d. "Harvest" means the removal of the ears and husks from the stalks for the purpose of delivery to the processor.

e. "Insurable acreage" means the land classified as insurable by us and shown as such by the actuarial table.

f. "Insured" means the person who submitted the application accepted by us.

g. "Loss ratio" means the ratio of indemnity(ies) to premium(s).

h. "Person" means an individual, partnership, association, corporation, estate, trust, or other business enterprise or legal entity, and wherever applicable, a State, a political subdivision of a State, or any agency thereof.

i. "Service office" means the office servicing your contract as shown on the application for insurance or such approved office as may be selected by you or designated by us.

j. "Tenant" means a person who rents land from another person for a share of the sweet corn or a share of the proceeds therefrom.

k. "Unit" means all insurable acreage of sweet corn in the county on the date of planting for the crop year:

(1) In which you have 100 percent share; or

(2) Which is owned by one entity and operated by another entity on a share basis. Land rented for cash, a fixed commodity payment, or any consideration other than a share in the sweet corn on such land will be considered as owned by the lessee. Land which would otherwise be one unit may be divided according to applicable guidelines on file in your service office or by written agreement with us. We will determine units as herein defined when the acreage is reported. Errors in reporting such units may be corrected by us to conform to applicable guidelines when adjusting a loss. We may consider any acreage and share thereof reported by or for your spouse or child or any member of your household to be your bona fide share or the bona fide share of any other person having an interest therein.

18. Descriptive headings.

The descriptive headings of the various policy terms and conditions are formulated for convenience only and are not intended to affect the construction or meaning of any of the provisions of the contract.

19. Determinations.

All determinations required by the policy will be made by us. If you disagree with our determinations, you may obtain reconsideration of or appeal those determinations in accordance with Appeal Regulations.

20. Notices.

All notices required to be given by you must be in writing and received by your service office within the designated time unless otherwise provided by the notice requirement. Notices required to be given immediately may be by telephone or in person and confirmed in writing. Time of the notice will be determined by the time of our receipt of the written notice.

Done in Washington, D.C., on December 26, 1984.

Peter F. Cole,

Secretary, Federal Crop Insurance Corporation.

Dated: January 8, 1985.

Approved by:

Merritt W. Sprague,

Manager.

[FR Doc. 85-1048 Filed 1-11-85; 8:45 am]

BILLING CODE 3410-08-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 498; Lemon Reg. 497; Amdt. 1]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action establishes the quantity of fresh California-Arizona lemons that may be shipped to the fresh market at 230,000 cartons during the period January 13–19, 1985, and increases the quantity of lemons that may be shipped to 255,000 cartons during the period January 6–12, 1985. Such action is needed to provide for orderly marketing of fresh lemons for such periods due to the marketing situation confronting the lemon industry.

DATES: The regulation becomes effective January 13, 1985, and the amendment is effective for the period January 6–12, 1985.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291 and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

This final rule is issued under Marketing Order No. 910, as amended (7 CFR Part 910) regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This action is based upon the recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy currently in effect. The committee met publicly on January 8, 1985, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified weeks. The committee reports that lemon demand is good.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effectve date until 30 days after publication in the Federal Register (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of lemons. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Marketing Agreements and Orders, California, Arizona, Lemons.

PART 910—[AMENDED]

1. Section 910.798 is added to read as follows:

§ 910.798 Lemon Regulation 498.

The quantity of lemons grown in California and Arizona which may be handled during the period January 13, 1985, through January 19, 1985, is established at 230,000 cartons.

2. Section 910.797 Lemon Regulation 497 is revised to read as follows:

§ 910.797 Lemon Regulation 497.

The quantity of lemons grown in California and Arizona which may be handled during the period January 6, 1985, through January 12, 1985, is established at 255,000 cartons.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: January 9, 1985.

Thomas R. Clark,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 85–1056 Filed 1–10–85; 8:45 am]

BILLING CODE 3410-02-M

7 CFR Part 989

[Docket No. F&V AO-198-A12]

Raisins Produced From Grapes Grown in California; Order Amending Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the California raisin marketing agreement and order program. The amendment was favored by the required two-thirds majority of growers voting in a referendum. The amendment adds authority for a Raisin Diversion Program (RDP). Provision was also made for an increase in the desirable carryout for Natural (sun-dried) Seedless (NS) raisins and for related conforming changes needed in the event the Committee determines an RDP is warranted. The RDP will provide the industry with a means of reducing raisin production by decreasing the quantity of grapes grown to be dried into raisins in order to bring the raisin supply more closely in line with market needs. The increase in the desirable carryout will make more NS raisins available from the prior year's production for early season shipment until new crop raisins are ready for processing and shipment in order to assist the industry to increase raisin shipments. The changes are expected to improve the effectiveness and operation of the marketing order program. The amendments were based on proposals submitted by the Committee which works with USDA in administering the program.

Based on the proposals made by the Committee, a public hearing was held on October 2, 1984, in Fresno, California. A referendum was conducted by the Department by mail ballot during December 15 through 24, 1984.

EFFECTIVE DATE: These regulations will become effective February 13, 1985, except that the addition of the RDP, § 989.56, will become effective January 8, 1985.

FOR FURTHER INFORMATION CONTACT: Frank M. Grasberger, Acting Chief, Specialty Crops Branch, Fruit and Vegetable Division, AMS, USDA, Washington, D.C. 20250. Telephone: (202) 447-5053.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of hearing—Issued September 20, 1984, and published September 24, 1984 (49 FR 37424); Final Decision—Issued December 5, 1984, and published December 11, 1984 (49 FR 48194). A correction to the final decision and referendum order was issued December 20, 1984 and published December 21, 1984 (49 FR 49834).

This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code, and therefore is not subject to the requirements of Executive Order 12291.

William T. Manley, Acting Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

Findings and determinations

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of the previously issued amendments thereto. Except the findings as to the base period for parity computation, and except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein, all of said prior findings and determinations are hereby ratified and affirmed.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon proposed amendment of the marketing agreement, as amended, and Order No. 989, as amended (7 CFR Part 989), regulating the handling of raisins produced from grapes grown in California.

Upon the basis of the record it is found that:

(1) The order, as amended and as hereby further amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The order, as amended, and as hereby further amended, regulates the handling of raisins produced from grapes grown in the production area in the same manner as, and is applicable only to persons in the respective classes of commercial and industrial activity specified in, the marketing agreement and order upon which hearings have been held;

(3) The order, as amended, and as hereby further amended, is limited in its application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the act;

(4) There are no differences in the production and marketing of raisins produced from grapes grown in the production area which make necessary different terms and provisions applicable to different parts of such area; and

(5) All handling of raisins produced from grapes grown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs or affects such commerce.

(b) *Additional findings.* For good cause it is necessary and in the public interest to make all of the amendatory provisions relating to the RDP effective upon signature. The authority for the RDP must be available immediately for the Committee to consider its adoption for the 1984–85 crop year. The raisin producers need to be given advance notice in order to consider their pruning and cultural practices during the dormant season which usually occurs during the months of December and January. If the 30 day requirement period after publication were adopted for this year, producers would not be permitted sufficient time to participate in the program.

The increase in the desirable carryout, the change in the "definition of producer", and the addition to the marketing policy of tonnage diverted will not be used until at least the end of the crop year ending July 31, 1985. Therefore, these changes will not become effective until 30 days after publication in the **Federal Register** (section 553(d), Administrative Procedure Act, 5 U.S.C. 551–559).

(c) *Determinations.* It is hereby determined that:

(1) The "Marketing Agreement, as Amended, Regulating the Handling of Raisins Produced from Grapes Grown in California" upon which the aforesaid public hearing was held has been signed by handlers (excluding cooperative associations of producers who are not engaged in processing, distributing, or shipping covered by the said order, as amended, and as hereby further amended) who, during the period August 1, 1983 through July 31, 1984, handled not less than 50 percent of the volume of such raisins covered by the said order, as amended, and as hereby further amended, and

(2) The issuance of this amendatory order, amending the aforesaid order, as amended, is favored or approved by at least two-thirds of the producers who participated in a referendum on the question of its approval and who during

the period August 1, 1983 through July 31, 1984 (which has been deemed to be a representative period), have been engaged within the State of California, in the production of grapes which were sun-dried or dehydrated by artificial means until they became raisins for market, such producers having also produced for market at least two-thirds of the volume of such commodity represented in the referendum.

List of Subject in 7 CFR Part 989

Marketing agreements and orders, Grapes, Raisins, California.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, the handling of raisins produced from grapes grown California shall be in conformity to and in compliance with the terms and conditions of the said order, as hereby amended, as follows:

PART 989—[AMENDED]

1. Section 989.11 is revised to read as follows:

§ 989.11 Producer.

"Producer" means any person engaged in a proprietary capacity in the production of grapes which are sun-dried or dehydrated by artificial means until they become raisins: *Provided*, That a "producer" shall include any person whose production unit has qualified for diversion under a diversion program announced by the Committee.

2. Section 989.54(a) is amended by revising the fifth sentence to read as follows:

§ 989.54 Marketing policy.

(a) *Trade demand.* * * * The desirable carryout shall be increased from 45,000 to 60,000 tons for Natural (sun-dried) Seedless raisins at a rate of 5,000 tons per year for three crop years following the effective date of this amended subpart. * * *

3. Section 989.54(b) is amended by adding a proviso at the end of the first sentence to read as follows:

§ 989.54 Marketing policy.

* * * * *

(b) * * *: *Provided*, That such production estimate shall include by varietal type the raisins handlers are expected to acquire from producers and the total tonnage of raisins diverted under a raisin diversion program.

* * * * *

4. A new § 989.56 is added to the order to read as follows:

§ 989.56 Raisin diversion program.

(a) *Announcement of program.* On or before November 30 of each crop year, the Committee shall hold a meeting to review production data, supply data, demand data, including anticipated demand to all potential market outlets, desirable carryout inventory and other matters relating to the quantity of raisins of all varietal types. When the Committee determines that raisins exist in the reserve pool in excess of projected market needs for any varietal type, it may announce the amount of such tonnage eligible for diversion during the subsequent crop year. At the same time, the Committee shall determine and announce to producers, handlers, and the cooperative bargaining association(s) the allowable harvest cost to be applicable to such diversion tonnage: *Provided*, That during the 1984–85 crop year, these actions shall be taken as soon as practicable after the effective date of this amended subpart.

(b) *Voluntary diversion.* No producer shall be required to participate in any raisin diversion program.

(c) *Issuance of diversion certificates.* After the Committee announces a raisin diversion program, any producer may divert grapes of his/her own production and receive from the Committee a diversion certificate in accordance with the applicable rules and regulations. Such certificates only may be submitted by producers to handlers in accordance with applicable rules and regulations. Diversion certificates issued by the Committee shall apply to a specific production unit and shall be equal to the creditable fruit weight of such raisins produced on such unit during the prior crop year or the last prior crop year eligible for such diversion.

(d) *Redemption of diversion certificates.* Handlers may redeem diversion certificates for reserve pool raisins. To redeem a certificate, a handler must present the diversion certificate to the Committee and pay the Committee an amount equal to the harvest cost it has established for the entire tonnage represented on the diversion certificates. Upon receipt of the diversion certificate, the Committee shall note on the certificate that it is cancelled.

(e) *Implementation of the program.* The Committee shall establish, with the approval of the Secretary, such rules and regulations as may be necessary for the implementation and operation of a raisin diversion program.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C 601–674)

Dated: January 8, 1985.

The amendatory provisions relating to the Raisin Diversion Program will become effective on January 8, 1985. All other changes will become effective 30 days after publication in the **Federal Register**.

C.W. McMillan,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 85-979 Filed 1-11-85; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

[Regulations No. 4]

Federal Old-Age, Survivors, and Disability Insurance; Sick Pay

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: These rules implement section 3 of Pub. L. 97–123 with respect to employees of State and local governments who are covered by Social Security pursuant to agreements under section 218 of the Social Security Act (the Act). They provide that sickness and accident disability payments (or sick pay) paid in the six calendar months after the calendar month the employee stopped working are wages (with certain exceptions) when paid to the employee or the employee's dependents. Corresponding provisions with respect to Social Security tax requirements for private sector employers and employees have been implemented by Internal Revenue Service (IRS) regulations. Also, to the extent that "wages" are defined for other purposes, e.g., Social Security benefit computation, these regulations are applicable to all covered employees. Under the prior law, sick pay paid in the six calendar months after the employee stopped working was not wages if paid under a qualified plan or system set up by the employer.

We published a Notice of Proposed Rulemaking on April 20, 1984 (49 FR 16805) concerning these sick pay provisions. No comments were received. No changes have been made with respect to these final regulations except for minor, technical corrections.

DATE: These regulations are effective January 14, 1985.

FOR FURTHER INFORMATION CONTACT: C.H. Campbell, Legal Assistant, Office of Regulations, Social Security

Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, (301) 597-3408.

SUPPLEMENTARY INFORMATION: Section 209(b) of the Social Security Act, which describes when sick pay under a plan or system is not treated as wages for Social Security coverage purposes, was amended by section 3(a) of Pub. L. 97-123. The amended section excludes from the term "wages" only payments received under a workmen's compensation law. The parallel section in the Internal Revenue Code (IRC)—section 3121(a)(2)—was similarly amended.

The statutory amendment was effective on January 1, 1982. The attached regulations which implement this statutory amendment provide that sick pay paid to an employee or his or her dependents on or after January 1, 1982 in the 6-calendar month period immediately following the last calendar month in which the employee worked is wages except that any portion of the sick pay attributable to the employee's own contribution to a sickness or accident disability plan is not wages. Under the law that was in effect prior to January 1, 1982, sick pay paid in the 6-calendar month period following the last month in which the employee worked and paid under a qualified plan or system set up by the employer, is not wages.

Sick pay paid more than six calendar months after the calendar month in which the employee stopped working continues to be excluded from wages. Also, payments to employees under a worker's compensation law continue not to be treated as wages and we are including in the attached regulations a statement to that effect.

Sick Pay Paid by a Third Party Payor

In accordance with the statutory amendment, these rules provide that sick pay includes third party payments (e.g., insurance company payments). Consequently, sick pay paid to an employee by a third party is wages unless it is attributable to the employee's contributions to a sickness or accident disability plan (e.g., employee-paid insurance premiums).

Note.—We published on September 30, 1983 in the **Federal Register** (see 48 FR 44771) a final regulation on a State government's responsibility to pay Social Security contributions (equivalent to the combined employer and employee tax imposed on private employers) on the sick pay paid the employee by the third party. This separate regulation provides that sick pay is considered paid when the employer receives notice of the payment from the third party. This regulation should allow employers adequate notice of the sick pay payment so that they may make timely payment of the Social Security contributions and avoid being assessed interest charges for late payment.

Temporary Disability Insurance (TDI) Payments

Section 3(e) of Pub. L. 97-123 provides that payments under a State's temporary disability insurance (TDI) laws are wages. These State TDI laws compensate employees who are unable to pursue gainful employment because of short-term nonoccupational sickness or accident disability. Only 6 States have such programs: California, Rhode Island, New York, New Jersey, Hawaii, and Puerto Rico.

These regulations provide that TDI payments made in the 6-calendar months period immediately following the last calendar month in which the employee worked for the employer are wages, excluding any portion of the payments attributable to the employee's contribution.

Regulatory Procedures

Executive Order 12291—These rules have been reviewed under Executive Order (EO) 12291 and do not meet the criteria for a major regulation. They will directly affect only States (and, indirectly local government employers). Determinations of amount of Social Security contributions due on wages of State and local employees for Social Security purposes is under the jurisdiction of the Social Security Administration (SSA). (Taxation of wages of other employees for Social Security purposes is under the jurisdiction of the Internal Revenue Service.) Increased contributions from coverage of sick pay of employees of State and local governments should remain in the $12 million through $14 million range for each fiscal year from 1984 through 1986. Since these rules do not have an effect on the economy of $100 million or more in a single year, they do not constitute a major regulation under E.O. 12291. Additionally, these costs are primarily attributable to a change in the law and not to any regulatory changes that are based on the statutory changes.

Paperwork Reduction Act—These regulations impose no reporting/recordkeeping requirements requiring OMB clearance.

Regulatory Flexibility Act—We certify that these regulations will not have a significant economic impact on a substantial number of small entities because any impact will be solely the result of legislation rather than these regulations. Therefore, a regulatory flexibility analysis, as required by Pub. L. 96-354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Programs: No. 13.802 Social Security Disability Insurance; No. 13.803 Social Security—Retirement Insurance; No. 13.805 Social Security—Survivors Insurance)

List of subjects in 20 CFR 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-Age, Survivors, and Disability Insurance.

Dated: October 5, 1984.

Martha A. McSteen,

Acting Commissioner of Social Security.

Approved: December 11, 1984.

Margaret M. Heckler,

Secretary of Health and Human Services.

PART 404—[AMENDED]

For the reasons set out in the preamble, Part 404 of Chapter III, title 20, of the Code of Federal Regulations is amended as follows:

Subpart K—Employment, Wages, Self-Employment and Self-Employment Income

1. The authority citation for Subpart K reads as follows:

Authority: Secs. 205, 209, 210, 211, 229, 230, 231, and 1102 of the Social Security Act, 53 Stat. 1368, 49 Stat. 625, 64 Stat. 492, 81 Stat. 833, 86 Stat. 416, 86 Stat. 1367, 49 Stat. 647; sec. 5 of Reorganization Plan No. 1 of 1953; 67 Stat. 631, 42 U.S.C. 405, 409, 410, 411, 429, 430, 431, and 1302; and 5 U.S.C. Appendix.

2. In § 404.1049 paragraph (a)(2) is revised to read as follows:

§ 404.1049 Payments under an employer plan or system that are excluded from wages.

(a) * * *

(2) You or your dependents'—

(i) Medical or hospitalization expenses connected with sickness or accident disability; or

(ii) Death.

* * * * *

3. In § 404.1051, the section title is revised to read as follows:

§ 404.1051 Payments on account of sickness and accident disability or related medical or hospitalization expenses—paid more than 6 months after work stopped.

* * * * *

4. A new § 404.1051A is added to read as follows:

§ 404.1051A Payments on account of sickness and accident disability—paid in the 6-month period after work stopped.

(a) *Payments made prior to January 1, 1982.* Sickness and accident disability

payments that are paid by the employer to or on behalf of the employee or employee's dependents or into a fund to provide for such payments are excluded from wages if—

(1) Paid prior to January 1, 1982 and

(2) Paid under a plan or system set up by the employer; or

(3) Paid more than 6 calendar months after the month the employee last worked.

(b) *Payments made after December 31, 1981.* (1) Except when the payment amount is attributable to the employee's contribution, any sickness or accident disability payments paid by an employer or third party to an employee or the employee's dependents, or paid under a State temporary disability insurance (TDI) program to an employee, that are paid within the initial 6-calendar month period after the last calendar month the employee worked, are wages.

(2) Employee contributions to employers' sickness and accident disability plans may include the premiums paid by an employee under an insurance contract providing for payments to the employee in the event of disability or the contributions paid by an employee to a State TDI fund for payments to the employee in the event of disability. Such contributions are wages when deducted from the employee's pay, but the benefits paid to the employee or employee's dependents as sickness or accident disability payments that are based on such contributions are not wages.

(c) Employer premium contributions for insurance or into a fund to provide payments to an employee upon the future occurrence of sickness and accident disability are not wages. However, see paragraphs (a) and (b) of this section regarding payments from the insurance or fund paid to the employee upon the occurrence of sickness or accident disability.

(d) Payments that are paid to the employee under a worker's compensation law are not wages.

(e) For purposes of this section, the employee's dependents include the employee's husband or wife, children, and members of the immediate family.

[FR Doc. 85-1008 Filed 1-11-85; 8:45 am]
BILLING CODE 4910-11-M

Food and Drug Administration

21 CFR Parts 105 and 107

[Docket No. 82N-0130]

Infant Formula; Labeling Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing labeling requirements for infant formula, including the label declaration of nutrients required by the Infant Formula Act of 1980; a "use by" date; a warning statement to inform consumers of consequences of improper preparation or use; a statement informing consumers that infant formula should be used as directed by a physician; and directions for preparation and use, including pictograms and a symbol to indicate the need for dilution. An exemption from certain labeling requirements is provided for individual containers containing infant formula in a ready-to-feed form in multiunit packages. This final rule provides necessary information to health care professionals and consumers, including those who cannot read English, on the appropriate preparation and use of infant formulas to assure the health and well being of formula-fed infants.

DATES: This final rule will become effective on January 14, 1986 for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after that date. Objections by February 13, 1985 on §§ 105.65 (c), (d), and (e) and 107.10.

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

FOR FURTHER INFORMATION CONTACT: Nicholas Duy, Center for Food Safety and Applied Nutrition (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3117.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 12, 1983 (48 FR 31880), FDA proposed to establish labeling regulations for infant formula to: (1) Require that nutrients be declared in a specified format; (2) require a statement of the number of fluid ounces supplying 100 kilocalories; (3) require the declaration of water and carbohydrate levels in addition to the nutrients required by the Infant Formula Act; (4) permit vitamin A, vitamin D, and vitamin E content to be declared parenthetically in alternative units in addition to the required International Units; (5) require a statement concerning iron content on the principal display panel; (6) require the heading "DIRECTIONS FOR PREPARATION AND USE" and beneath this heading directions for storage, preparation, and use; (7) require a pictogram depicting the major steps for preparation of that infant formula; (8) require a "Use by" or "Expiration" date and its declaration; (9) require the statement "add water" or "do not add water", as appropriate, to appear on the principal display panel; and (10) require, for concentrated infant formulas, a symbol indicating the need for the addition of water on the principal display panel. Interested persons were given until September 12, 1983, to comment on the proposal.

In response to the proposal, FDA received 96 letters, each containing 1 or more comments, from consumers, health care professionals, universities, food assistance program directors, trade organizations, State and county departments of health, consumer advocacy organizations, a foreign government, and professional organizations. All letters, except one, supported the proposal, at least in part. A number of comments did not address the issues raised by the proposal and are not discussed in this document. In response to the comments, FDA revised some proposed requirements and added some provisions. These changes (1) permit sodium, potassium, and chloride levels to be declared parenthetically in alternative units; (2) permit, under certain conditions, the declaration of nutrients not required by the Infant Formula Act; (3) require "use by" dating, rather than "use by" or "expiration" dating; (4) delete the proposed requirement for declaration of maximum recommended storage temperatures; (5) require a warning statement about the importance of following directions for preparation or use; (6) require a statement that parents should consult their physicians about the use of infant formulas; and (7) provide an exemption from some labeling requirements for individual containers of ready-to-feed formulas in multiunit packages.

The comments on the proposal and the agency's responses are as follows:

GENERAL COMMENTS

1. One comment requested that the lettering size for the nutrient information be increased to at least one-eighth inch high and that any warning or directional information be increased to at least one-quarter inch high.

FDA advises that this requested change is inappropriate for this proceeding. The agency's minimum type size requirements (one-sixteenth inch high) for most food packages, including infant formulas, are set forth in § 101.2 (21 CFR 101.2) and therefore any change in these requirements would have to be proposed in the **Federal Register** with an opportunity for interested persons to comment. The agency will entertain petitions to amend § 101.2 from anyone

interested in changing the minimum type size requirements for infant formula labels where the petitioner can demonstrate a need for such a change.

2. One comment suggested requiring package inserts so that written information that could be verified by the consumer could be provided.

The agency has not adopted this requirement because it would be merely a duplication of the label information required by these regulations. Thus, requiring package inserts would be costly to manufacturers, thereby increasing the cost without additional benefits to the consumer. The comment provided no information to justify the additional cost of requiring package inserts.

3. One comment asked how much cost would be added to infant formulas by requiring these label changes.

The agency stated in the preamble to the proposal that these regulations will impose a one-time estimated cost of $50,000 for the industry. Because sales of infant formulas in the United States are estimated to exceed $500 million annually, the cost of these regulations will not have a perceptible effect on the retail price of infant formula. The few revisions made in the final rule will not significantly change these estimates.

4. One comment stated that artificial colors or flavors should not be in foods.

The agency advises that it is unaware of any manufacturer who uses color additives or artificial flavors in infant formulas. The agency further advises, however, that if a manufacturer wanted to use color additives or artificial flavors in infant formulas, the agency could not preclude such usage if all applicable regulations governing the use of color additives and flavoring ingredients are complied with. The agency points out that, in the event color additives or artificial flavors are used, § 101.22(c) requires their declaration on the label, thereby giving those consumers who wish to avoid these ingredients the opportunity to do so.

5. One comment recommended extending the effective date to at least 1 year after the date of publication. The comment stated that this final rule requires changing labels for every product made by every infant formula manufacturer, and that these changes cannot be completed in 6 months.

The agency agrees with this recommendation. The agency encourages manufacturers to make these changes as soon as possible. Except as to any provisions that may be stayed by the filing of proper objections, all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 14, 1986 shall fully comply with this final rule.

6. One comment suggested the elimination of concentrated infant formulas because of the possibility of inappropriate and unsafe use of the product. Another comment recommended that FDA prohibit the sale of infant formulas in areas where consumers may not fully understand how to prepare and use the product safely.

The agency advises that Congress has not given FDA the authority to prohibit the sale of a food or the authority to seize a food unless it is adulterated or misbranded. Moreover, FDA has no data to suggest that concentrated infant formulas present a safety problem.

7. Two comments expressed concern about "overloaded" and complex regulations and their lack of clarity.

The agency does not believe that the regulations are unclear, overloaded, or overly complex. To the contrary, the objective of this final rule is to simplify, clarify, and provide a uniform format for infant formula labeling. Many manufacturers are currently voluntarily providing much of the information required by this final rule. However, the information provided is not always presented in a clear, concise, uniform manner. The agency believes that this final rule will rectify this.

8. One comment suggested providing the same information that is required in the United States on labels of exported infant formula.

Such a requirement would be impossible to meet if the labeling requirements of the country of destination are incompatible with U.S. labeling requirements. Furthermore, under section 801(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(d)), an infant formula produced in the United States but intended for export need not comply with these labeling regulations if it complies with the requirements of the country of destination. Therefore, FDA has not made the requested change.

9. One comment suggested that labeling information should include whether or not the product is kosher.

Section 101.29 specifically permits the voluntary use of the term "kosher" on labels and gives guidance on its use. Therefore, the agency concludes that the current regulations contain adequate provisions for the labeling of infant formulas as "kosher" and has not made the requested change.

Nutrient Information

10. Several comments suggested that the source of major nutrients, such as protein or fat, be identified clearly on the label because some infants have allergies to specific sources of a nutrient such as milk protein. A few comments recommended listing items such as salt, sugar, water, fat, and monosodium glutamate (MSG) on the label.

The label declaration of the ingredients requested by these comments is already required by existing regulations. Section 105.65(a) (21 CFR 105.65(a)) specifically requires that foods represented for special dietary use for infants bear the common or usual name of each ingredient including flavors and colors. Section 105.65(b) states that if such food for infants, or any ingredient thereof, consists of an ingredient that does not clearly reveal the specific plant or animal that is its source, such name shall be so qualified as to reveal clearly the specific plant or animal that is the source. Therefore, those individuals concerned with the source of an ingredient or with the presence of salt, sugar, water, fat, or MSG can obtain the information they need from the ingredients statement. In addition, if the infant formula is not a milk-based formula, the source of the protein, i.e., soy or meat, is also typically identified prominently on the principal display panel. Therefore, no changes are made in this final rule concerning the declaration of these ingredients.

11. Two comments recommended that "cow's milk" be declared on the label rather than the generic word "milk."

The agency advises that § 131.110 (21 CFR 131.110) defines milk as the lacteal secretion obtained from one or more healthy cows. All foods containing "cow's milk" list "milk" as the ingredient. If some other milk is an ingredient then the description of the ingredient includes the animal's name (e.g., goat's milk). The comment provided no information or data to justify making the suggested change. Therefore, no changes are made in the final rule concerning the declaration of "cow's milk."

12. One comment stated that a tabular format for nutrient information cannot be accommodated on labels for 8- and 13-fluid ounce cans because current minimum type size requirements, along with additional required information in the "Directions For Preparation and Use" section, preclude compliance with this requirement.

The agency disagrees that the information required by this regulation cannot be accommodated on the labels of 8- and 13-fluid ounce cans. Many 8- and 13-fluid ounce cans used by infant formula manufacturers either now bear or previously bore a tabular declaration

of nutrients and most of the other information required by this final rule. This indicates to the agency that all the information required by the regulations can be accommodated on the cans.

13. One comment, from an official of a foreign government, suggested that the proposed order of declaring nutrients in a tabular format be modified to be consistent with their regulation in an attempt to "harmonize" the regulations of the two countries.

The agency concludes that it is impossible to completely "harmonize" the regulations of the United States and foreign countries. Each country has its own labeling requirements, such as language, units of measurements, etc., which may require the development of separate labels for each country to which a manufacturer wishes to export. The agency agrees that modifying the order of the nutrient declarations on the label may "harmonize" somewhat the product labels of the United States and one foreign country, but it provides no guarantees for any international consistency in infant formula labeling. Therefore, no change in the order of declaring nutrients has been made in this final rule.

14. One comment stated that there was no reason to include a listing of specific nutrients in the labeling of an infant formula and suggested that the statement "the product provides 100% of the known nutrient needs of a normal infant" replace the proposed nutrient table. The comment further suggested that the labeling information be targeted for use by consumers and that professionals could obtain this information in other ways. Another comment recommended that the declaration of linoleic acid be deleted because all infant formulas contain essential fatty acids well in excess of the statutory minimum and because this information might cause a consumer to select a formula with higher levels of linoleic acid even though there is no added benefit from the higher levels. One comment specifically supported the declaration of linoleic acid.

Based on evidence received during hearings held in 1968, FDA concluded in the **Federal Register** of December 10, 1971 (36 FR 23553), that it is "reasonable and necessary" for physicians and consumers to be informed fully of the value of foods for special dietary use for infants by requiring that the labels of such foods bear information concerning the kinds and amounts of nutrients present. The continued need for this information was supported during the public hearing on the nutrient composition of infant formulas held March 12, 1980, and by comments received in response to the proposed regulation. Moreover, no data were submitted in support of the position that such information is unnecessary. Therefore, the agency reaffirms the conclusion that the nutrient information is necessary for fully informing health care professionals and consumers about the nutrient composition of infant formula so that they may deal effectively with problems that may present themselves in infant feeding. The agency is requiring the declaration of all required nutrients on infant formula labels, including linoleic acid, as proposed.

15. One comment suggested that a description of the value of the nutrients contained in infant formulas appear on the label, or if that was not possible, that the label list the essential nutrients that may be missing and state how they should be added to the diet.

The agency is not requiring a description of each nutrient's value on the label because the label is not the appropriate medium for discussion of the importance of nutrients in foods. This information, if needed, can be obtained from a nutrition text book. The agency is also not requiring the listing of missing nutrients on the label because the level of all nutrients recommended to be in infant formulas by the American Academy of Pediatrics is required to be present. Therefore, no change in this final rule has been made concerning describing a nutrient's value and declaring any missing nutrients.

16. Some comments suggested changing the units of measure of one or all nutrients. Recommendations for individual nutrients included changing the units for thiamine, riboflavin, niacin, vitamin B_6, pantothentic acid, and copper from micrograms to milligrams to be consistent with units specified in the U.S. Recommended Daily Allowance (U.S. RDA) as used in nutrition labeling of ordinary foods.

The agency is not making the suggested changes. The agency recognizes that its measurement system cannot be consistent with the measurement systems of all recognized nutritional authorities. However, the units of measure contained in the final rule are consistent with both the Committee on Nutrition/American Academy of Pediatrics and the Joint Food and Agriculture Organization/World Health Organization's Codex Alimentarius Commission recommendation, which express the levels of these nutrients in units of micrograms.

17. One comment suggested changing the unit of measure for niacin from micrograms to niacin equivalents.

This issue is being addressed in a separate rulemaking proceeding in which the agency proposed revising the unit of measure for niacin from micrograms to niacin equivalents (see 49 FR 14396; April 11, 1984). This comment will therefore be considered in that rulemaking proceeding.

18. Two comments suggested that alternative units for the label declaration for vitamins A, D and E not be provided. Both comments recommended a single standardized unit for easy product comparison.

The agency disagrees. The final rule allows voluntary declaration of vitamins A, D, and E in alternative units because many health care professionals use this nomenclature and calculations of levels of these nutrients in a diet are made easier when their concentrations are provided in these units. Furthermore, use of these alternative units is in addition to, not instead of, declaration of these nutrients in standard units, thereby giving the consumer a basis for easy product comparison. Therefore, § 107.10(b)(1) has not been changed to delete this provision.

19. One comment recommended declaring sodium, potassium, and chloride in units of millimoles or micromoles. Another comment suggested the use of milliequivalents.

The agency recognizes the usefulness to health professionals of information on sodium, potassium, and chloride in terms of millimoles, micromoles, or milliequivalents. Accordingly, the agency has revised § 107.10(b)(1) to provide for the voluntary label declaration of the level of these minerals in millimoles, micromoles, or milliequivalents parenthetically, immediately following the declaration in milligrams per 100 kilocalories.

20. Several comments responded to the agency's request for information from health care professionals and consumers on their ability to understand and use the required nutrient declarations when expressed on a per 100 kilocalorie basis. Some of these comments suggested that the use of a 100 kilocalorie basis was satisfactory as long as the label clearly indicates what volume is equivalent to 100 kilocalories. One comment recommended that the number of milliliters, as well as fluid ounces, supplying 100 kilocalories be declared. Other comments recommended caloric density declarations, i.e., specifying the number of kilocalories per liter or 100 milliliters. One comment recommended specifying the number of kilocalories per fluid ounce. One comment requested that the caloric value of protein, fat, and

carbohydrate be listed as kilocalories per 100 kilocalories. Other comments recommended listing amounts of nutrients or caloric concentration on a volume basis (such as per liter, per cup, per serving, or per can) as more meaningful to consumers.

To attempt to accommodate this diversity of opinion and still provide sufficient uniformity so that different products can be easily compared, the agency is requiring that nutrients be declared on a 100 kilocalorie basis and is allowing for additional bases or units of measurement to be declared voluntarily by the manufacturer as proposed. Therefore, no change was made in proposed § 107.10(a)(2).

The agency agrees with the comments suggesting that an alternative declaration of caloric density be permitted and proposed § 107.10(b)(3) has been revised to so provide. By allowing this flexibility, the agency believes the final rule will accommodate this diversity of opinion and also allow for future changes.

21. One comment objected to the wording in the proposed iron labeling requirement, but suggested that if such a statement was necessary, it appear on the information panel because the statement "Additional Iron May Be Necessary" is precautionary in nature. The comment suggested that a statement of identity such as "Low Iron" is more appropriate.

The agency believes that iron fortification is the one characteristic that distinguishes the two basic types of infant formulas. Therefore, the statement about iron content is considered to be part of the name of the infant formula and must appear on the principal display panel, rather than on the information panel.

"Additional Iron May Be Necessary" is only an example of the kind of statement that can be used to convey the message that the product is not iron fortified. The agency does not believe that it is necessary to revise § 107.10(b)(4)(ii) to include additional examples of the label statement to be made when an infant formula contains less than 1 milligram of iron per 100 kilocalories.

22. One comment stated that it understood that additional nutrients (other than those required by the Infant Formula Act) could be declared as long as they are listed at the bottom of the appropriate category.

The comment's understanding of the agency's position on declaration of additional nutrients is essentially correct. However, to avoid any inconsistencies in label declarations, the agency is adding § 107.10(b)(5) to specify how these declarations are to be made. This section provides for the voluntary declaration of any additional nutrients at the bottom of the vitamin list if the nutrient is a vitamin, and between iodine and sodium if the nutrient is a mineral, provided that any additionally declared nutrient (1) has been identified as an essential dietary nutrient by the National Academy of Sciences (NAS) through its development of a recommended dietary allowance or an estimated safe and adequate daily dietary intake range, or has been identified as essential by FDA through publication in the **Federal Register** or establishment of a U.S. RDA, and (2) is provided at a level considered in these publications as having biological significance, when these levels are known.

Declaration of nutrients that are not required by the Infant Formula Act, not considered to be essential by the NAS or FDA, and not at levels considered to have biological significance is considered to be a misbranding violation under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)), because including such nutrients in the nutrient table or declaring a nutrient at a level that may not have biological significance implies a level of significance or usefulness in human nutrition that has not been established.

23. Two comments recommended that the amount of fluoride in the formula be declared on the label.

FDA believes that consumers associate the declaration of nutrients in infant formulas with the dietary need for those nutrients and the presence of such nutrients at biologically significant levels. The agency recognizes that fluoride is an essential element in the development and formation of bones and teeth and, at appropriate levels, is a major factor in the prevention of dental caries. However, the agency has concluded that infant formula is not an appropriate vehicle in which to provide fluoride in an infant's diet and is therefore not requiring a minimum (biologically significant) level of fluoride to be added to infant formulas. FDA is also not requiring the declaration of fluoride on the label because a biologically significant level is not being required.

The basis for this decision is threefold. First, because of the wide variation of fluoride levels in public water sources, there is the possibility that infants could receive excessive fluoride in their diets if they were also to receive biologically significant levels of fluoride from infant formulas. This could lead to mottling of the infant's teeth. Second, because of the wide variation in fluoride levels in public water sources, manufacturers have made it a common practice to limit the amount of fluoride in infant formulas. Third, it has become a common practice for physicians to prescribe fluoride supplements that may be adjusted according to the amounts of fluoride present in the water supply in their particular area.

24. One comment suggested that labels for iron fortified infant formula contain the warning statement that iron will cause stool darkening that is harmless to the infant.

The agency is not providing for this warning statement because stool darkening may be caused by components of the diet other than infant formula and can be an indication of a serious medical condition such as internal bleeding which may need medical attention.

Directions for Use

25. One comment stated that the infant formula label should designate the need for "pure drinking water." Another comment referred to the need for "potable" or "sterile" water.

The agency agrees that "potable" or "sterile" or "pure drinking water" must be used in preparing infant formula and advises that the directions for preparation and use already indicate this need by specifically directing consumers to the need for "sterilizing" water used in preparing the infant formula. Therefore, no changes are made in the final rule concerning the use of "potable," "sterile," or "pure drinking water."

26. Several comments supported requiring bilingual directions for the preparation and use of infant formulas. Some of these comments realized the space restrictions on a label and suggested that formula labels in Spanish be made available only to retailers with a high proportion of Spanish-speaking clientele. Others suggested following the labeling used by an infant formula manufacturer that uses the reverse side (inside) of the label for Spanish directions for use. One comment asserted that the argument against requiring bilingual labeling due to space limitations is not persuasive given that the infant formula companies already comply with Canadian laws mandating bilingual labeling.

As indicated in the preamble to the proposal, difficulties with a requirement for multilingual labeling include literacy in any language and space limitations on labels. The comment that the space limitation argument is invalid because bilingual labeling is already used in Canada does not take into account that

Canadian regulations do not include requirements for pictograms, symbols, or statements that are required by this final rule. The agency believes that providing labels in the Spanish language to those retailers with a high proportion of Spanish-reading clientele has been addressed by manufacturers by providing pamphlets in Spanish. Pamphlets in other languages have also been provided for retail establishments frequented by other non-English-reading clientele.

In addition, the agency advises that it cannot legally require bilingual or multilingual labeling on the reverse side (inside) of the label because section 403(f) of the act (21 U.S.C. 343(f)) deems a food to be misbranded if any word, statement, or other information required by or under its authority to appear on the label or labeling is not prominently placed, with such conspicuousness and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The agency does not believe that labeling information placed on the reverse side (inside) of the label is prominently placed with such conspicuousness as to render it likely to be read under customary conditions of purchase and use. The agency also believes that the use of symbols and pictograms will adequately convey essential label information to consumers who cannot read English or perhaps any language. Therefore, the agency is not requiring bilingual or multilingual labeling in this final rule. However, the agency does not object to voluntary use of the reverse side (inside) of a label for multilingual labeling.

27. Several comments recommended mandatory label color coding to assist consumers, particularly those consumers who have difficulty reading English, to differentiate between the various types of infant formulas. One comment was opposed to color coding due to cost considerations. Another comment pointed out the problem of brand differentiation that could result if all formulas of a given type were the same color. One comment suggested colors for six types of formula. Another comment expressed concern about the possibility of one type of infant formula selling better because of an assigned color. Another comment suggested that regular infant formulas and infant formula for infants with special dietary needs could be distinguished by a color code. Two comments suggested that FDA study (using a contractor) the appropriate use of colors to distinguish types of formulas.

As indicated in the preamble to the proposal, food and other consumer product manufacturers routinely conduct proprietary research on the effectiveness of package designs. However, there is no satisfactory body of scientific or other empirical data from which the effectiveness of label color can be judged. No data were submitted in the comments to add insight to this problem. Because there is no single or consistent pattern for the use of colors within the infant formula industry, considerable consumer reeducation may be necessary before consumers would associate a single attribute with some of the colors now being used. Even if FDA determined a color scheme to be assigned to certain types of infant formula, this would not alleviate the problems associated with consumer reeducation. Also, manufacturers have reduced the potential for confusion that may have existed in the past between concentrated and ready-to-feed formulas by voluntarily standardizing can sizes used for these infant formulas. Liquid concentrated infant formulas are only being sold in 13- or 14-ounce cans and ready-to-feed formulas are sold in multiunit packages and 8- and 32-ounce cans. For these reasons, the agency has not included a color coding requirement in this final rule.

28. One comment suggested deleting the reference to maximum recommended storage temperature and replacing it with a general statement indicating that prolonged storage at excessive temperatures should be avoided. The comment asserts that improper temperature storage of unopened infant formula containers in the home has not been and is not now a problem.

The agency agrees that unopened infant formula containers are likely to withstand the various storage conditions in the home and these conditions are not likely to affect the nutrient levels of the product. To require a label statement that may suggest that homes be kept at 72° F (or some other proven safe temperature) may cause unwarranted concern and confusion. Therefore, FDA has revised § 107.20(a)(1) to require a statement indicating that prolonged storage at excessive temperatures should be avoided.

29. One comment suggested changing directions proposed in § 107.20(a)(4) for reconstituting infant formula powder from including the weight and volume of powdered formula to the weight or volume of powdered formula. One comment suggested the use of the two measures would complicate instructions, and that fewer alternatives result in more effective and useful instructions.

The agency does not agree that the use of two measures (such as "one scoop (8 grams)") will complicate instructions. When larger amounts of infant formula are prepared (for example, a quart), it is easier and more accurate to weigh an amount of powdered formula than to measure several scoops of infant formula. Therefore, the final rule does not reflect the suggested change.

30. Several comments stated that the pictograms in the proposal were not adequate because they did not include such significant steps as sterilizing the utensils, cooling the formula, washing utensils, and refrigeration of unused formula. One comment expressed concern that the pictograms illustrated in the proposal would be misinterpreted. Two comments suggested, in lieu of the three-step pictogram used as an example, pictograms showing the emptying of the formula can into a container, filling the formula can with water, pouring the water into the container, stirring, and then pouring the mixture into a baby bottle. The comment indicated that this type of pictogram would reduce the possibility of over or under diluting. The comment also stated that the "1+1" indication in the three-step pictograms may not be clear to some individuals who are not familiar with such an algebraic concept.

The pictograms and symbols used in the proposal are examples. As in the proposal, the final rule requires pictograms but not particular pictograms. Manufacturers are free to use the pictograms they prefer. However, as discussed in the preamble to the proposal, infant formula manufacturers have conducted research on the comprehension of the three-step pictograms, used in the proposal, that illustrate the boiling, measuring, and mixing of water with a measured amount of concentrated or powdered infant formula. These studies showed that these three-step pictograms significantly increased the understanding of the major steps in the preparation of concentrated or powdered infant formulas. The agency is reluctant to use other pictograms as examples because it is not aware of studies showing the effectiveness of such other pictograms. Therefore, the pictograms included in the proposal as an example are being retained in the final rule. The agency agrees that clear, understandable pictograms should be used. However, the agency also urges that pictograms used in infant formula labeling be validated through studies

showing increased understanding by consumers illiterate in the English language and showing that the pictogram does not inadvertently promote confusion. When such increased understanding has been determined, the agency would support the introduction of new pictograms.

31. Two comments recommended that the pictogram not be required on the reverse side (inside) of a label as is being voluntarily provided by one manufacturer. Another comment thought that using the inside of the label was an excellent way of solving the label space problem.

As discussed under comment 26 above, the agency cannot legally require information on the reverse side (inside) of the label. However, the agency does not object to the voluntary use of the reverse side of a label for multilingual labeling, additional pictograms, or other nonmandatory information.

32. Several comments suggested providing only for a "use by" date and not an "expiration" date because it is more understandable. The comments also suggested that the "use by" date appear prominently on the lid of the containers and that it consist of a month and a year and not a specific day or date. One comment suggested a "sell by" date which would assist retail stores in in-store rotation of stock. One comment suggested that the language relating the "use by" date to stability testing be deleted because it is implicit and therefore unnecessary.

The agency agrees that a "use by" date placed prominently on the label would be most understandable to consumers. The agency also agrees that a "use by" date consisting of a month and a year is sufficient and the costs of expanding that requirement to include a specific day or date are not justified. FDA has revised § 107.20(c) accordingly.

The agency does not believe it is necessary to require the placement of a "use by" date on the lid of a container to assure that consumers know when the product is to be used. This information can be clearly conveyed to consumers by declaring the information prominently elsewhere on the container. With respect to a "sell by" date, this final rule has been developed to provide standardized labeling requirements to assist consumers and health professionals. Retail store employees can easily determine when to remove stock from store shelves based on a "use by" date. Also, the agency does not agree with the suggestion that the final rule be revised to delete the reference to stability testing for determining an appropriate "use by" date just because it is implicit.

33. Several comments suggested the addition of a "Do Not Add Water" symbol to the label of a ready-to-feed infant formula. One comment suggested that an X be placed over the "Add Water" symbol, while another suggested the international negative symbol of a slash, which also would be placed over the "Add Water" symbol.

The agency agrees that clear understandable symbols should be used as much as possible to augment written directions for use. As stated previously, the agency is reluctant to recommend pictograms or symbols when it is not aware of studies showing their effectiveness. The agency encourages manufacturers to develop new symbols and to validate these symbols through studies showing an increased understanding by consumers illiterate in the english language and showing that the symbols do not inadvertently promote confusion. Therefore, the agency has continued to include the symbols used in the proposal because it is not aware of any studies to verify the effectiveness of any new symbols. When such studies have been conducted showing increased understanding by consumers illiterate in the English language, the agency would support the introduction of new symbols.

34. Several comments stated that infant formula should contain a statement on the label indicating that breastfeeding is recommended by physicians and is the most healthful form of nourishment for infants. The comments indicated that low income families need, for reasons of economics and sanitation, the benefits of breastfeeding more than than any other sector of the population yet have the lowest percentage of breastfed infants. In addition, the comments pointed out that many infants are both breastfed and formula-fed and a statement on the superiority of breastfeeding on the label of a can is relevant to these mothers. The comments also argued that such a label statement may provide the encouragement a mother needs to continue to breastfed and may influence her choice of feeding with her next child. Also, comments stated that persons who have not had children may be influenced by a breastfeeding recommendation on an infant formula container. In addition, comments stated that many women receive their first container of infant formula in the hospital before they have fully decided on a method of feeding and that these women deserve to know that breastfeeding is the preferred method of feeding infants.

Some manufacturers have voluntarily included on their labels statements encouraging breastfeeding, and the agency encourages such statements when manufacturers believe it is appropriate. However, there are no studies or data regarding the usefulness or the effectiveness of labeling statements that describe the benefits of breastfeeding in affecting the decision of the mother to breastfeed her child or encouraging the practice of breastfeeding. In addition, requiring a statement encouraging breastfeeding may cause mothers who have decided not to breastfeed their infants to feel guilty or inferior because of their decision. There are many valid reasons for mothers to decide not to nurse their infants or to decide to stop nursing their infants. For these reasons, in this final rule the agency is not including the requirement for a statement encouraging breastfeeding.

35. Several comments stated that every consumer should be told of the potential consequences of not using or preparing the infant formula properly. One comment explained that almost all consumer products come with directions but, if ignoring the directions may result in an infant's illness, then the mother should be informed of these consequences. The comment went on to explain that frequently the decision to over dilute a formula is the result of poverty and the need to stretch the family budget, and that the incentive to over dilute would be reduced if the mother was made aware of its potential consequences.

The agency agrees that mothers may not realize the consequences of improper preparation of infant formula. The agency also agrees that if more mothers understood these consequences, improper preparation, such as deliberate over dilution, could be reduced. Therefore, the agency has added in § 107.20(e) the requirement for a statement beneath or in close proximity to the "Directions For Preparation and Use" that identifies the risk of improper preparation or use of an infant formula, such as "THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE".

36. One comment suggested a statement indicating that parents should consult with their pediatricians before using infant formulas. Another comment suggested the label statement "USE UNDER THE SUPERVISION OF MEDICAL PERSONNEL".

The agency agrees with the thrust of these suggestions and has added § 107.20(f) to include a statement indicating that parents should consult their physicians on the use of infant

formulas, such as "USE AS DIRECTED BY A PHYSICIAN". Current labeling practices include label statements such as "USE AS INSTRUCTED BY YOUR PHYSICIAN" or "USE AS DIRECTED BY A PHYSICIAN".

37. A few comments recommended label statements or pictograms concerning instructions on how to feed infants. Recommended instructions included "hold your baby while bottle feeding" and "do not prop your baby's bottle." These statements were suggested as warning statements designed to prevent bottle mouth syndrome (nursing bottle syndrome). This situation exists when babies fall asleep with a pool of sweetened liquid in their mouths. The liquid then remains in contact with the teeth when salivary flow is minimal and leads to dental caries.

FDA does not believe it is appropriate to require label instructions on how to feed infants because nursing bottle syndrome can occur as the result of feeding infants any sweetened liquid by bottle at bedtime. It is therefore a broader issue that should be explained to parents by health care providers so the parents will understand the reason for the instruction and apply it whenever bottle feeding their infants at bedtime.

Exemption for Individual Containers

38. One comment requested that FDA permit, for single feeding (ready-to-feed) containers, the declaration of the required labeling information on the outer container of the multiunit package and allow reduced labeling information on the individual container within a multiunit package because of a lack of space on the individual container.

FDA agrees that, for ready-to-feed infant formulas, it is not necessary to require complete label information on each individual container within a multiunit package; only more essential information necessary at the time of preparation and use needs to appear on the individual container labels. Accordingly, the agency has determined that the following labeling information need not be on the individual containers, provided that all required information is on the outer label of the multiunit package: (1) Name and place of business of the manufacturer, packer, or distributor; (2) ingredients listing; (3) nutrients listing; and (4) some directions for preparation and use.

The label declaration "With Iron" or "Additional Iron May Be Necessary" or similar statement must be present on the principal display panel of each individual container because iron fortification is the one characteristic that distinguishes the two basic types of ready-to-feed infant formulas and is therefore considered to be part of the name of the formula. Likewise, with respect to the "Directions For Preparation and Use" requirements, the label declaration "Shake Well Before Opening" and the directions for washing and sterilizing baby bottle nipples (when necessary) also must be present on each individual container because both are essential aspects of preparing ready-to-feed infant formulas for use. Therefore, the agency has added § 107.30 to allow for these exemptions.

As a safeguard to protect consumers, a proviso to § 107.30 provides that these exemptions only apply when (1) the multiunit package meets all the requirements of Part 107; (2) individual containers are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; and (3) the label on each individual container includes the statement "This Unit Not Intended for Individual Sale" in a type size not less than one-sixteenth inch in height. The word "Retail" may be used in lieu of or immediately following the word "Individual" in the statement.

Public Hearings

39. Several comments requested public hearings on the proposed rule prior to its finalization. These comments stated that hearings would be useful because the infant formula industry has begun to institute several new policies on pictograms and bilingual labeling. The comments suggested that public hearings should be held in areas with a high concentration of low income families of various ethnic backgrounds in order to examine the effectiveness of the various forms of pictograms, symbols, and bilingual labels. The comments stated that this would help the agency to determine which form of labeling is most effective.

As indicated in the preamble to the proposal, the agency held a public meeting and an informal public hearing in February and March 1980 that considered a number of issues concerning infant formulas including pictograms, symbols, bilingual labeling, and other labeling issues.

The agency concludes that another hearing would not serve a useful purpose. The requests for hearings did not provide any information to justify a hearing, and the agency is not aware of any new survey or scientific information upon which to base another hearing.

FDA has made several minor corrections in the final rule that are editorial in nature.

Economic Considerations

In accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), the economic impacts of the final rule have been analyzed. The one-time cost of changing infant formula labels estimated in the preamble to the proposal was $50,000. This final rule makes slight modifications in the statements required on the new labels. Consequently, the estimated cost remains the same. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities and that the rule is not a major rule as defined by Executive Order 12291.

Environmental Considerations

The agency has determined pursuant to 21 CFR 25.24(d)(13) (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.

Sections 107.10 (a) and (b)(2) and 107.20 (a) and (c) of this final rule contain collection of information requirements that were submitted, as proposed, to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. These requirements were approved and assigned OMB control number 0910-0159. These sections, as revised in the final rule, and new § 107.30 do not substantively change the information collection requirements.

List of Subjects

21 CFR Part 105

Dietary foods, Food labeling, Infant foods, Nutrition, Vitamins and minerals.

21 CFR Part 107

Food labeling, Infant formula, Nutrient information.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201 (n) and (aa), 403 (a) and (j), 412, 701 (a) and (e), 52 Stat. 1041 as amended, 1047 as amended, 1048, 1055, 70 Stat. 919 as amended, 94 Stat. 1190 (21 U.S.C. 321 (n) and (aa), 343 (a) and (j), 350a, 371 (a) and (e))) and under 21 CFR Part 5.11, Parts 105 and 107 are amended as follows:

PART 105—FOODS FOR SPECIAL DIETARY USE

§ 105.65 [Amended]

1. Part 105 is amended in § 105.65 *Infant foods* by removing paragraphs (c), (d), and (e).

2. By adding new Part 107, to read as follows:

PART 107—INFANT FORMULA

Subpart A—[Reserved]

Subpart B—Labeling

Sec.

Authority: Secs. 201(n) and (aa), 403(a) and (j), 412, 701(a) and (e), 52 Stat. 1041 as amended, 1047 as amended, 1048, 1055, 70 Stat. 919 as amended, 94 Stat. 1190 (21 U.S.C. 321(n) and (aa), 343(a) and (j), 350a, 371(a) and (e)).

Subpart A—[Reserved]

Subpart B—Labeling

§ 107.10 Nutrient information.

(a) The labeling of infant formulas, as defined in section 201(aa) of the Federal Food, Drug, and Cosmetic Act, shall bear in the order given, in the units specified, and in tabular format, the following information regarding the product as prepared in accordance with label directions for infant consumption:

(1) A statement of the number of fluid ounces supplying 100 kilocalories (in case of food label statements, a kilocalorie is represented by the word "Calorie"); and

(2) A statement of the amount of each of the following nutrients supplied by 100 kilocalories:

Nutrients	Unit of measurement
Protein	Grams.
Fat	Do.
Carbohydrate	Do.
Water	Do.
Linoleic acid	Milligrams.
Vitamins:	
Vitamin A	International units.
Vitamin D	Do.
Vitamin E	Do.
Vitamin K	Micrograms.
Thiamine (Vitamin B_1)	Do.
Riboflavin (Vitamin B_2)	Do.
Vitamin B_6	Do.
Vitamin B_{12}	Do.
Niacin	Do.
Folic acid (Folacin)	Do.
Pantothenic acid	Do.
Biotin	Do.
Vitamin C (Ascorbic acid)	Milligrams.
Choline	Do.
Inositol	Do.
Minerals:	
Calcium	Milligrams.
Phosphorus	Do.
Magnesium	Do.
Iron	Do.
Zinc	Do.
Manganese	Micrograms.
Copper	Do.
Iodine	Do.
Sodium	Milligrams.
Potassium	Do.
Chloride	Do.

(b) In addition the following apply:

(1) Vitamin A content may also be declared on the label in units of microgram retinol equivalents, vitamin D content in units of micrograms cholecalciferol, vitamin E content in units of milligram alpha-tocopherol equivalents, and sodium, potassium, and chloride content in units of millimoles, micromoles, or milliequivalents. When these declarations are made they shall appear in parentheses immediately following the declarations in International Units for vitamins A, D, and E, and immediately following the declarations in milligrams for sodium, potassium, and chloride.

(2) Biotin, choline, and inositol content shall be declared except when they are not added to milk-based infant formulas.

(3) Each of the listed nutrients, and the caloric density, may also be declared on the label on other bases, such as per 100 milliliters or per liter, as prepared for infant consumption.

(4) One of the following statements shall appear on the principal display panel, as appropriate:

(i) The statement "Infant Formula With Iron", or a similar statement, if the product contains 1 milligram or more of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.

(ii) The statement "Additional Iron May Be Necessary", or a similar statement, if the product contains less than 1 milligram of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.

(5) Any additional vitamin may be declared at the bottom of the vitamin list and any additional minerals may be declared between iodine and sodium, provided that any additionally declared nutrient (i) has been identified as essential by the National Academy of Sciences through its development of a recommended dietary allowance or an estimated safe and adequate daily dietary intake range, or has been identified as essential by the Food and Drug Administration through a **Federal Register** publication or establishment of a U.S. Recommended Daily Allowance, and (ii) is provided at a level considered in these publications as having biological significance, when these levels are known.

(Collection of information requirements were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0159)

§ 107.20 Directions for use.

In addition to the applicable labeling requirements in Parts 101 and 105 of this chapter, the product label shall bear:

(a) Under the heading "Directions For Preparation and Use", directions for:

(1) Storage of infant formula before and after the container has been opened, including a statement indicating that prolonged storage at excessive temperatures should be avoided;

(2) Agitating liquid infant formula before opening the container, such as "Shake Well Before Opening";

(3) "Sterilization" of water, bottle, and nipples when necessary for preparing infant formula for use;

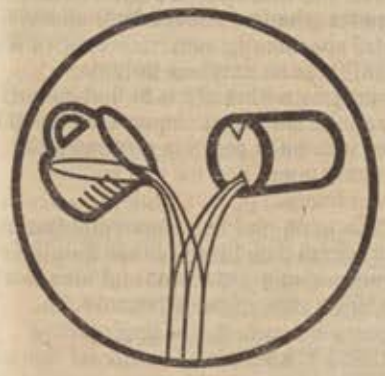
(4) Dilution of infant formula, when appropriate. Directions for powdered infant formula shall contain the weight and volume of powdered formula to be reconstituted.

(b) In close proximity to the "Directions for Preparation and Use" a pictogram depicting the major steps for preparation of that infant formula, such as (for a concentrated formula):

(c) A "Use by ————" date, the blank to be filled in with the month and year selected by the manufacturer, packer, or distributor of the infant formula on the basis of tests or other

information showing that the infant formula, until that date, under the conditions of handling, storage, preparation, and use prescribed by label directions, will: (1) when consumed, contain not less than the quantity of each nutrient, as set forth on its label; and (2) otherwise be of an acceptable quality (e.g., pass through an ordinary bottle nipple).

(d) The statement "Add Water" or "Do Not Add Water", as appropriate, to appear on the principal display panel of concentrated or ready-to-feed infant formulas. In close proximity to the statement "Add Water", a symbol such as



if the addition of water is necessary. The symbol shall be placed on a white background encircled by a dark border.

(e) A warning statement beneath or in close proximity to the "Directions For Preparation and Use" that cautions against improper preparation or use of an infant formula, such as "THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE".

(f) A statement indicating that parents should consult their physicians about the use of infant formulas, such as "USE AS DIRECTED BY A PHYSICIAN".

(Collection of information requirements were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0159)

§ 107.30 Exemptions.

When containers of ready-to-feed infant formula, to be sold at the retail level, are contained within a multiunit package, the labels of the individual containers shall contain all of the label information required by section 403 of the Federal Food, Drug, and Cosmetic Act (the act), §§ 107.10 and 107.20, and all appropriate sections of Part 101 of this chapter, except that the labels of the individual containers contained within the outer package shall be exempt from compliance with the requirements of section 403 (e)(1) and (i)(2) of the act; and §§ 107.10 (a) and (b)(2) and 107.20 (b), (e), and (f), provided that (a) the multiunit package meets all the requirements of this part; (b) individual containers are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; and (c) the label on each individual container includes the statement "This Unit Not Intended For Individual Sale" in type size not less than one-sixteenth inch in height. The word "Retail" may be used in lieu of or immediately following the word "Individual" in the statement.

Any person who will be adversely affected by the foregoing regulations may at any time on or before February 13, 1985, submit to the Dockets Management Branch (address above) written objections pertaining to §§ 105.65 (c), (d), and (e) and 107.10 and may make a written request for a public hearing on the stated objections. Objections and requests for hearing concerning other sections of the foregoing regulations should not be submitted, as the objections will have no legal effect and a hearing will not be granted. This subject was discussed in detail in the preamble to the proposal.

Each objection shall be separately numbered and each numbered objection shall specify with particularity the provisions of the regulations to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 14, 1986 shall fully comply. Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

(Secs. 201 (n) and (aa), 403 (a) and (j), 412, 701 (a) and (e), 52 Stat. 1041 as amended, 1047 as amended, 1048, 1055, 70 Stat. 919 as amended, 94 Stat. 1190 (21 U.S.C. 321 (n) and (aa), 343 (a) and (j), 350a, 371 (a) and (e)))

Dated: December 6, 1984.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-957 Filed 11-11-85; 8:45 am]

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21 CFR Part 177

[Docket No. 84F-0301]

Indirect Food Additives; Polymers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polyoxymethylene copolymers with a minimum number average molecular weight of 15,000 rather than the 20,000 as currently listed. This action responds to a petition filed by Celanese Engineering Resins.

DATES: Effective January 14, 1985, objections by February 13, 1985.

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

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 26, 1984 (49 FR 37851), FDA announced that a petition (FAP 4B3784) had been filed by Celanese Engineering Resins proposing that the food additive regulations be changed to provide for the safe use of polyoxymethylene copolymers with a minimum number average molecular weight of 15,000 for the copolymer rather than the 20,000 as presently listed.

FDA has evaluated data in the petition and other relevant material and concludes that the proposed food additive use is safe, and that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the