



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2015-F-3663]

Grocery Manufacturers Association; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Grocery Manufacturers Association, proposing that the food additive regulations be amended to provide for the safe use of partially hydrogenated vegetable oils (PHOs) in various food applications.

DATES: This food additive petition was filed on October 1, 2015. Submit either electronic or written comments on the petitioner's environmental assessment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-F-3663 for "Grocery Manufacturers Association; Filing of Food Additive Petition". Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions,"

publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper 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 and/or go to the Division of Dockets Management, 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: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 5A4811), submitted by the Grocery Manufacturers Association, 1350 I Street, NW., suite 300, Washington, DC 20005. The petition proposes to amend the food additive regulations in 21 CFR part 172 Food Additives Permitted for Direct Addition to Food for Human Consumption to provide for the safe use of PHOs in the following food applications at specified maximum use levels: As a carrier or component thereof for flavors or flavorings, as a diluent or component thereof for color additives, as an incidental additive or processing aid, and as a direct additive in specific foods.

We are reviewing the potential environmental impact of this petition. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), we are 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.

We will also place on public display, in the Division of Dockets Management and at <http://www.regulations.gov>, any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on our review, we find that an environmental impact statement is not required, and this petition results in a

regulation, we will publish the notice of availability of our finding of no significant impact and the evidence supporting that finding with the regulation in the Federal Register in accordance with 21 CFR 25.51(b).

Dated: October 22, 2015.

Dennis M. Keefe,

Director, Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2015-27277 Filed: 10/27/2015 08:45 am; Publication Date: 10/28/2015]