection be exempted from requiring a sulfite warning when prescribed for emergency situations. The comment emphasized that epinephrine for injection is a life-saving therapy for allergic emergencies and is not known to cause an allergic reaction of its own due to the sulfites present in the product.

The agency agrees with the comment that epinephrine for injection is a life-saving therapy for allergic emergencies. Sulfites are generally added to epinephrine products to maintain the potency. Health care professionals should not be deterred from using sulfite-containing epinephrine for injection in life-threatening emergency situations, even for patients known to be sulfite sensitive. Accordingly, the agency is amending the final rule by

adding an alternate warning statement in § 201.22(c) (21 CFR 201.22(c)) to inform health care professionals that the benefits of using injectable epinephrine that contains sulfite for the treatment of allergic-type reactions as well as other emergency situations outweigh possible disadvantages.

9. Sixty-three comments requested that a sulfite warning be required on OTC drug products, claiming that voluntary labeling efforts have not worked in the past. A number of these comments pointed out that there appears to be an inconsistency in the agency's rationale in the proposed rule for not including such a warning on OTC products while requiring the warning on all prescription drug products. As the comments noted, the agency's rationale for not including OTC drug products in the proposed rule was the fact that the agency is unaware of any adverse reaction from sulfites in OTC drug products. The proposal also stated that the agency is not aware of any adverse reactions from oral prescription drug products but determined that they should require a warning statement because of their potential for adverse reactions.

The agency believes that labeling for OTC drug products and prescription drug products should be treated differently. The warning is necessary in the labeling for prescription drugs to alert the prescriber that the product may cause allergic-type reactions in certain susceptible persons. The warning may, for example, increase the likelihood that before prescribing the drug a physician will ask the patient whether the patient has a known sulfite sensitivity. Simply declaring the presence of sulfites may not be enough to alert the prescriber to the potential for allergic-type reactions. In the case of OTC drugs, however, unlike prescription drugs, the person using the drug receives the package labeling for the product. The person who has been determined to be susceptible to sulfite allergic-type reactions presumably is aware of this sensitivity and is accustomed to taking precautions to avoid using sulfite-containing products. Warnings are probably not necessary for such people provided that the presence of sulfites is declared in the ingredient statement of the package labeling.

As stated in the proposed rule, the Proprietary Association, representing 85 companies that account for 90 percent of all OTC drugs marketed in the United States, has initiated a labeling program under which its member firms will voluntarily list all inactive ingredients. The program called for the labeling of OTC products manufactured by its members after December 1, 1985, to list the presence of inactive ingredients, such as sulfites. Since publication of the proposal, the association has informed the agency that according to its surveys, few OTC products contained sulfites and that over the past year, many have been reformulated to omit this ingredient. Moreover, the association also noted that, as of July 1, 1986, all 20 sulfite-containing products produced by member companies list sulfites in the inactive ingredient labeling section of the product label (see July 21, 1986, letter from the Proprietary Association; filed under Docket No. 84N-0113).

10. Forty-four comments asked that the agency either ban sulfites from all drug products or at least from all drug products used to treat asthma.

The agency disagrees with this comment. Because sulfites serve a necessary public health function by maintaining the potency of certain medications, some of which may be life saving, prohibiting sulfite use in drug products would be justified only if acceptable alternatives were available. The agency is not aware of any generally suitable substitute for sulfites in prescription drug products.

11. Five comments asked FDA to encourage pharmaceutical companies to develop substitutes for sulfites in drugs or to use ascorbic acid as a replacement for sulfites.

Currently, there is no general replacement for sulfites. Moreover, except for ascorbic acid, alternative antioxidants have not had wide exposure and could pose greater safety problems than sulfites. However, the agency encourages pharmaceutical manufacturers to find alternative antioxidants that are shown to maintain a stable and acceptable drug product.

12. One comment asked that the agency design educational programs to increase awareness among health care professionals of potential adverse reactions to sulfite-containing drugs.

The agency has published several articles in the *FDA Drug Bulletin*, which were mailed to health care professionals to increase the overall awareness of adverse reactions to sulfites in certain persons and to provide information necessary to avoid prescribing sulfite-containing drugs to sulfite-sensitive persons. The agency is considering updating these articles in future issues of the *FDA Drug Bulletin*.

13. One comment stated that the agency should monitor and study adverse reactions to sulfites in OTC products.

The agency has an ongoing program monitoring the adverse drug reactions of all new drugs, which includes most prescription drugs and some OTC drug products. Under § 314.80 (21 CFR 314.80), manufacturers of all approved new drug products or drugs approved for marketing under section 505 of the Federal Food, Drug, and Cosmetic Act must inform the agency of adverse drug experience that may be related to the use of their drug products. In the **Federal Register** of July 3, 1986 (51 FR 24476), the agency published a final regulation requiring the reporting of adverse drug experiences for all prescription drug products that are not the subject of approved new drug applications. The agency does not have a formal procedure for monitoring adverse reactions to OTC drugs that are not new drugs, but such reactions do come to the attention of the agency in journal articles and from consumers. Information from these sources is evaluated in the same manner as other adverse drug reaction reports.

Effective Date

Labeling for prescription drug products for human use containing sulfite added as an inactive ingredient, and initially introduced or initially delivered for introduction into interstate commerce on or after June 3, 1987, is required to contain the appropriate warning statement specified in either 21 CFR 201.22 (b) or (c).

The use of sulfite(s) in a human prescription drug product initially introduced or initially delivered for introduction into interstate commerce on or after June 3, 1987, would cause the drug to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) if its labeling failed to contain a required warning statement.

Manufacturers of drug products, including approved new drugs, are encouraged to revise their labeling to conform to the final rule at the earliest possible time. In accordance with 21 CFR 314.70(c), such changes for new drugs may be placed in effect upon submission of a supplemental application, and need not wait for prior approval from the agency.

Economic Assessment

The agency has reexamined the regulatory impact and regulatory flexibility implications of the final regulation in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). The agency has estimated that the regulation would generate costs that are well below the thresholds that signify a major rule and, thus, the final regulation

does not require a regulatory impact analysis.

FDA's Center for Drugs and Biologics estimates that there are approximately 1,100 prescription drug products currently marketed which contain an added sulfite. The final regulation would require a one-time addition to existing prescription drug product professional labeling—adding a warning statement.

FDA estimates that a drug manufacturer would incur label printing and redesign expenses that include typesetting the warning statement, graphics redesign to position the warning statement on the labeling, and preparing a new negative. FDA estimates that these one-time labeling changes would cost a pharmaceutical manufacturer on an average approximately $60 per drug product. Thus, the total cost to manufacturers of complying with the final regulation would be $66,000 ($60×1,100).

FDA also certifies that the final regulation would not have a significant economic impact on a substantial number of small entities and, thus, does not require a regulatory flexibility analysis. Although many of the manufacturers involved are small firms, the costs incurred by these small entities would fall short of the threshold required for a regulatory flexibility analysis.

Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 201

Drugs; Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 201 is amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR Part 201 is revised to read as follows:

Authority: Secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended (21 U.S.C. 321, 352, 355, 371); 21 CFR 5.10 and 5.11.

2. In Subpart A by adding new § 201.22 to read as follows:

§ 201.22 Prescription drugs containing sulfites; required warning statements.

(a) Sulfites are chemical substances that are added to certain drug products to inhibit the oxidation of the active drug ingredient. Oxidation of the active drug ingredient may result in instability and a loss of potency of the drug product. Examples of specific sulfites used to inhibit this oxidation process include sodium bisulfite, sodium metabisulfite, sodium sulfite, potassium bisulfite, and potassium metabisulfite. Recent studies have demonstrated that sulfites may cause allergic-type reactions in certain susceptible persons, especially asthmatics. The labeling for any prescription drug product to which sulfites have been added as an inactive ingredient, regardless of the amount added, must bear the warning specified in paragraph (b) or (c) of this section.

(b) The labeling required by §§ 201.57 and 201.100(d) for prescription drugs for human use containing a sulfite, except epinephrine for injection when intended for use in allergic or other emergency situations, shall bear the warning statement "Contains (*insert the name of the sulfite, e.g., sodium metabisulfite*), a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people." This statement shall appear in the "Warnings" section of the labeling.

(c) The labeling required by §§ 201.57 and 201.100(d) for sulfite-containing epinephrine for injection for use in allergic emergency situations shall bear the warning statement "Epinephrine is the preferred treatment for serious allergic or other emergency situations even though this product contains (*insert the name of the sulfite, e.g., sodium metabisulfite*), a sulfite that may in other products cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite(s) in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations." This statement shall appear in the "Warnings" section of the labeling.

Dated: November 6, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

[FR Doc. 86-27319 Filed 12-4-86; 8:45 am]

BILLING CODE 4160-01-M

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Exchange Visitor Program

AGENCY: United States Information Agency.

ACTION: Final rule.

SUMMARY: The United States Information Agency has utilized alien employees recruited abroad and within the United States for service in the United States as foreign language translators, narrators, producers and editors. Historically, these aliens were employed by the Voice of America and by the Press and Publication Service of the Agency. With the inauguration of a worldwide television service known as WORLDNET and some regional television programs, the Office of Television and Film Service will also need foreign language services by alien employees. The rule change will permit that Office to recruit alien employees and to assure their service within the United States under the J–1 Visa. The rule change will also enable any other bureau or office of the Agency to employ aliens and to utilize the J–1 Visa for the purpose without need of further change in regulation.

EFFECTIVE DATE: The rule change shall become effective December 5, 1986.

FOR FURTHER INFORMATION CONTACT: Richard L. Fruchternan, Assistant General Counsel, United States Information Agency, Room 700, 301 Fourth Street SW., Washington, DC 20547, (202) 485–7976.

SUPPLEMENTARY INFORMATION: The United States Information Agency has utilized alien employees recruited abroad and within the United States for service in the United States as foreign language translators, narrators, producers and editors. Historically, these aliens were employed by the Voice of America and by the Press and Publication Service of the Agency. With the inauguration of a worldwide television service known as WORLDNET and some regional television programs, the Office of Television and Film Service will also need foreign language services by alien employees. The rule change will permit that Office to recruit alien employees and to assure their service within the United States under the J–1 Visa. The rule change also will enable any other bureau or office of the Agency to employ aliens and to utilize the J–1 Visa for that purpose without need of further change in regulation.

The provisions of section 1474 of Title 22 of the United States Code, as amended, state, inter alia, that in carrying out his functions the Director of the Agency may:

(1) Employ, without regard to the civil service and classification laws, aliens within the United States and abroad for service in the United States relating to the translation or narration of colloquial speech in foreign languages or the preparation and production of foreign language programs when suitably qualified United States citizens are not available, and aliens so employed abroad may be admitted to the United States, if otherwise qualified, as nonimmigrants under section 101(a)(15) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(15)) for such time and under such conditions and procedures as may be established by the Director of the International Communication Agency and the Attorney General;

The rule change is made pursuant to this authority. Consequently, the Agency does not deem it necessary or appropriate to publish a notice of proposed rulemaking with the opportunity for the public to comment.
E.O. 12291 Federal Regulations

USIA has determined that this is not a major rule for the purpose of E.O. 12291, Federal Regulation, because it will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 22 CFR Part 514

Cultural Exchange Programs.

Accordingly, Part 514 of Title 22 of the Code of Federal Regulations is amended as follows:

PART 514—EXCHANGE VISITOR PROGRAM

1. The authority citation for 22 CFR Part 514 is revised to read as follows:

Authority: Sec. 804(1), United States Information and Educational Exchange Act of 1948, as amended (86 Stat. 493, as amended; 22 U.S.C. 1474(1), as amended; Pub. L. 87–256, 75 Stat. 527, 534, 535 (8 U.S.C. 1101, 1182, 1258, and 22 U.S.C. 2452); Pub. L. 97–241, 96 Stat. 291; 66 Stat. 166, 182, 184, 204 (8 U.S.C. 1101(a)(15)(J), 1182(e), 1182(j), 1258); Pub. L. 91–225, 84 Stat. 116, 117 (8 U.S.C. 1101, 1182); Reorg. Plan No. 2 of 1977; E.O. 12048 of March 27, 1978; USIA Delegation Order No. 85–5 (50 FR 27393).

2. Section 514.23(a)(1)(viii) is revised to read as follows:

§ 514.23 General limitations of stay.

(a) * * *

(1) * * *

(viii) Alien employees of the United States Information Agency engaged in the translation of broadcast narration of foreign languages or the preparation and production of foreign language programs—ten years, and such additional periods of time as the Director of the United States Information Agency may from time to time determine in individual cases.

* * * * *

Dated: October 21, 1986.

C. Normand Poirier,

Acting General Counsel.

[FR Doc. 86-27301 Filed 12-4-86; 8:45 am]

BILLING CODE 8230-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 232 and 235

[Docket No. R-86-1315; FR-2313]

Mortgage Insurance—Changes in Interest Rates

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This change in the regulations decreases the maximum allowable interest rate on section 232 (Mortgage Insurance for Nursing Homes) and on section 235 (Homeownership for Lower Income Families) insured loans. This final rule is intended to bring the maximum permissible financing charges for these programs into line with competitive market rates.

EFFECTIVE DATE: November 24, 1986.

FOR FURTHER INFORMATION CONTACT: John N. Dickie, Chief Mortgage and Capital Market Analysis Branch, Office of Financial Management, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Telephone (202) 755-7270. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The following amendments to 24 CFR Chapter II have been made to decrease the maximum interest rate which may be charged on loans insured by this Department under section 232 (fire safety equipment) and section 235 of the National Housing Act. The maximum interest rate on the HUD/FHA section 232 (fire safety equipment) and section 235 insurance programs has been lowered from 9.50 percent to 9.00 percent.

The Secretary has determined that this change is immediately necessary to meet the needs of the market and to prevent speculation in anticipation of a change.

As a matter of policy, the Department submits most of its rulemaking to public comment, either before or after effectiveness of the action. In this instance, however, the Secretary has determined that advance notice and public comment procedures are unnecessary and that good cause exists for making this final rule effective immediately.

HUD regulations published at 47 FR 56266 (1982), amending 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, contain categorical exclusions from their requirements for the actions, activities and programs specified in § 50.20. Since the amendments made by this rule fall within the categorical exclusions set forth in paragraph (l) of § 50.20, the preparation of an Environmental Impact Statement or Finding of No Significant Impact is not required for this rule.

This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 on Federal Regulation issued on February 17, 1981. Analysis of the rule indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State or local governmental agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In accordance with the provisions of 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. The rule provides for a small decrease in the mortgage interest rate in programs of limited applicability, and thus of minimal effect on small entities.

This rule was not listed in the Department's Semiannual Agenda of Regulations published on October 27, 1986 (51 FR 38424) pursuant to Executive