Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 1.230 through 1.235 and 21 CFR 1.245 have been approved under OMB control number 0910–0502.

Dated: November 3, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–26930 Filed 11–7–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 573

**[Docket No. FDA–2014–F–0452]**

## Novus International, Inc.; 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 Novus International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement dairy heifers. Additionally, the petition proposes that the food additive regulations be amended to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food.

**DATES:** Submit either electronic or written comments on the petitioner's environmental assessment by December 8, 2016.

**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–0452 for ''Food Additives Permitted in Feed and Drinking Water of Animals; 2-Vinylpyridine-Co-Styrene.'' 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:** Carissa Doody, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6283, *carissa.doody@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 a food additive petition (FAP 2295) has been filed by Novus International, Inc., 20 Research Park Dr., Saint Charles, MO 63304. The petition proposes to amend part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement dairy heifers, and to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food.

The potential environmental impact of this action 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 **ADDRESSES**) for public review and comment. Interested persons may submit to the Division of Dockets Management (see **DATES** and **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. 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: November 2, 2016.

**Tracey H. Forfa,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. 2016–26922 Filed 11–7–16; 8:45 am]

**BILLING CODE 4164–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R08–OAR–2012–0933; FRL–9954–92–Region 8]**

## Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 2008 Lead, 2008 Ozone, 2010 $NO_2$, 2010 $SO_2$, and 2012 $PM_{2.5}$ National Ambient Air Quality Standards; Wyoming

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve elements of State Implementation Plan (SIP) revisions from the State of Wyoming to demonstrate the State meets infrastructure requirements of the Clean Air Act (Act or CAA) for the National Ambient Air Quality Standards (NAAQS) promulgated for ozone on March 12, 2008, lead (Pb) on October 15, 2008, nitrogen dioxide ($NO_2$) on January 22, 2010, sulfur dioxide ($SO_2$) on June 2, 2010, and fine particulate matter ($PM_{2.5}$) on December 14, 2012. The EPA is also proposing to approve SIP revisions the State submitted regarding state boards. Section 110(a) of the CAA requires that each state submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by the EPA.

**DATES:** Written comments must be received on or before December 8, 2016.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R08–OAR–2012–0933 at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

**FOR FURTHER INFORMATION CONTACT:** Abby Fulton, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6563, *fulton.abby@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*What should I consider as I prepare my comments for the EPA?*

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to the EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** volume, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and,
- Make sure to submit your comments by the comment period deadline identified.

### II. Background

On March 12, 2008, the EPA promulgated a new NAAQS for ozone, revising the levels of the primary and secondary eight-hour ozone standards from 0.08 parts per million (ppm) to 0.075 ppm (73 FR 16436, March 27, 2008). Subsequently, on October 15, 2008, the EPA revised the level of the primary and secondary Pb NAAQS from 1.5 micrograms per cubic meter ($\mu g/m^3$) to 0.15 $\mu g/m^3$ (73 FR 66964, Nov. 12, 2008). On January 22, 2010, the EPA promulgated a new one-hour primary NAAQS for $NO_2$ at a level of 100 parts per billion (ppb) while retaining the annual standard of 53 ppb. The 2010 $NO_2$ NAAQS is expressed as the three-year average of the 98th percentile of the annual distribution of daily maximum one-hour average concentrations. The secondary $NO_2$ NAAQS remains unchanged at 53 ppb (75 FR 6474, Feb. 9, 2010). On June 2, 2010, the EPA promulgated a revised primary $SO_2$ standard at 75 ppb, based on a three-year average of the annual 99th percentile of one-hour daily maximum concentrations (75 FR 35520, June 22, 2010). Finally, on December 14, 2012, the EPA promulgated a revised annual $PM_{2.5}$ standard by lowering the level to 12.0 $\mu g/m^3$ and retaining the 24-hour $PM_{2.5}$ standard at a level of 35 $\mu g/m^3$ (78 FR 3086, Jan. 15, 2013).

Under sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure their SIPs provide for implementation, maintenance and enforcement of the NAAQS. These submissions must contain any revisions needed for meeting the applicable SIP requirements of section 110(a)(2), or certifications that their existing SIPs for $PM_{2.5}$, ozone, Pb, $NO_2$, and $SO_2$ already meet those requirements. The EPA highlighted this