

discouraged by transshipping.* It follows, then, that the only pre-sale "service" which is fostered by this ban on transshipping is a non-discountable price, which some would say conveys an image of quality. I have never accepted this argument because it leads very logically to the position that resale price maintenance is an even stronger guarantee of that precious "prestige image".

Bulova demands the following of its authorized dealers in post-sale service capabilities: "The Bulova dealer must be capable of servicing and repairing the Bulova product or to [sic] expeditiously forward the product to Bulova corporate headquarters for service". Sixty percent of Bulova's authorized dealers fulfill their service obligations via the mailbox option. (Bulova petition pp. 4-5) Under these circumstances, I fail to see how a discount house's "no frills" sale tarnishes Bulova's image by allegedly offering the consumer less than is provided by authorized dealers.

[FR Doc. 83-34577 Filed 12-28-83; 8:45 am]

BILLING CODE 6750-01-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Baby Crib Requirements; Clarification of Effective Dates

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its baby crib rules to include the date that the Commission's requirements concerning the safety of cut-outs on panels of baby cribs became effective. Although the Federal Register issuance giving official notice of the requirements for crib panel cut-outs included the date the requirements were put into effect, the date did not specifically appear in all the applicable sections when the requirements were published in the Code of Federal Regulations (CFR). This amendment means only that the effective date of these requirements, which is already in operation, will

appear in all the applicable sections in future issues of the CFR.

EFFECTIVE DATE: The clarification will become effective December 29, 1983.

FOR FURTHER INFORMATION CONTACT: Christine Nelson, Directorate for Compliance and Administrative Litigation, Consumer Product Safety Commission, Washington, D.C. 20207, Phone (301) 492-6400.

SUPPLEMENTARY INFORMATION: Since February 1, 1974, in order to avoid being designated a banned hazardous substance under the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.), every full-size baby crib shipped in interstate commerce, must meet certain spacing requirements for components such as crib slats. (16 CFR 1500.18(a)(13)) Such slats must be sufficiently narrow to avoid entrapment of a baby. (16 CFR Part 1508) Since August 9, 1976, the same spacing requirements apply to non-full-size baby cribs. (16 CFR 1500.18(a)(14) and 1509).

From subsequent information and investigations, the Commission learned of deaths and injuries to children due to an additional head entrapment hazard—this one associated with certain cut-out designs near or at the top of crib panels (such as headboards or footboards). Investigation showed that children were able to stand at or climb up to the top of crib panels and become trapped by a cut-out opening large enough for the baby's neck to enter but too small for self-extrication of the baby's head.

To remedy the hazard, the full-size and non-full size crib rules were amended to address a neck and head entrapment hazard associated with certain design configurations of cut-outs on crib panels, by prohibiting cribs with such configurations (47 FR 47534, Oct. 27, 1982).

The Federal Register notice of the final rule addressing the neck and head entrapment hazard from cut-out designs on full-size and non-full-size crib panels, included the effective date of the rule, April 27, 1983. However, in transposing this document from the Federal Register to the CFR, the effective date of the new requirements which is cited at Parts 1508 and 1509 of 16 CFR, does not appear in the sections prohibiting shipment in interstate commerce of cribs with noncomplying cut-outs at § 1500.18(a)(13) and manufacture at § 1500.18(a)(14). To conform the prohibitions sections with the requirements sections of the regulations, the Commission amends the prohibitions sections of the crib rules to include all the effective dates now actually required for cribs shipped in interstate commerce. The Commission

believes this conformity will remove any confusion that may exist for the public due to the separation of the prohibitions and requirements of the crib rules.

Under the Administrative Procedure Act, the issuance or amendment of a rule must generally be preceded by a notice of proposed rulemaking and an opportunity for submission of written comments; a substantive rule is required to be published at least 30 days before its effective date. An exception exists for the notice and comment procedure when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that public procedure thereon are unnecessary or contrary to the public interest." 5 U.S.C. 553(b)(B).

In this case, the Commission finds that notice and comment rulemaking procedure is unnecessary because the regulations are to be amended only to include an effective date which is already in operation and which is duly noted in the requirements for full-size and non-full-size cribs. For this reason, the Commission also finds good cause to dispense with the 30-day delay in effective date provided at 5 U.S.C. 553(d) for publication of a substantive rule, particularly in light of the fact that these are technical amendments designed to clarify an effective date already noted in the requirements regulations.

List of Subjects in 16 CFR Part 1500

Consumer protection, Cribs, Infants, Children.

Part 1500—[Amended]

Therefore, pursuant to provisions of the Administrative Procedure Act, 5 U.S.C. 553, § 1500.18(a)(13) and section 1500.18(a)(14) of Title 16, Chapter II, Subchapter C of the Code of Federal Regulations are amended as follows:

§ 1500.18 [Amended]

1. In § 1500.18(a)(13), remove the words "Part 1508 of this chapter" and substitute therefor, the following:

(a) * * *

(13) * * * §§ 1508.2 through 1508.10 of this chapter; and any full size baby crib (as defined in § 1508.1(a) of this chapter) that is manufactured on or after April 27, 1983, and that does not comply with §§ 1508.2 through 1508.11 of this chapter.

* * *

2. In § 1500.18(a)(14), remove the words "Part 1509 of this chapter" and substitute therefor, the following:

(a) * * *

(14) * * * §§ 1509.3 through 1509.12 of this chapter; and any non-full size baby crib (as defined in § 1509.2 of this

* Even the seminal "Chicago School" exploration of the free rider theory limited its applicability to special services "specific to the commodity and unrelated to the retailers' methods of generally doing business. . . . This argument applies to products which are unfamiliar to the mass of consumers either because the product is new (or embodies new features) or because it is purchased infrequently by a relatively small proportion of households." Telser, "Why Should Manufacturers Want Fair Trade," J. Law Econ., 80, 89, 105 (October, 1960).

chapter) that is manufactured on or after April 27, 1983, and that does not comply with §§ 1509.3 through 1509.13 of this chapter.

Effective Date: The amendments shall become effective December 29 1983.

(5 U.S.C. 553; 15 U.S.C. 1261 et seq.)

Dated: December 23, 1983.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 83-34554 Filed 12-28-83; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 80N-0266]

Gras Status of Carbon Dioxide, Nitrogen, Helium, Propane, N-Butane, Iso-Butane, and Nitrous Oxide

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

SUMMARY: The Food and Drug Administration (FDA) is affirming that carbon dioxide, nitrogen, helium, propane, *n*-butane, iso-butane, and nitrous oxide are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: January 30, 1984.

FOR FURTHER INFORMATION CONTACT: Leonard C. Gosule, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 1, 1982 (47 FR 43392), FDA published a proposal to affirm that carbon dioxide, nitrogen, helium, propane, *n*-butane, iso-butane, and nitrous oxide are GRAS for use as direct human food ingredients. 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 reviews and the reports of the Select Committee on GRAS Substances (the Select Committee) on these gases are 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 also

are 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 carbon dioxide, nitrogen, helium, propane, *n*-butane, iso-butane, and nitrous oxide, FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients 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 8, 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 prior-sanctioned uses of these ingredients 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 carbon dioxide, nitrogen, helium, propane, *n*-butane, iso-butane, or nitrous oxide were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of these gases under conditions different from those set forth in this final rule has been waived.

FDA received one comment on carbon dioxide in response to the proposal. The comment submitted information on the use of carbon dioxide under high pressure in a liquid or supercritical fluid state as a solvent or vehicle for food processing and requested that the final rule be modified to include this use.

FDA has reviewed the information submitted with this comment and concludes that carbon dioxide liquid and supercritical fluid are significantly different from carbon dioxide gas both in their physical and chemical properties and in their potential use in foods. Therefore, the agency concludes that these substances are beyond the scope of the proposal, and the agency is not modifying the proposed regulation for carbon dioxide in response to this comment. However, FDA will consider issuing a separate GRAS or food additive regulation for liquid carbon dioxide and for supercritical carbon dioxide if GRAS or food additive petitions containing appropriate information are submitted to the agency in accordance with 21 CFR 170.35 or 171.1.

Thus, FDA is adopting the GRAS affirmation regulations for these gases with minor editorial changes.

In the proposal, FDA stated that it would work with the Committee on Codex Specifications (now known as the Committee on the Food Chemicals Codex) of the National Academy of Sciences to develop acceptable specifications for these gases used as direct food ingredients and would incorporate those specifications into the regulation when they were developed. To date, work on the specifications remains incomplete. Until the specifications are developed, the butanes, carbon dioxide, helium, nitrogen, nitrous oxide, and propane for direct food uses must comply with the descriptions in 21 CFR 184.1165, 184.1240, 184.1335, 184.1540, 184.1545, and 184.1655, respectively, and must be of a purity suitable for their intended use.

The agency has previously determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. FDA has not received any new information or comments that would alter its previous determination.

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

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

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§§ 182.1165, 182.1240, 182.1355, 182.1540, 182.1545, and 182.1655 [Removed]

1. Part 182 is amended by removing § 182.1165 *Butane*, § 182.1240 *Carbon dioxide*, § 182.1355 *Helium*, § 182.1540 *Nitrogen*, § 182.1545 *Nitrous oxide*, and § 182.1655 *Propane*.

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

2. Part 184 is amended:

a. By adding new § 184.1165, to read as follows:

§ 184.1165 n-Butane and iso-butane.

(a) *n*-Butane and iso-butane (empirical formula C_4H_{10} , CAS Reg. Nos. 106-97-8 and 75-28-5, respectively) are colorless, odorless, flammable gases at normal temperatures and pressures. They are easily liquefied under pressure at room temperature and are stored and shipped in the liquid state. The butanes are obtained from natural gas by fractionation following absorption in oil, adsorption to surface-active agents, or refrigeration.

(b) The Food and Drug Administration is developing food-grade specifications for *n*-butane and iso-butane in cooperation with the National Academy of Sciences. In the interim, the ingredients must be of a purity suitable for their intended use.

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

(1) The ingredients are used as propellants, aerating agents, and gases as defined in § 170.3(o)(25) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

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

b. By adding new § 184.1240, to read as follows:

§ 184.1240 Carbon dioxide.

(a) Carbon dioxide (empirical formula CO_2 , CAS Reg. No. 124-38-9) occurs as a colorless, odorless, noncombustible gas at normal temperatures and pressures. The solid form, dry ice, sublimates under atmospheric pressure at a temperature of $-78.5^\circ C$. Carbon dioxide is prepared as a byproduct of the manufacture of lime during the "burning" of limestone, from the combustion of carbonaceous material, from fermentation processes, and from gases found in certain natural springs and wells.

(b) The Food and Drug Administration is developing food-grade specifications for carbon dioxide in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations 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 leavening agent as defined in § 170.3(o)(17) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

c. By adding new § 184.1355, to read as follows:

§ 184.1355 Helium.

(a) Helium (empirical formula He, CAS Reg. No. 7440-59-7) is a colorless, odorless, flavorless, nonflammable, inert gas. It is lighter than air and is produced by the liquefaction and purification of natural gas.

(b) The Food and Drug Administration is developing food-grade specifications for helium in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no

limitations 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 processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

d. By adding new § 184.1540, to read as follows:

§ 184.1540 Nitrogen.

(a) Nitrogen (empirical formula N_2 , CAS Reg. No. 7727-37-9) is a colorless, odorless, flavorless gas that is produced commercially by the fractionation of liquid air.

(b) The Food and Drug Administration is developing food-grade specifications for nitrogen in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations 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 propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

e. By adding new § 184.1545, to read as follows:

§ 184.1545 Nitrous oxide.

(a) Nitrous oxide (empirical formula N_2O , CAS Reg. No. 10024-97-2) is also known as dinitrogen monoxide or laughing gas. It is a colorless gas, about 50 percent heavier than air, with a slightly sweet smell. It does not burn but will support combustion. Nitrous oxide is manufactured by the thermal decomposition of ammonium nitrate. Higher oxides of nitrogen are removed by passing the dry gas through a series of scrubbing towers.

(b) The Food and Drug Administration is developing food-grade specifications for nitrous oxide in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations 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 propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in dairy product analogs as defined in § 170.3(n)(10) of this chapter at levels not to exceed current good manufacturing practice.

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

f. By adding new § 184.1655, to read as follows:

§ 184.1655 Propane.

(a) Propane (empirical formula C_3H_8 , CAS Reg. No. 74-98-6) is also known as dimethylmethane or propyl hydride. It is a colorless, odorless, flammable gas at normal temperatures and pressures. It is easily liquefied under pressure at room temperature and is stored and shipped in the liquid state. Propane is obtained from natural gas by fractionation following absorption in oil, adsorption to surface-active agents, or refrigeration.

(b) The Food and Drug Administration is developing food-grade specifications for propane in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations 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 propellant, aerating agent, and gas as defined in § 170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

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

Effective date. This regulation is effective January 30, 1984.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))

Dated: November 23, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-34427 Filed 12-28-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Pyrantel Tartrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Hubbard Milling Co., providing for use of a 48-gram-per-pound pyrantel tartrate premix in making 9.6- and 19.2-gram-per-pound pyrantel tartrate intermediate premixes. The intermediate premixes are subsequently used to make complete swine feeds.

EFFECTIVE DATE: December 29, 1983.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: Hubbard Milling Co., 424 North Front St., Mankato, MN 56001, is sponsor of NADA 133-509 submitted on its behalf by Pfizer, Inc. The NADA provides for use of a 48-gram-per-pound pyrantel tartrate premix, supplied by Pfizer, Inc., in making 9.6- and 19.2-gram-per-pound pyrantel tartrate intermediate premixes. The intermediate premixes are used in making complete swine feeds for aid in prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; for aid in prevention of establishment, removal, and control of nodular worm (*Oesophagostomum*) infections; and for removal and control of large roundworm (*Ascaris suum*) infections.

The NADA is approved and the regulations are amended to reflect this approval. The basis for approval of this NADA is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) [21 CFR 514.11(e)(2)(ii)], a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch

(HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animals feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.485 by adding new paragraph (a)(16) to read as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.485 Pyrantel tartrate.

(a) * * *

(16) To No. 012190: 9.6 and 19.2 grams per pound, paragraph (e) (1) through (3) of this section.

Effective date. This amendment is effective December 29, 1983.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: December 19, 1983.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 83-34429 Filed 12-28-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Mac-Page, Inc., providing for safe and effective use of a 48-gram-per-pound pyrantel tartrate premix in making 9.6- and 19.2-gram-per-pound pyrantel tartrate intermediate premixes. The intermediate premixes are subsequently used to make complete swine feeds.

EFFECTIVE DATE: December 29, 1983.