dated September 12, 2012: Before further flight, contact the Manager, Seattle ACO, FAA, for instructions using the procedures specified in paragraph (o) of this AD and do the actions required by the FAA.

(n) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraphs (j) and (k) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 737–53A1200, Revision 1, dated July 7, 2011, which is not incorporated by reference in this AD.

(o) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(4) AMOCs approved previously in accordance with paragraphs (f) and (i) of AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008), are approved as AMOCs for the corresponding provisions of paragraphs (g) and (i) of this AD.

(p) Related Information

(1) For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6450; fax: 425–917–6590; email: *Alan.Pohl@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; phone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: *https://www.myboeingfleet.com*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 4, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–08908 Filed 4–15–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. FDA–2013–N–0067]

Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula.

DATES: Submit either electronic or written comments on the proposed rule by July 1, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 16, 2013, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0067, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document):

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0067 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''How Do You Submit Comments on This Rule?'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: With regard to the proposed rule: Benson M. Silverman, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 240–402–1450.

With regard to the information collection issues: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the background of this proposed rule?

Section 412(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(i)) establishes requirements for the nutrient content of infant formulas. Under section 412(i)(2) of the FD&C Act, the Secretary of Health and Human Services (the Secretary) is authorized to revise the list of required nutrients and the required level for any required nutrient, which authority has been delegated to the Commissioner of Food and Drugs (the Commissioner). The table in section 412(i) of the FD&C Act and FDA regulations, 21 CFR 107.100, specify that infant formulas must contain 29 nutrients; minimum levels for each nutrient and maximum levels for 9 of the nutrients are also specified.

At the time FDA established nutrient specifications for infant formula, selenium was not recognized as an essential nutrient and was not one of the nutrients required by statute in infant formula. As explained in detail in this document, selenium has subsequently been recognized as an essential nutrient. Therefore, we are proposing to amend the nutrient specifications for infant

formula in § 107.100 to include selenium as a required nutrient and to establish minimum and maximum values for selenium. We are also proposing to amend the labeling requirements for infant formula in 21 CFR 107.10 to add selenium to the list of nutrients along with the requirement to list the amount of selenium per 100 kilocalories in the formula.

Selenium is an essential trace element for humans that functions largely through an association with proteins known as selenoproteins. The known biological functions of selenium include defense against oxidative stress, regulation of thyroid hormone action, and regulation of the oxidation/reduction status of vitamin C and other molecules.

Plant foods are the major dietary sources of selenium although selenium is also found in some meats, seafood, and nuts. The selenium content of a food depends on the selenium content of the soil where the plant was grown or where the animal was raised. In the United States, food distribution patterns across the country help prevent people living in geographic areas with low-selenium levels in the soil from having low dietary selenium intakes. Keshan disease, a cardiomyopathy that occurs almost exclusively in children, has been linked to selenium deficiency. Keshan disease occurs in areas of China where the population has severe selenium deficiency. Chronic selenium toxicity (selenosis) has also been observed in persons consuming diets containing high levels of selenium. Reported characteristics include hair and nail brittleness and loss, gastrointestinal upsets, skin rash, garlic breath odor, fatigue, irritability, and nervous system abnormalities. Acute selenium toxicity is rare and the few reports in the literature of acute fatal or near fatal selenium poisoning have occurred because of accidental or suicidal ingestion of selenium (Ref. 1).

In the United States, selenium is not routinely added to food. An exception is infant formula, a food that is intended to be the sole source of nutrition for infants and therefore, must provide sufficient amounts of all nutrients essential for infants. In 1989, the Food and Nutrition Board of the National Research Council established a Recommended Dietary Allowance (RDA) for selenium for infants 0 to 6 months of age of 10.0 micrograms per day (μg/day), a level extrapolated from adult values on the basis of body weight and with a factor allowed for growth (Ref. 2). Although selenium is not currently required in infant formula by § 107.100, all U.S. manufacturers are adding selenium to their infant formulas. Based on labeling information, currently marketed infant formulas contain 1.8 μg to 3.0 μg selenium per 100 kilocalorie (kcal) of formula.

II. What levels of selenium are we proposing for infant formula?

As discussed in more detail in this document, we are proposing 2.0 μg selenium/100 kcal as the minimum level for selenium in infant formulas and 7.0 μg/100 kcal as the maximum level of selenium in infant formulas

III. What scientific evidence did we consider for the proposed requirement to add selenium to infant formulas?

In order to add a selenium requirement and to establish minimum and maximum levels of selenium in infant formula, we first identified and reviewed three relevant technical reports on recommended nutrient levels for formulas for term infants and nutrient needs of healthy term infants: (1) The Life Sciences Research Office (LSRO) report ''Assessment of Nutrient Requirements for Infant Formulas'' (Ref. 3); (2) ''Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids'' (Ref. 1); and (3) ''Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group'' (Ref. 4). These reports are referred to as the LSRO report, the Institute of Medicine (IOM) report, and the European Society on Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) report, respectively, in the remainder of this proposal. We also searched the published scientific literature from 1998 through 2012 for published studies not included in these reports or not identified in a 2008 published study by Daniels et al. (Ref. 5). (The Daniels et al. study is discussed in this section of the document.)

A. Available Evidence for Setting a Minimum Level of Selenium in Infant Formula

1. LSRO Report

In 1998, Raiten et al. published a report summarizing the scientific literature on the nutrient needs of healthy term infants, with an emphasis on research studies published since 1983 (Ref. 3). The report was prepared for FDA's Center for Food Safety and Applied Nutrition and Health Canada's Health Protection Branch by the LSRO in consultation with expert scientists and professional organizations involved in the field of infant nutrition. The goal of the deliberations of this LSRO Expert Panel was to provide recommendations for nutrient content of infant formulas that could serve as the sole source of nutrition for term infants throughout the first year of life.

On the basis of the evidence for the dietary essentiality of selenium, the LSRO Expert Panel recommended that selenium be included as a required nutrient in infant formula. The Panel also recommended a minimum selenium content of 1.5 μg/100 kcal (10.0 μg/liter (L)), which) and a maximum level of 5.0 μg/100 kcal (33.5 μg/L). The minimum value approximated the estimated value for the mean minus one standard deviation (SD) for the selenium concentration in human milk in countries in which selenium deficiency has not been recognized in breast-fed infants. This recommended minimum level would provide an estimated 7.5 μg/day of selenium for young infants exclusively fed infant formula,[1] an amount below the 1989 RDA (10.0 μg/day). The LSRO Panel was aware that there were disparities between some of its recommendations for nutrient levels in infant formulas and the 1989 RDAs; however, the history of use for a large population in which selenium deficiency has not been reported was regarded as a reasonable basis for recommending a minimum value for selenium in infant formula.

2. IOM Report

In 2000, the IOM published Dietary Reference Intakes (DRI) for selenium. The DRI concept evolved from the Recommended Dietary Allowances reports that have been published periodically since 1941 by the National Academies of Science. As described by the IOM (Ref. 1), the term Dietary Reference Intake encompasses three nutrient-based reference values in addition to the RDA. The RDA and the three nutrient-based reference values were described by the IOM as follows:

- *The Recommended Dietary Allowance* (RDA) is the average dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group.

[1] This estimate is based on a calculation used to convert nutrient intake values (e.g., milligram (mg)/day) to formula nutrient content values (e.g., mg/100 kcal) (Raiten, et al., 1998; Koletzko, et al, 2006). The calculation is based on the following assumptions: (1) The mean intake of formulas for infants 0 to 6 months of age is 750 milliliter (ml)/day; (2) a representative body weight for infants over this period is 5 kilogram (kg); and (3) a representative caloric intake of infants over this period is 500 kcal/day (or 100 kcal/kg/day).

The RDA is intended to be the goal for daily intake by individuals.

• *The Estimated Average Requirement* (EAR) is the daily intake value that is estimated to meet the requirement, as defined by the specified indicator of adequacy, in half of the healthy individuals in a life stage and gender group. The EAR is used to set the RDA. If the standard deviation (SD) of the EAR is available and the requirement for the nutrient is normally distributed, the RDA is defined as the EAR plus two SDs of the EAR.

• *An Adequate Intake* (AI) is established for a nutrient when sufficient scientific evidence is not available to calculate an EAR. An AI is based on experimentally-derived intake levels of approximations of observed mean nutrient intakes by a group of healthy people. The AI for children and adults is expected to meet or exceed the amount needed to maintain a defined nutritional state or exceed the amount needed to maintain a defined nutritional state or criterion of adequacy in essentially all members of a specific healthy population because it is set using healthy populations. Like the RDA, the AI is intended to be the goal for individual intake and it is intended to cover the needs of nearly all persons in a life stage group.

• *The Tolerable Upper Intake Level* (UL) is the highest daily intake level of a nutrient that is likely to pose no risk of adverse health effects in almost all individuals in a life stage group.

At the time of its report, the IOM did not find sufficient evidence to calculate an EAR for selenium for infants during the first year of life and, therefore, did not have a basis to set an RDA for selenium for infants. For this reason, the IOM set an AI for selenium for infants 0 to 6 months of age, the age when the recommended sole source of nutrition is human milk, infant formula, or a combination of the two.

The IOM's primary basis for deriving an AI for most nutrients for the first 6 months of life was the average intake by full term infants born to healthy, well-nourished mothers and exclusively fed human milk. To derive the AI values for infants ages 0 to 6 months of age, the mean intake of a nutrient was calculated based on the average concentration of the nutrient in human milk from 2 to 6 months of lactation, using agreed-upon values from several reported studies and an average volume of milk intake. To calculate the AI for selenium, IOM used the average concentration of selenium in human milk from mothers in the United States and Canada (18.0 µg/L) and an intake of 0.78 L/day, as reported from differences in weights of full-term infants before and after feedings. A reference weight of 7 kg for infants 2 to 6 months of age, adapted from National Health and Nutrition Examination Survey (NHANES) III 1988–1994 data (Ref. 6), was used by the IOM to calculate the AI on a body weight basis. (Ref. 1). The IOM established a selenium AI of 15.0 µg/day (approximately 2.1 µg/kg body weight/day) for infants 0 to 6 months of age (IOM, 2000). Assuming a typical intake of 100 kcal/kg/day for infants 0 to 6 months of age, this approximates a need for selenium, relative to energy consumption, of 2.1 µg/100 kcal.

3. ESPGHAN Report

In 2005, an International Expert Group (IEG) coordinated by the Committee on Nutrition of the ESPGHAN prepared a report on nutrient levels in infant formula, based on scientific analysis and taking into account existing scientific reports on current infant formula nutrient content (Ref. 4). The report was prepared at the request of the Codex Committee on Nutrition and Foods for Special Dietary Uses for use by that Committee in revising the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Stan 72–1981) (Ref. 7). The goal of establishing minimum and maximum nutrient values for the Codex standard was to ensure that infant formulas adhering to the Standard would be safe and would meet infants' normal nutritional requirements.

The ESPGHAN IEG reported that their recommended minimum nutrient values were based on scientific evidence of the amounts needed to meet infants' nutritional requirements when such information was available. When scientific information was lacking, an established history of apparent safe use was taken into account. The IEG recommended a minimum selenium value of 1 µg/100 kcal for infant formula and they indicated that the reported median selenium content of human milk and values set for infant reference nutrient intakes formed the basis for their recommendation. Further detail was not provided on how this information was used by the IEG in making their recommendation.

4. Recent Published Literature

One recent report in the published scientific literature also provides important information on necessary infant selenium intake levels. Daniels, et al. reported the results of a randomized, double-blinded dose-response study of healthy term infants fed infant formula containing selenium at three concentrations (6.0 µg/liter, 13.0 µg/liter, or 21.0 µg/liter) and a breast-fed reference group (Ref. 5). The concentrations of selenium in the study formulas correspond to 0.9 µg/100 kcal (low selenium control), 1.9 µg/100 kcal, and 3.1 µg/100 kcal, respectively. The mean concentration of selenium in breast milk reported in this study was 11.0 µg/liter (1.6 µg/100 kcal). Infants participating in the study consumed the assigned infant formula or breast milk as the sole source of nutrition from birth to 16 weeks of age.

Consumption of formulas containing both of the higher levels of selenium (1.9 µg/100 kcal and 3.1 µg/100 kcal) resulted in changes in plasma and erythrocyte indicators of selenium status at the end of the study that did not differ statistically from each other or from the breast-fed control group. However, indicators of selenium status for all of these groups differed statistically from the plasma and erythrocyte indicators of selenium status in the infants fed the control formula containing only 0.9 µg selenium/100 kcal. A dose-related increase in urinary selenium excretion in the formula-fed groups was also reported. When infants consumed formulas containing selenium at levels of 1.9 µg/100 kcal or 3.1 µg/100 kcal, there were no statistically significant dose-related changes in plasma and erythrocyte indicators of selenium status. However, there was a statistically significant increase in urinary selenium excretion in the infants fed the formula containing 3.1 µg/100 kcal compared to the infants fed the formula containing 1.9 µg/100 kcal. This latter finding, in combination with the finding of no dose-related changes in the circulating indicators of selenium status, suggests that infants fed the formula containing a level of 1.9 µg selenium/100 kcal received sufficient selenium to meet their nutritional needs and that by virtue of the body's homeostatic mechanisms, it would appear that much of the selenium intake above the level of 1.9 µg selenium/100 kcal was eliminated from the body.

B. Available Evidence for Setting a Maximum Level for Selenium in Infant Formula

1. LSRO Report

The LSRO Expert Panel recommended a maximum selenium level for infant formula of 5.0 µg/100 kcal (33.5 µg/L) (Ref. 3). This recommendation was based on the upper limit of the range of selenium in human milk, which was considered to represent a history of use for a large population in which

selenium toxicity had not been reported. The LSRO report also indicated that, on a body weight basis, this level is far below the intake associated with the development of selenosis in adults.

2. IOM Report

The IOM established an upper limit (UL) for selenium for infants 0 to 6 months of age relying on data on the concentration of selenium in human milk, which is not associated with known adverse effects. The IOM calculated an UL of 47.0 µg/day or approximately 7.0 µg/kg body weight/day for infants 0 to 6 months of age, which approximates 7.0 µg/100 kcal.

3. ESPGHAN Report

The ESPGHAN IEG recommended a maximum level of 9 µg/100 kcal for selenium in infant formula. The IEG based their recommendations for maximum nutrient values on scientific evidence regarding the absence of adverse effects, when such information was available. When scientific information was lacking, an established history of apparent safe use was taken into account. Further detail was not provided on how this information was used by the IEG in making its recommendation.

IV. Which products are subject to this proposed rule?

Products that meet the statutory definition of ''infant formula'' in section 201(z) of the FD&C Act (21 U.S.C. 321(z)) (''a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk'') are subject to this proposed rule.

V. What does this proposed rule do?

This proposed rule, if finalized, will add selenium to the list of required nutrients for infant formulas and establish minimum and maximum levels of selenium in FDA's nutrient specifications regulations for infant formulas under § 107.100(a). In addition, the proposed rule would add selenium to the list of nutrients that must be listed in the table of nutrition information required on infant formula labeling by § 107.10(a)(2).

A. Revision to § 107.100(a) Nutrient Specifications

We are proposing to mandate that selenium be added to infant formula by requiring that this mineral be listed in the table of nutrients for infant formulas in § 107.100(a). We are also proposing to establish minimum and maximum levels for selenium in infant formula because evidence exists for both deficiency and toxicity of selenium, and there is no room for error in production of a food that serves as the sole source of nutrition for infants.

1. Proposed Minimum Level of Selenium in Infant Formulas

After considering the scientific reports discussed previously in this document and evidence published by Daniels, et al. after those reports were completed, we are proposing 2.0 µg selenium/100 kcal as the minimum level for selenium in infant formulas. This proposed minimum level is based on the IOM's AI for selenium for infants 0 to 6 months of age (2.1 µg/day) (Ref. 1) and the level suggested by the data in the study by Daniels, et al. (1.9 µg/100 kcal) (Ref. 5), rounded to the nearest whole microgram. As noted, the Daniels, et al. study demonstrated that infants who consumed infant formula containing 1.9 µg selenium/100 kcal had plasma and erythrocyte indicators of selenium status that were statistically higher than those of infants consuming formula containing less selenium (0.9 µg/100 kcal) but these levels did not differ from those of infants consuming infant formula containing more selenium (3.1 µg/100 kcal). Infants consuming the formula containing 3.1 µg/100 kcal of selenium also had significantly higher urinary excretion of selenium. In the absence of statistically significant changes in plasma and erythrocyte indicators of selenium status, the substantially higher urinary excretion of selenium of the infants fed the 3.1 µg selenium formula compared to that of the infants fed the 1.9 µg selenium formula, suggests that a selenium intake of 3.1 µg/100 kcal is likely to be greater than the amount needed to meet an infant's nutritional needs. Thus, FDA tentatively concludes that 2.0 µg selenium/100 kcal is an appropriate required minimum for selenium in infant formulas.

We also propose to correct a typographical error in the table that appears in § 107.100(a). In the second column of that table, each abbreviation for ditto (''do'') will now be followed by a period.

2. Proposed Maximum Level of Selenium in Infant Formulas

FDA is also proposing to set a maximum level for selenium in infant formula of 7.0 µg/100 kcal. This level is based on the UL for infants 0 to 6 months of age established by the IOM (Ref. 1), and defined as highest level of daily nutrient intake that is likely to pose no risk of adverse health effects in the population of interest. FDA is relying on the IOM's recommendation because the IOM report was the most transparent in terms of the basis for its recommended UL. Also, unlike the minimum level, there is no study that provides direct evidence to establish a maximum level and thus, in proposing a maximum level, the agency must rely on a recommendation for an intake level that is likely to pose no risk of adverse health effects.

3. Comments Specifically Requested

We find that there is scientific evidence sufficient to support the minimum proposed level of 2.0 µg selenium/100 kcal and the proposed maximum level of 7.0 ug selenium/100 kcal, although there is less evidence directly applicable to the proposed maximum level. While we are interested in comments regarding the proposed minimum level for selenium, we are particularly interested in comments regarding the proposed maximum level of 7.0 µg selenium/100 kcal, including whether such a maximum level is needed and the scientific data or information that form the basis of any comments.

Although, in our judgment, it will be feasible for formula manufacturers to achieve consistent production of infant formulas with selenium levels that are at or above the proposed minimum level of 2.0 µg/100 kcal while not exceeding the proposed maximum level of 7.0 µg/100 kcal, we specifically request comments about whether the proposed minimum and maximum selenium levels provide sufficient flexibility and can be achieved from a practical manufacturing standpoint. In addition, because unduly high levels of nutrients should be avoided in products that serve as the sole source of nutrients for infants, a population that is particularly vulnerable to nutritional inadequacies and excesses, we are also particularly interested in receiving comments about available means to ensure that nutrient levels in infant formulas, including selenium, are not excessive.

B. Revision to § 107.10(a)(2) Nutrient Information

We are proposing to add selenium to the statement of the amounts of nutrients required for infant formula labeling in § 107.10(a)(2). This additional mineral would be required to be listed between iodine and sodium, as directed by § 107.10(b)(5).

VI. What is the legal authority for this proposed rule?

Section 412(i) of the FD&C Act contains a table of nutrients (including

minimum and, in some cases, maximum levels for such nutrients) that are required to be in an infant formula. Section 412(i)(2) of the FD&C Act authorizes the Secretary to revise the statutory table of nutrients and to revise the level of any required nutrient. The Secretary has delegated this authority to the Commissioner. In the **Federal Register** of October 31, 1985, FDA published a final rule revising the statutory table of nutrients, which was published as § 107.100. This proposed rule, if finalized, would amend § 107.100. Accordingly, the legal authority for the proposed revision to § 107.100, which revises the statutory list of nutrients required for infant formula, is section 412(i)(2) of the FD&C Act.

Additionally, this proposed rule, if finalized, would require the addition of selenium to the statement of the amounts of nutrients required for infant formula labeling in § 107.10(a)(2). As noted previously in this document, ''infant formula'' is defined as a food for ''special dietary use'' under section 201(z) of the FD&C Act. Under sections 403(j) and 701(e) of the FD&C Act (21 U.S.C. 343(j) and 21 U.S.C. 371(e)), the Secretary, and by delegation the Commissioner, may prescribe regulations concerning the vitamin and mineral content of foods for special dietary uses, in order to fully inform purchasers as to the value of the food for such uses. As such, FDA has the authority to revise the statement of the amounts of nutrients required for infant formula labeling in § 107.10(a)(2) under sections 201(z), 403(j), 412(i), and 701(e) of the FD&C Act. When the Agency issues a final rule for the provisions in proposed § 107.10(a)(2), it will provide an opportunity for filing objections and requests for a formal evidentiary public hearing under 21 CFR part 12.

VII. What is the environmental impact of this proposed rule?

FDA has determined under 21 CFR 25.32(n) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because only one firm is affected by this rule, and it is considered large by Small Business Administration standards, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal Mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

X. Regulatory Impact Analysis

A. Need for This Regulation

FDA is proposing to amend its infant formula nutrient requirement regulations. If the proposed rule is finalized, infant formulas will be required to contain selenium at a level not less than 2.0 µg and not more than 7.0 µg for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container. This regulation is needed because selenium is now recognized as an essential nutrient for humans.

Additionally, if finalized, this proposed rule will require that infant formula manufacturers add selenium to the list of nutrients on infant formula labels, and to list the amount of selenium per 100 kilocalories in the formula.

Selenium is a trace mineral that is essential to good health but required only in small amounts. Selenium is incorporated into proteins to make selenoproteins, which are important antioxidant enzymes, the natural by-products of oxygen metabolism that may contribute to the development of chronic diseases such as cancer and heart disease. In most countries throughout the world, plant foods are major dietary sources of selenium. However, selenium is also found in some meats, seafood, and nuts. In the United States, food distribution patterns across the country help prevent people in geographic areas with low-selenium levels in the soil from having low dietary selenium intakes. Food is not generally fortified with selenium in the United States, but an exception to this is infant formula.

B. Regulatory Options

In formulating the analysis of this proposed rule, three options were analyzed: (1) No new regulatory action (baseline); (2) require the provisions of this proposed rule and make the provisions of the rule effective 180 days after publication; and (3) require the provisions of this proposed rule, but make the provisions of the rule effective 12 months after publication.

Option 1: No New Regulatory Action (Baseline)

The first option is no new regulatory action. We include it here because OMB cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. There are zero costs and benefits associated with this option, and it serves as the baseline against which other options will be measured for assessing costs and benefits.

Option 2: Finalize the proposed rule and make the provisions effective 180 days after publication.

XI. Costs

One cost of this proposal, if finalized, will be reformulation costs resulting from firms adding selenium to infant formulas in order to comply with this rule. Currently, there are five firms that produce infant formula in the United States. Of these firms, only one will need to add slightly more selenium to its infant formulas. Based on information provided by the infant formula industry, it appears that all other infant formula manufacturers already added selenium to their infant formula products at a level within the range identified by the proposed rule. Therefore, any reformulation cost of this proposal will come from a single firm adding slightly more selenium to its infant formula products that currently do not meet the proposed minimum level of 2.0 µg/100 kcal.

Table 1 of this document outlines low, medium, and high cost estimates based on a change in the formulation of infant formula. Costs are estimated using a reformulation model, developed under contract with Research Triangle Institute (RTI). This model provides estimates of the costs of reformulation of the range of food, dietary supplement, and cosmetic products under FDA's jurisdiction, including infant formulas, and has been adjusted to reflect 2012 dollars. In this model, the cost of the reformulation depends on the affected ingredient and the likely response of manufacturers. The cost per infant formula associated with reformulation is estimated to be a function of product research, product development, coordinating activities, startup and verification, and nutrient testing of finished product. To the extent that any of these activities is not necessary for adding selenium to an infant formula that already has selenium added, costs will be overestimated. Table 1 of this document presents total estimated low, medium, and high costs of reformulation for this proposed rule. The totals are based on the reformulation of 46 separate infant formulas manufactured by one firm, the current formulation of which would not meet the requirements of this rule, if finalized. Therefore, the total industry costs are each of the low, medium, and high costs multiplied by 46.

TABLE 1—ESTIMATION OF FIRST-YEAR COSTS OF INFANT FORMULA REFORMULATION, PER INFANT FORMULA

Variable	Low	Medium	High
Product Research	$1,685	$16,853	$33,706
Product Development	4,598	13,023	28,259
Coordinating Activities	2,938	8,818	14,690
Startup and Verification	1,442	7,207	15,890
Nutrient Testing of the Finished Product	15	15	15
Total Per Formula	10,678	45,916	92,560
Total Industry Cost of Reformulation (Cost × 46 infant formulas)	497,188	2,112,136	4,257,760

Another component of the costs of this option is cost related to the relabeling of reformulated infant formula. The proposed rule requires infant formula manufacturers to include selenium in the nutrient content statement on containers of infant formula. All manufacturers currently disclose selenium in the nutrient list as specified under § 107.10(b)(5). However, as noted previously in this document, one manufacturer would be required to add more selenium to its formulas under this proposal. Therefore, it is estimated that the same firm that would be required to add more selenium to its formulas under this proposal will also incur relabeling costs to comply with this proposed rule.

Table 2 of this document outlines low, medium, and high cost estimates of relabeling based on a minor change to the infant formula label and an effective date of 180 days after publication. Costs are estimated using a relabeling model developed under contract by RTI. This model estimates the costs of relabeling food, dietary supplements, and cosmetic products under FDA's jurisdiction and these estimates have been adjusted to reflect 2012 dollars. In this model, relabeling costs depend on the type of change (major, minor, or extensive) and the effective date of the rule. This model estimates that longer periods of time before a rule becomes effective are associated with lower relabeling costs because any change is more likely to be able to be coordinated with a change in a label that may already be scheduled, and will diminish the need to, for example, purchase and apply stickers to packages affected by the change. The Agency acknowledges the uncertainty in this estimation and how it may specifically apply to the infant formula industry and requests comment regarding the extent to which the effective date is likely to affect the cost of compliance with this proposed rule.

TABLE 2—ESTIMATED FIRST YEAR RELABELING COSTS

Low	Medium	High
$3,565,880	$8,735,802	$23,619,959

The final component of cost is related to one firm assembling information for submission to the Agency related to the reformulated infant formulas, as required under section 412(d)(3) of the FD&C Act. The addition of more selenium constitutes a change in the formulation of these formulas that the Agency considers may affect whether the formulas are adulterated; therefore, we are including the submission of information about the change in the formulas before the first processing of such formulas as a cost.

It is estimated that a scientist from one firm will spend 10 hours assembling the information to be submitted, which will address the 46 reformulated infant formulas. This is estimated as a one-time cost. It is estimated that this scientist is paid a wage of $52.88; that is, $35.25 plus 50 percent overhead. Therefore, 10 hours × $52.88 = $528.80.

TABLE 3—SUMMARY OF TOTAL COST OF OPTION 1

	Low	Medium	High
Reformulation Cost	$491,188	$2,112,136	$4,257,760.
First Year Relabeling Costs	$3,467,560	$8,735,802	$23,619,959.
First Year Submission Costs	$529	$529	$529.
Total Cost of Option 1	$3.95 million	$10.85 million	$27.88 million.

As seen in table 3 of this document, the total cost of this option ranges from $3.95 million to $27.88 million, with the majority of cost coming from relabeling.

XII. Benefits

The potential benefits from this proposed rule, if finalized, are any cases of selenium deficiency that are avoided as a result of infant formulas meeting the 2.0 µg/100 kcal requirement. However, selenium deficiency is extremely rare, occurring primarily in areas of the world where the levels of selenium in the environment are low, such as China (Ref. 1). Therefore, it is not possible to quantify benefits accrued as a result of this rule and benefits will be discussed qualitatively.

The consequences of selenium deficiency may be of greatest concern in infants and children, who have relatively greater requirements for selenium than adults due to their rapid growth (Ref. 1). According to Daniels, et al. (2008), suboptimal selenium status is associated with a range of negative health outcomes including thyroid and immune dysfunction, viral infection, cardiovascular disease, inflammatory conditions, infertility, and an increased risk of some cancers (Ref. 5). Overt selenium deficiency is manifested as Keshan disease, an endemic fatal cardiomyopathy. Because infant formula may be an infant's only source of nutrition, the potential for developing a deficiency is averted if selenium is added to the formula.

XIII. Summary of Costs and Benefits of This Proposed Rule

The total costs of this proposed rule, if finalized, consist of one time reformulation costs, one time submission costs and one time relabeling costs. The total cost ranges between about $4 million and $28 million. Because the costs of this proposed rule are one time only costs, no annual costs are estimated for this proposal. Furthermore, because selenium deficiency is so rare, it is not possible to quantify benefits from any final rule resulting from this proposal.

Option 3: Finalize the proposed rule and make the provisions effective 12 months after publication.

In this option, firms are required to meet the requirements of the proposed rule for infant formula, that is, have formulas contain selenium at 2.0 µg and not more than 7.0 µg for each 100 kilocalories of the infant formula, and have manufacturers add selenium to the list of nutrients on infant formula labels. However, under Option 3, industry would have at least 12 months before they were required to comply with the rule.

XIV. Costs of Option 3

For this option, the primary costs of this proposed rule will be reformulation costs resulting from the firm that needs to add slightly more selenium to certain infant formulas in order to comply with any final rule resulting from this proposal, along with relabeling and submission costs. These costs are presented in 2012 dollars. In contrast to Option 2, relabeling costs for this option are less, because of the estimation of the cost model that, over a longer period of time, any labeling change is more likely to be able to be coordinated with a change in a label that may already be scheduled, and will diminish the need to, for example, purchase and apply stickers to packages affected by the change. As in Option 2, the Agency acknowledges the uncertainty in this estimation and how it may specifically apply to the infant formula industry and requests comment regarding the extent to which the effective date is likely to affect the cost of compliance with this proposed rule.

TABLE 4—SUMMARY OF COSTS OF OPTION 3

	Low	Medium	High
Reformulation Cost	$491,188	$2,112,136	$4,257,760
One Time Submission Cost	529	529	529
Relabeling Costs	438,747	765,439	1,271,285
Total Cost of Option 3	930,464	2,878,104	5,529,574

Therefore, the costs from this rule, as shown in table 4, range from about $930,464 to about $5.5 million.

XV. Benefits of Option 3

Benefits from this option are identical to Option 2, however, under this option, benefits are delayed by 6 months. The potential benefits from this proposed option are any cases of selenium deficiency avoided as a result of infant formulas meeting the 2.0 ug/100kcal requirement. As stated earlier, selenium deficiency is extremely rare, occurring primarily in areas of the world where the levels of selenium in the environment are low (Ref. 1).

XVI. Preliminary Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), this proposal, if finalized, will not have a significant impact on a substantial number of small entities, as only one firm is affected by this rule and it is considered large by Small Business Administration standards.

XVII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in this section of the document with an estimate of the annual third-party disclosure burden. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Third-Party Disclosure Requirements for Selenium in Infant Formula

Description of Respondents: The respondents to this information collection are manufacturers of infant formula marketed in the United States.

Description: The proposed rule, if finalized, would revise § 107.10(a) to require that selenium be listed in the nutrient list on the label for all infant formulas. In particular, in the nutrient list, selenium would be required to be listed between iodine and sodium and the amount per 100 calories declared; and, because selenium would be a required ingredient in infant formula, selenium would also be required to be declared in the formula's ingredient statement by its common or usual name and positioned according to the descending order of its predominance in the formula, under § 101.4. The present version of § 107.10(a) is approved by OMB in accordance with the PRA and has been assigned OMB control number 0910–0256. This proposed rule, if finalized, would modify the information collection associated with the present version of § 107.10(a) by adding 23 hours to the burden associated with the collection. A manufacturer not in compliance with the new minimum and maximum levels for selenium in infant formula would be required to make a one-time change to the nutrient list information disclosed to consumers on the label of its infant formula, to account for the required change in the amount of selenium in its products. The nutrient information disclosed by manufacturers on the infant formula label is necessary to inform purchasers of the value of the infant formula. As discussed previously in this document, FDA has the authority to revise the statement of the amounts of nutrients required for infant formula labeling in § 107.10(a)(2).

FDA estimates the burden of this collection of information as follows:

TABLE 5—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital cost
§ 107.10 Nutrient labeling for infant formula.	1	46	46	0.5 (30 minutes)	23	$765,439

[1] There are no operating and maintenance costs associated with this collection of information.

FDA tentatively concludes that the additional burden to disclose selenium in the ingredient statement resulting from the proposed amendment of § 107.10 would be negligible because all U.S. infant formula manufacturers currently add selenium as an ingredient to their infant formula products, and all manufacturers currently disclose the selenium in the ingredient statement, as specified by § 101.4. Additionally, all manufacturers currently disclose selenium in the nutrient list, as required by § 107.10(b)(5). Only one manufacturer produces infant formula that would not meet the requirements of this rule, if finalized, and would thus need to be reformulated. Under proposed § 107.10(a)(2), this one manufacturer would need to make a one-time labeling change to modify its nutrient list to account for the addition of more selenium to its infant formula.

The third-party disclosure burden consists of the setup time required to design a revised label and incorporate it into the manufacturing process. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that the affected manufacturer would require less than 0.5 hour per product to modify the label's nutrient list to reflect the addition of more selenium to the product. The Regulatory Impact Analysis estimates that this manufacturer produces 46 separate infant formulas that would need to be reformulated, and thus require relabeling. The one-time third-party disclosure burden for the proposed rule is estimated in table 5 of this document.

The final column of table 5 gives the estimated capital cost associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. The cost stated in table 5, $765,439, is based on the estimate in the Regulatory Impact Analysis under Option 3, which assumes that the proposed rule is finalized with an effective date of 1 year after publication. These costs are based on the estimation of the cost model that, over a longer period of time, any labeling change is more likely to be able to be coordinated with a change in a label that may already be scheduled, and will diminish the need to, for example, purchase and apply stickers to packages affected by the change. Additionally, because of the change in formulation of its products that would be required if the rule is finalized as proposed, a manufacturer would need to determine whether they are required to make a one-time submission to FDA before the first processing of its formulas, as required by section 412(d)(3) of the FD&C Act. This reporting requirement is approved by OMB under OMB control number 0910–0256. The current hour burden approved by OMB for section 412(d) of the FD&C Act is 10 hours per report. Based on the Agency's experience with infant formula submissions, FDA estimates that the affected manufacturer will submit one report that will cover all 46 reformulated infant formulas. In a future request for extension of the 0910–0256 information collection, FDA will include the additional report in its estimates.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Third-Party Disclosure Requirements for Selenium in Infant Formula.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by May 16, 2013, to the Office of Information and Regulatory Affairs, OMB.

XVIII. How do you submit comments on this rule?

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

XIX. References

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

1. Food and Nutrition Board. Institute of Medicine. Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids. Washington, DC: National Academy Press, p. 21–33; 292–299; 315–316, 2000.
2. Food and Nutrition Board. National Research Council. Recommended Dietary Allowances. 10th Edition. Washington, DC: National Academy Press, p. 221, 1989.
3. Raiten, D. J., J. M. Talbot, and J. H. Waters, ''Assessment of Nutrient Requirements for Infant Formulas,'' *Journal of Nutrition,* 128: 2059S–2249S, 1998.
4. Koletzko, B., S. Baker, G. Cleghorn, U. F. Neto, et al., ''Global Standard for the Composition of Infant Formula. Recommendations of an ESPGHAN Coordinated International Expert Group,'' *Journal of Pediatric Gastroenterology and Nutrition,* 41:584–599, 2005.
5. Daniels, L., R.A. Gibson, K. Simmer, P. Van Dael, M. Makrides, ''Selenium Status of Term Infants Fed Selenium-Supplemented Formula in a Randomized Dose-Response Trial,'' *American Journal of Clinical Nutrition,* 88:70–76, 2008.
6. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2013.
7. Codex Alimentarius Commission, ''Standards for Infant Formulas for Special Medical Purposes Intended for Infants, 72–1981,'' 1981.

List of Subjects in 21 CFR Part 107

Exempt infant formulas, Food labeling, General provisions, Infant formula, Infant formula recalls, Infants and children, Labeling, Nutrition, Nutrient requirements, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 107 is proposed to be amended as follows:

PART 107—INFANT FORMULA

The authority citation for 21 CFR part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

■ 1. In § 107.10, revise paragraph (a)(2) to read as follows:

§ 107.10 Nutrient Information.

(a) * * *

(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.
Selenium	Do.
Sodium	Milligrams.
Potassium	Do.
Chloride	Do.

* * * * *

■ 2. In § 107.100, revise paragraph (a) to read as follows:

§ 107.100 Nutrient specifications.

(a) An infant formula shall contain the following nutrients at a level not less than the minimum specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container:

Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	do	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300	
	Percent calories	2.7	
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	do	40	100
Vitamin E	do	0.7	

Nutrients	Unit of measurement	Minimum level	Maximum level
Vitamin K	Micrograms	4	
Thiamine (Vitamin B_1)	do	40	
Riboflavin (Vitamin B_2)	do	60	
Vitamin B_6	do	35	
Vitamin B_{12}	do	0.15	
Niacin [1]	do	250	
Folic Acid (folacin)	do	4	
Pantothenic acid	do	300	
Biotin [2]	do	1.5	
Vitamin C (ascorbic acid)	Milligrams	8	
Choline [2]	do	7	
Inositol [2]	do	4	
Minerals			
Calcium	do	60	
Phosphorus	do	30	
Magnesium	do	6	
Iron	do	0.15	3.0
Zinc	do	0.5	
Manganese	Micrograms	5	
Copper	do	60	
Iodine	do	5	75
Selenium	do	2	7
Sodium	Milligrams	20	60
Potassium	do	80	200
Chloride	do	55	150

[1] The generic term ''niacin'' includes niacin (nicotinic acid) and niacinamide (nicotinamide).
[2] Required only for non-milk-based infant formulas.

* * * * *

Dated: April 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08855 Filed 4–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 736, 737, 738, and 750

[Docket ID OSM–2012–0003]

RIN 1029–AC65

Cost Recovery for Permit Processing, Administration, and Enforcement

Correction

In proposed rule document R1–2013–06950, appearing on pages 20394–20408 in the issue of Thursday, April 4, 2013, make the following correction:

§ 738.11 [Corrected]

In the table on page 20407, in the third row, fourth column, ''1,300'' should read ''13,000''.

[FR Doc. C1–2013–06950 Filed 4–15–13; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF EDUCATION

34 CFR Chapter II

RIN 1810–AB17

[Docket ID ED–2013–OS–0050]

Proposed Priorities, Requirements, Definitions, and Selection Criteria—Race to the Top—District [CFDA Number: 84.416.]

AGENCY: Office of the Deputy Secretary, Department of Education.

ACTION: Proposed priorities, requirements, definitions, and selection criteria.

SUMMARY: The Secretary proposes priorities, requirements, definitions, and selection criteria under the Race to the Top—District program. The Secretary may use one or more of these priorities, requirements, definitions, and selection criteria for competitions using funds from fiscal year (FY) 2013 and later years. The Race to the Top—District program builds on the experience of States and districts in implementing reforms in the four core educational assurance areas through Race to the Top and other key programs and supports applicants that demonstrate how they can personalize education for all students in their schools. The U.S. Department of Education (Department) conducted one competition under the Race to the Top—District program in FY 2012, and we propose to maintain the overall purpose and structure of the FY 2012 Race to the Top—District competition. These proposed priorities, requirements, definitions, and selection criteria are almost identical to the ones we used in the FY 2012 competition. We describe the changes at the beginning of each section of this document.

DATES: We must receive your comments on or before May 16, 2013, and we encourage you to submit comments well in advance of this date.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email. To ensure we do not receive duplicate comments, please submit your comments only once. In addition, please include the Docket ID and the phrase ''Race to the Top—District-Comments'' at the top of your comments.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''How to use Regulations.gov'' in the Help section.

Postal Mail, Commercial Delivery, or Hand Delivery. If you mail or deliver your comments about these proposed priorities, requirements, definitions, and selection criteria, address them to the