

routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zones.

Adoption of the Amendment

PART 71—[Amended]

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

2. Section 71.171 is amended as follows:

Marysville Yuba County Airport, CA—
[Amended]

Add the following sentence to the end of the present control zone description: "This control zone is effective from 0600 to 2100 hours local time, daily or during specific dates and times established in advance by a Notice to Airmen which thereafter will be continuously published in the *Airport/Facility Directory*."

Issued in Los Angeles, California, on July 22, 1986.

Wayne C. Newcomb,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 86-17016 Filed 7-29-86; 8:45 am]

BILLING CODE 4910-13-M

INTERNATIONAL TRADE COMMISSION

19 CFR Part 213

Trade Remedy Assistance

AGENCY: International Trade Commission.

ACTION: Final rules; correction.

SUMMARY: Through an administrative error, the effective date was deleted from a U.S. International Trade Commission document containing the Final Commission Rules pertaining to Trade Remedy Assistance. This notice corrects that deletion.

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Gertler, Esq., Trade Remedy Assistance Center, U.S. International Trade Commission, Room 130, 701 E Street NW., Washington, DC 20436, telephone (202) 523-0488.

Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 724-0002.

In FR Doc. 86-16023, published in the Federal Register of Friday, July 18, 1986 on page 25999, the preamble is corrected by adding an effective date for the document to read as follows:

"Effective Date: July 18, 1986."

By order of the Commission.

Issued: July 22, 1986.

Kenneth Mason,
Secretary.

[FR Doc. 17095 Filed 7-29-86; 8:45 am]

BILLING CODE 7020-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 81N-0368]

Hydrogen Peroxide; Affirmation of GRAS Status With Specific Limitations

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that hydrogen peroxide is generally recognized as safe (GRAS) with specific limitations as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: August 29, 1986.

FOR FURTHER INFORMATION CONTACT:

Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 17, 1983 (48 FR 52323), FDA published a proposal to affirm that hydrogen peroxide is GRAS, with specific limitations, for use as a direct human food ingredient. FDA published this proposal in accordance with its announced review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on hydrogen peroxide have been made available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers

Lane, Rockville, MD 20857. Copies of these documents are available for public purchase from the National Technical Information Service (NTIS), as announced in the proposal.

In addition to proposing to affirm the GRAS status of hydrogen peroxide with specific limitations, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture (USDA) or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have the prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

One comment expressed a belief that a prior sanction exists for the use of hydrogen peroxide as an antimicrobial agent. The comment, however, did not present any proof of such a prior sanction. The comment did provide a copy of a 1940 patent for the use of hydrogen peroxide to produce thermophile-free starch. The agency finds that this patent is not evidence of a prior sanction. However, the agency has considered the claim that hydrogen peroxide is GRAS for use as an antimicrobial agent to produce thermophile-free starch as a comment on the proposal and is including this use in this GRAS regulation.

No other reports of prior sanctions were received. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

In response to the publication of the proposed regulation on hydrogen peroxide, FDA received two requests for an extension of the comment period. In a notice published in the Federal Register of January 27, 1984 (49 FR 3490), the agency granted a 90-day extension.

I. Uses of Hydrogen Peroxide Reported in Comments

FDA received seven comments on the proposed rule during the comment period. None of these comments

questioned the agency's tentative determination that the use of hydrogen peroxide is GRAS. Therefore, FDA is affirming as GRAS the uses of the substance that were listed in the proposal.

Each of the comments, however, requested that FDA revise the proposed regulation to affirm as GRAS certain current industry uses of hydrogen peroxide as a processing aid. The following is a summary of the additional uses of hydrogen peroxide that were reported to the agency in these seven comments:

1. One comment from the representative of a manufacturer of food emulsifiers that contain fatty acid esters requested that the agency amend the final rule to permit the use of hydrogen peroxide as a bleaching agent in these emulsifiers. The comment described the process for bleaching food emulsifiers that contain fatty acid esters used by this manufacturer and presumably by others. The comment described this bleaching process as including the addition of a 50-percent aqueous solution of hydrogen peroxide to these emulsifiers at levels that do not exceed 2.5 percent (1.25 percent hydrogen peroxide on a 100-percent active basis). The comment reported that residual hydrogen peroxide is removed from the emulsifiers by heating the bleached product under reduced pressure. The comment reported that residual peroxide has not been detected in the bleached product when analyzed using standard peroxide analytical methods.

2. A comment from a national trade association reported the use of hydrogen peroxide as an antimicrobial and a bleaching agent in the production of starch and food starch modified and as an agent to remove residual sulfur dioxide in the production of starch and corn syrup. The comment submitted a copy of an exchange of letters between the Corn Industries Research Foundation and FDA. In a letter dated August 17, 1959, the research foundation described in detail the conditions and levels of use of hydrogen peroxide in the manufacture of corn starch and bleached corn starch. In its response to that letter, FDA confirmed an opinion that had been given orally by an agency official that corn starch and bleached corn starch, among several corn products, were GRAS. From this agency response, the comment inferred that hydrogen peroxide is GRAS when used in the production of such corn products. In support of this conclusion, the comment also submitted a copy of a U.S. patent dated October 15, 1940, that describes the use of between 0.05 to 0.15

percent (on a 100-percent basis) hydrogen peroxide as an antimicrobial agent in the manufacture of thermophile-free starch. The comment stated that thermophile-free starches are those starches that meet specifications of the canning industry. These specifications require that starches be substantially free of thermophilic spores, flat sour spores, thermophilic anaerobic spores, and sulphide spoilage spores.

The comment also reported the use of hydrogen peroxide to reduce the level of sulfur dioxide after the corn steeping and grinding operations in corn refining. (Sulfur dioxide is used to facilitate the separation of the starch and protein components of corn.) The comment stated that the usual level of use of hydrogen peroxide for this purpose was 0.04 percent.

The comment also provided the results of a survey of corn products producers concerning the extent to which hydrogen peroxide is used in the processing of starch. Those producers that responded to the survey reported usage levels ranging from 0.03 to 0.17 percent (on a 100-percent active basis). The comment reported that residual hydrogen peroxide is removed from the starch by washing with potable water and drying in high temperature dryers at intake temperatures of 400 to 500 °Fahrenheit (F) and exhaust temperatures in the range of 160 °F to 170 °F.

The comment also reported the use of hydrogen peroxide as a processing aid to reduce sulfur dioxide levels in the production of corn syrup. The comment reported that the sulfur dioxide content of corn syrup during processing is in the range of 0.002 to 0.003 percent. The comment explained that hydrogen peroxide is added to the corn syrup at a level that is 1 to 3 times the sulfur dioxide content but does not exceed 0.15 percent of the corn syrup. The comment stated that the heat used in the evaporation steps in the manufacture of the corn syrup destroys the hydrogen peroxide, thus leaving no peroxide residue. The comment expressed its belief that the information it provided showed that hydrogen peroxide had been used in the processing of starch since the 1930's, and that this use was known by regulatory officials. Therefore, the comment requested that this use of hydrogen peroxide be affirmed as GRAS.

3. Three comments from tea producers reported the use of hydrogen peroxide as a bleaching agent in instant tea. All three comments reported similar processing procedures, i.e., water extraction of tea leaves, concentration

of the extract, bleaching and polishing of the concentrate, and, finally, heat drying. Bleaching is accomplished by adding hydrogen peroxide at a level of 1 to 3 percent of the concentrated extract. Residual hydrogen peroxide is removed during the evaporation and heat spray drying process. The comment described the use of hydrogen peroxide in instant tea processing as self-limiting because excessive levels of residual hydrogen peroxide results in a product of no commercial value.

4. One comment asked that the proposed rule be amended to permit hydrogen peroxide as a bleach for annatto-colored whey. The comment reported that residual hydrogen peroxide is removed from the bleached whey by a potable water wash and spray drying at elevated temperatures. The comment noted that hydrogen peroxide is already affirmed as GRAS as an antimicrobial agent in the processing of modified wheys in § 184.1979 (21 CFR 184.1979). The comment reported that the level of use of hydrogen peroxide as a bleach of annatto-colored whey is approximately the same as the level at which it is used as an antimicrobial agent in modified wheys, i.e., at a level of 0.05 percent.

5. One comment reported the use of hydrogen peroxide as a processing aid to reduce the level of sulfur dioxide in wine used to make wine vinegar. The comment stated that the use of 757 milliliters of an aqueous solution of 35 percent hydrogen peroxide will inactivate 30 parts per million sulfur dioxide in 1,000 gallons of wine, i.e., at a level of 0.02 percent. (The amount of hydrogen peroxide needed to remove sulfur dioxide will vary depending upon the sulfur dioxide content of the wine.) The comment submitted a copy of Alcohol Tax Circular No. 1066, Amendment No. 1, dated June 16, 1950, which authorizes the use of hydrogen peroxide to reduce the sulfur dioxide content of distilling material so long as no hydrogen peroxide remains in the finished product. The comment also submitted a copy of Internal Revenue Ruling 63-331, dated June 19, 1963, which authorizes the use of hydrogen peroxide to facilitate secondary fermentation in the production of champagne and other sparkling wines. The comment also cited a July 1, 1967, Bureau of Alcohol, Tobacco, and Firearms authorization for the use of hydrogen peroxide at a maximum of 200 parts per million to reduce aldehydes in distilling material.

The comment suggested that it is not necessary to include a limitation on the level of addition of hydrogen peroxide

for this use because any residual hydrogen peroxide is removed during the acetification, aeration, and pasteurization steps in the production of the wine vinegar.

II. Consideration of GRAS Status of Reported Uses

In the proposal, the agency stated that it was likely that the National Academy of Sciences/National Research Council (NAS/NRC) survey did not report all existing uses of hydrogen peroxide, and that, as a result, some uses of hydrogen peroxide were not included in § 184.1366(c) of the proposed GRAS affirmation regulation (48 FR 52323). The seven comments that FDA received demonstrate that the agency was correct.

In the preamble to the proposal (48 FR 52323), the agency set forth the specific types of information that should be submitted by persons who wanted the agency to consider additional uses of hydrogen peroxide. The agency finds that the seven comments that presented additional uses of this substance have submitted the necessary information to permit the agency to evaluate these uses. The agency has reviewed the use level information, technical effects data, and the processing procedures for each use of hydrogen peroxide cited in the seven comments. Based upon its review, FDA finds that it can affirm most of the uses reported in the comments as GRAS. However, for starch, FDA is affirming as GRAS only the use of hydrogen peroxide as an antimicrobial agent to produce thermophile-free starch and as an agent to remove sulfur dioxide from starch slurry, with a maximum use level of 0.15 percent for these uses. The technical effect associated with the reported use of 0.17 percent hydrogen peroxide in starch processing was not identified. Based on the approximate range of levels reported in the survey and the fact that the reported maximum level in the related use of hydrogen peroxide in corn syrup is 0.15 percent, the agency concludes that a maximum level of 0.15 percent will adequately cover the use of hydrogen peroxide in starch processing.

FDA finds that the food additive regulation on food starch-modified (21 CFR 172.892) already provides for the use of hydrogen peroxide in the bleaching of this type of starch. Therefore, the agency is not modifying the final rule to incorporate this use.

FDA considers it likely that there will be little if any increased exposure to hydrogen peroxide from the uses of this substance that were reported in the comments because (1) each comment described a step in which any residual

hydrogen peroxide would be removed or destroyed, and (2) food processors were already using hydrogen peroxide for these uses. Therefore, based on the small increase in exposure and on the agency's review of the data on the safety of hydrogen peroxide, FDA is affirming these uses of hydrogen peroxide as GRAS and is incorporating them in 21 CFR 184.1366(c).

III. Modification of the Regulation

The proposal prescribed a specific method for removing residual hydrogen peroxide for each use of this substance that the agency proposed to affirm as GRAS. Based upon its review of the comments and of the original report from the Select Committee, the agency finds that a number of physical and chemical methods exist that food manufacturers can use to reduce or to eliminate residues of hydrogen peroxide. The agency also finds that many of these methods can be used to reduce the level of residual hydrogen peroxide in a variety of foods.

The agency is concerned that if it attempts to identify specific procedures for reducing hydrogen peroxide residues in specific foods, it may inhibit future innovation in the development of manufacturing procedures for the foods in which hydrogen peroxide is used. For this reason, the agency is deleting the column for limitations or restrictions from the table in paragraph (c) of § 184.1366 and instead is establishing a new paragraph (d) that contains a general requirement that residual hydrogen peroxide is to be removed from food by appropriate physical and chemical processes. Because this general requirement is consistent with the limitations originally proposed for the table in paragraph (c) and merely reflects the fact, as pointed out in the comments, that a number of alternate methods for removing hydrogen peroxide exist, the agency concludes that it is not necessary to seek comments on new paragraph (d).

IV. Environmental and Economic Assessments

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (November 17, 1983; 48 FR 52323). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this

rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

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

List of Subjects

21 CFR Part 182

Food ingredients, Spices and flavorings.

21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.11.

2. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by removing the entry "Hydrogen peroxide."

§ 182.1366 [Removed]

b. by removing § 182.1366 *Hydrogen peroxide*.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

4. Part 184 is amended in § 184.1366 by revising paragraphs (c), (d), and (e) to read as follows:

§ 184.1366 Hydrogen peroxide.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under Part 133 of this chapter.	0.05	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter
Whey, during the preparation of modified whey by electrodialysis methods.	0.04	do
Dried eggs, dried egg whites, and dried egg yolks as in §§ 160.105, 160.145, and 160.185 of this chapter	Amount sufficient for the purpose.	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter
Tripe	do	Bleaching agent.
Beef feet	Amount sufficient for the purpose. (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide).	Bleaching agent.
Herring	Amount sufficient for the purpose.	do
Wine	do	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter.
Starch	0.15	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter, to produce thermophile-free starch; Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.
Instant tea	Amount sufficient for the purpose.	Bleaching agent.
Corn syrup	0.15	Reduce sulfur dioxide levels in the finished corn syrup.
Colored (annatto) cheese whey.	0.05	Bleaching agent.
Wine vinegar	Amount sufficient for the purpose.	Remove sulfur dioxide from wine prior to fermentation to produce vinegar.

Food	Maximum treatment level in food (percent)	Functional use
Emulsifiers containing fatty acid esters.	1.25	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: July 17, 1986.

James W. Swanson,
Acting Associate Commissioner for
Regulatory Affairs.
[FR Doc. 17036 Filed 7-29-86; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 184

[Docket No. 81N-0348]

Benzoyl Peroxide; Affirmation of GRAS Status

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that benzoyl peroxide is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective August 29, 1986. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1157 effective on August 29, 1986.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 1, 1982 (47 FR 43402), FDA published a proposal to affirm that benzoyl peroxide is GRAS for use as a direct human food ingredient. FDA published this proposal in accordance with its announced review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the reports of the Select Committee on GRAS Substances (the Select Committee) on benzoyl peroxide

have been made available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents are also available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of benzoyl peroxide, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those prior sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for benzoyl peroxide were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

FDA received three comments in response to the proposal.

One comment, from a soya products company, supported the regulation as proposed. Thus, no response to that comment is necessary.

The other two comments did not question the agency's tentative determination that the use of benzoyl peroxide is GRAS. However, the comments did request that proposed § 184.1157(c)(2) be amended to include the use of benzoyl peroxide as a substitute for hydrogen peroxide for bleaching annatto-colored whey. Both comments presented published studies on the effectiveness of benzoyl peroxide for this use, as well as a study on the decomposition of benzoyl peroxide in whey.

One of these two comments, in response to a request from FDA, provided supplemental information clarifying the conditions of use of benzoyl peroxide in the manufacture of

whey, including the proposed level of use, the residue level, and the method of analysis for residues of benzoyl peroxide in bleached whey.

FDA has thoroughly reviewed these two comments as well as the supplemental information that was submitted. The agency finds that the use of benzoyl peroxide to bleach annatto-colored whey is a new use. FDA has estimated the increase in use of benzoyl peroxide in food that would result from this use. It finds that this use of benzoyl peroxide will result in an increase in dietary exposure to this substance that is so small that it falls within the level that the Select Committee considered to be safe.

This latter finding is based on (1) the Select Committee's conclusion that no evidence in the available information on benzoyl peroxide demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when benzoyl peroxide is used at levels that are now current or that might reasonably be expected in the future; (2) the Select Committee's estimate in its reports that the then current per capita level of addition of benzoyl peroxide to food was about 8.5 milligrams per day; (3) the agency's estimate that the per capita level of addition of benzoyl peroxide to food resulting from its use as a bleach for annatto-colored whey would be no more than 0.023 milligram per day; and (4) the Select Committee's finding, supported by the data in the comments to the proposal, that most of the benzoyl peroxide employed as a bleach would be converted to benzoic acid during food processing, and that only traces of residual peroxide would be ingested.

Based on the findings of the Select Committee and on its own review of the data, the agency concludes that it can affirm the use of benzoyl peroxide in food, including its use in whey, as GRAS. The agency is issuing § 184.1157(c)(2) to affirm these uses as GRAS.

The agency has made a minor editorial change in 21 CFR 184.1157(c)(2). The agency reconsidered the proposed language in this section that referred to the use of benzoyl peroxide in milk used in the production of certain cheeses, as specified in the appropriate food standards. Because the proposed language could be considered vague and could be misinterpreted, the agency has revised § 184.1157(c)(2) to list the specific food standards for cheese under which benzoyl peroxide may be used.

The agency has carefully considered the potential environmental effects of this action and has concluded that the

action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the *Federal Register* of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an environmental assessment under 21 CFR 25.31a(a)(1).

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

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

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21

U.S.C., 321(s), 342, 348, 371); 21 CFR 5.10 and 5.61.

2. Part 184 is amended by adding new § 184.1157, to read as follows:

§ 184.1157 Benzoyl peroxide.

(a) Benzoyl peroxide $(C_6H_5CO)_2O_2$, CAS Reg. No. 94-36-0) is a colorless, rhombic crystalline solid. It is prepared by reaction of benzoyl chloride, sodium hydroxide, and hydrogen peroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 35, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a bleaching agent in food.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: flour; milk used for production of Asiago fresh and Asiago soft cheese (§ 133.102), Asiago medium cheese (§ 133.103), Asiago old cheese (§ 133.104), Blue cheese (§ 133.106), Caciocavallo siciliano cheese (§ 133.111), Gorgonzola cheese (§ 133.141), Parmesan and reggiano cheese (§ 133.165), Provolone cheese (§ 133.181), Romano cheese (§ 133.183), and Swiss and emmentaler cheese (§ 133.195) in Part 133 of this chapter; and annatto-colored whey, such that the final bleached product conforms to the descriptions and specifications for whey, concentrated whey, or dried whey in § 184.197(a) (1), (2), or (3), respectively.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: July 17, 1986.

James W. Swanson,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 86-17035 Filed 7-29-86; 8:45 am]

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