

a warning. Because individual magnets are easily shared among children, many end users of the product are likely to have had no exposure to any warning.

Unreasonable risk. As noted previously, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. Injuries resulting from such ingestions of magnets can be severe and life-threatening. The risk posed by these magnets may not be appreciated by caregivers and children, as they may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

We estimate that the societal costs of resulting injuries could amount to \$25 million annually. This would be the expected benefits that could result from the proposed rule. The costs of the proposed rule would consist of the lost profits of firms that produce and sell magnet sets, plus the lost use value that consumers would experience when the product is no longer available. We estimate these costs to be about \$7.5 million in lost profits and some unknown quantity of lost utility. Considering the injuries associated with magnet sets and the resulting societal costs, balanced against the likely impact that the proposed rule would have on firms producing and selling the product, and the impact on consumers who would lose the utility of the product, we conclude, preliminarily, that magnet sets pose an unreasonable risk of injury. Additionally, we conclude that the proposed rule is reasonably necessary to reduce that risk.

Public interest. This proposed rule is in the public interest because it may reduce magnet-related deaths and injuries in the future. A rule prohibiting certain magnet sets from the chain of commerce will mean that children will have less access to this product, thereby reducing the number of incidents of children swallowing the magnets and the resulting cost to society of treating these injuries.

Voluntary standards. Currently, there is no voluntary standard for magnetic sets. A group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The companies have requested the formation of a voluntary standard to: (1) Provide for appropriate warnings and labeling

on packages of these magnet sets, and (2) establish guidelines for restricting the sale of these magnet sets to, or for the use of children, such as by not selling to stores that sell children's products exclusively, and by not selling magnet sets in proximity to children's products. Such a voluntary standard would have many of the same limitations as a labeling standard.

Relationship of benefits to costs. Based on reports to the CPSC, ingestions of small magnets contained in magnet sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. Although there is some uncertainty concerning the benefits that would result from the proposed rule, we estimate that benefits of the rule might amount to about \$25 million annually. The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009–2011 study period, these costs could amount to about \$7.5 million in lost profits and some unknown quantity of lost utility. We believe that there would be a reasonable relationship between the anticipated benefits and costs of the proposed rule.

Least burdensome requirement. We have considered several alternatives to the proposed rule prohibiting certain magnet sets. We conclude that none of these alternatives would adequately reduce the risk of injury. Alternative performance requirements might allow a different flux index for magnets contained in magnetic sets. Theoretically, this might allow some current products to continue to be produced. However, it is unclear whether a different flux index would permit products that have the desired physical qualities to make them enjoyable to adults would reduce adequately the characteristics that make these strong magnets hazardous to children. Some type of special storage containers or other packaging requirements might be possible. However, it is unlikely that consumers would use such containers, particularly if they wish to keep the magnets out of the container and maintain whatever shape they have constructed with the magnets. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently on the market provide warnings concerning the potential hazard to children. It is unlikely that even strengthened warnings would substantially reduce the incidence of magnet ingestions. This

is particularly true for incidents involving older children and adolescents. Moreover, children who are old enough to understand the warnings still may not abide by them. Some type of sales restriction limiting the location where magnet sets could be sold might be possible. However, even with restrictions on sales, ingestions are still likely to occur as children encounter these magnets in the home, at school, or in other locations when adults have bought them and they are available to children. Finally, the Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.*, recalls of the product. However, such action would do nothing to prevent additional companies from continuing to enter the market and import magnet sets into the country. The Commission has the option of taking no regulatory action. Although it is possible that, with increased awareness of the hazard over time, some reduction in ingestions could occur, the magnitude of any such reduction in incidents is uncertain and would likely be smaller than if the Commission issues the proposed rule.

Dated: August 28, 2012.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2011–F–0765]

Nexira; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Nexira proposing that the food additive regulations be amended to provide for the expanded safe use of acacia gum (gum arabic) in foods.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by October 4, 2012.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–

305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1309.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** on December 20, 2011 (76 FR 78866), FDA announced that a food additive petition (FAP 1A4784) had been filed by Nexira, c/o Keller and Heckman LLP, 1001 G St. NW., Suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 172.780 *Acacia (gum arabic)* (21 CFR 172.780) to provide for the expanded safe use of acacia gum (gum arabic) in food.

Under 21 CFR 171.1(c)(H), either a claim of categorical exclusion under 21 CFR 25.30 or § 25.32 (21 CFR 25.32) or an environmental assessment under 21 CFR 25.40 is required to be submitted in a food additive petition. A claim of categorical exclusion under § 25.32(k) was submitted with the petition, which applies to substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food. The Agency reviewed the claim of categorical exclusion submitted by the petitioner and stated in the original filing notice its determination that, under § 25.32(k), the proposed action was of a type that does not individually or cumulatively have a significant effect on the human environment, and therefore, neither an environmental assessment nor an environmental impact statement is required.

However, upon further review of the petition, the Agency has decided that the food additive may act to replace macronutrients in food and, therefore, the categorical exclusion in § 25.32(k) is not applicable for the proposed action. The Agency informed the petitioner of this decision, who subsequently submitted an environmental assessment.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **DATES** and **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the Agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: August 28, 2012.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 172

[FHWA Docket No. FHWA-2012-0043]

RIN 2125-AF44

Procurement, Management, and Administration of Engineering and Design Related Services

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA proposes to update the regulations governing the procurement, management, and administration of engineering and design related services directly related to a highway construction project and reimbursed with Federal-aid highway program (FAHP) funding. The intent is to make the regulations consistent with prior changes in legislation and other applicable regulations. These revisions also address certain findings and recommendations for the oversight of consultant services contained in national review and audit reports.

DATES: Comments must be received on or before November 5, 2012. Late

comments will be considered to the extent practicable.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, or submit electronically at <http://www.regulations.gov> or fax comments to (202) 493-2251. All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Page 19477-78), or you may visit <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Obenberger, Preconstruction Team Leader, FHWA Office of Program Administration, (202) 366-2221, or via email at jon.obenberger@dot.gov, or Mr. Steven Rochlis, Attorney Advisor, FHWA Office of the Chief Counsel, (202) 366-1395, or via email at steve.rochlis@dot.gov. Office hours for the FHWA are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at: <http://www.regulations.gov>. The Web site is available 24 hours each day, 366 days this year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: <http://www.archives.gov/federal-register/>, or the Government Printing Office's Web page at: <http://www.gpo.gov/fdsys>.

Background

The FHWA proposes to modify existing regulations for the administration of engineering and design related service contracts to ensure consistency and compliance with prior changes in authorizing