DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Final Regulatory Impact Analysis
FDA-2013-N-0067

April 2015

I. Executive Order 12866 and Executive Order 13563: Cost Benefit Analysis

On April 16, 2013, we proposed to amend our 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 (78 FR 22442). The Economic Impact Analysis in the proposed rule explained the economic impact of the changes to regulations at part 107. We did not receive any comments on the costs or benefits of the proposed rule.

FDA has examined the impacts of this final 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 (Public Law 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). We believe that the final rule is not a significant regulatory action under Executive Orders 12866 and 13563.

The Regulatory Flexibility Act requires Agencies to determine whether a final rule will have a significant impact on small entities when an Agency issues a final rule "after being required . . . to publish a general notice of proposed rulemaking." We certify that this 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 $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Currently, five firms are registered with FDA and produce infant formula marketed in the United States. Based on information provided by the infant formula industry, it appears that all infant formula manufacturers already add selenium to their infant formula products at a level within or very close to the range identified by the final rule. Therefore, we estimate the costs for reformulating infant formula as a result of this final rule to be zero. The final 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). We estimate that one firm will incur relabeling costs to comply with this final rule. Costs are estimated using a relabeling model which estimates the costs of relabeling food, dietary supplements, and cosmetic products under FDA's jurisdiction, and these estimates have been adjusted to reflect 2014 dollars. These relabeling costs are estimated to be $792,439.

The potential benefit of this final rule is avoiding any cases of selenium deficiency as a result of infant formulas' meeting the 2.0 μg/100 kcal requirement. However, selenium deficiency is extremely rare. Therefore, it is not possible to quantify benefits accrued as a result of this rule.

II. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

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 will be required to relabel as required by this rule, and it is considered large by Small Business

Administration standards, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.