4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2014-F-0988]

# BASF Corp.; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BASF Corp., as a part of their petition (FAP 2286) proposing that the food additive regulations be amended to provide for the safe use of feed grade sodium formate as a feed acidifying agent in complete swine feeds, also proposed that FDA amend the animal food additive regulations for formic acid and ammonium formate to limit formic acid and formate salts from all added sources.

DATES: Submit either electronic or written comments on FDA'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 comment, 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-2014-F-0988 for "Food Additives Permitted in Feed and Drinking Water of Animals; Feed Grade Sodium Formate." 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 comment 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 dockets, 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: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that the food additive petition (FAP 2286) filed by BASF Corp., 100 Park Ave., Florham Park, NJ 07932 proposing to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of feed grade sodium formate as a feed acidifying agent in complete swine feeds, also proposed that FDA amend the animal food additive regulations for formic acid (§ 573.480) and ammonium formate (§ 573.170) to limit formic acid and formate salts from all added sources to 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination. This element of the petition was not described in the July 25, 2014, notice of petition (79 FR 43325).

Elsewhere in this issue of the Federal Register, FDA is publishing a regulation providing for the safe use of feed grade sodium formate as a feed acidifying agent in complete swine feeds.

The potential environmental impact of this action is being reviewed. The Agency will prepare a claim of categorical exclusion or an environmental assessment to evaluate the potential environmental impacts of these actions. 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 comments on potential environmental impact without

further announcement in the Federal Register. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, FDA will prepare an environmental assessment and place it on public display at the Division of Dockets Management (see DATES AND ADDRESSES) for public review and comment.

Dated: September 26, 2016.

Tracey H. Forfa,

Deputy Director,

Center for Veterinary Medicine.

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