

§ 923.85 Procedural requirements of other Federal law.

(a) NOAA shall determine on a case-by-case basis whether each program change requires NOAA to take additional actions under any other federal requirement described below.

(1) If a state's program change will affect the resources or interests of any federally-recognized American Indian or Alaska Native tribal government (tribe), NOAA shall contact the affected tribe(s) and determine if Government-to-Government consultation is desired under Executive Order 13175 (Nov. 6, 2000).

(2) If, for the purposes of ESA, NHPA, MSFCMA or MMPA compliance, NOAA determines that a state's program change will have effects on listed threatened or endangered species, historic properties, essential fish habitat or marine mammals, then NOAA shall determine if consultation is needed with the applicable federal agency under the ESA, NHPA, MSFCMA and MMPA.

(3) When NOAA determines whether to consult under other federal statutes or tribal executive orders, NOAA's ability to require changes to a state's proposed program change are limited by the following:

(i) Once NOAA approves a state's management program, NOAA cannot require a state to change its program. NOAA can, through periodic evaluations of a state's management program under section 312 of the Act, establish necessary actions if NOAA finds a state is not adhering to its NOAA-approved program, but NOAA can only recommend that a state change its program to create a different state standard or to address emerging issues; and

(ii) NOAA can approve or disapprove a program change request. When NOAA reviews a program change, NOAA has a limited ability to require a state to make changes to state policies. If NOAA disapproves a program change request, this does not require a state to change state law. Therefore, there is no effect from NOAA's denial on the implementation of state law at the state (or local government) level. NOAA's denial means the disapproved state policy is not part of the state's NOAA-approved management program and cannot be used for CZMA federal consistency purposes. NOAA cannot use a program change to require changes to other parts of a state's management program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 1**

[Docket No. FDA-2012-D-1002]

Questions and Answers Regarding Food Facility Registration (Seventh Edition); Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." This draft guidance contains 15 sections of a multisection guidance intended to provide updated information relating to the food facility registration requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 6, 2017.

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-2012-D-1002 for the draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition)." 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/>

[regulatoryinformation/dockets/default.htm](http://www.regulations.gov/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.

Submit written requests for single copies of the draft guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Courtney Buchanan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2487.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

On October 10, 2003, FDA issued an interim final rule (68 FR 58893) to implement amendments to the FD&C Act made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. Section 102 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act to, among other things, require facilities engaged in manufacturing, processing, packing, or

holding food for consumption in the United States to submit additional registration information to FDA. Section 102 of FSMA also directed FDA to amend the definition of "retail food establishment" in 21 CFR 1.227. On July 14, 2016, FDA issued a final rule (Registration Final Rule) to amend and update FDA's registration regulation and implement the FSMA revisions (81 FR 45912; July 14, 2016).

This draft guidance was developed to answer frequently asked questions relating to the registration requirements of section 415 of the FD&C Act. The first edition of the guidance was issued as Level 2 guidance consistent with our good guidance practices regulation (21 CFR 10.115) and was made available on FDA's Web site on December 4, 2003. The second, third, fourth, and fifth editions of the guidance were issued as Level 1 guidance documents under 21 CFR 10.115 and were made available on FDA's Web site on January 12, 2004; February 17, 2004; August 6, 2004; and December 17, 2012, respectively. The sixth edition of the guidance was issued as Level 1 guidance and included one additional question and answer relating to a proposed amendment to the "farm" definition in 21 CFR 1.227 (see 79 FR 58523; September 29, 2014). Since publication of the sixth edition of the guidance, we have issued the Registration Final Rule. In addition, we have issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule (Preventive Controls for Human Food Final Rule) (80 FR 55908; September 17, 2015) that, among other things, revised the definition of "farm" in 21 CFR 1.227. We have also issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule (Preventive Controls for Animal Food Final Rule) (80 FR 56169; September 17, 2015). We are issuing a seventh edition of the guidance to add information relating to the Registration Final Rule and the revised "farm" definition, as well as to address questions received from stakeholders since publication of the sixth edition. We are reserving two sections in the draft guidance and will issue a revised draft guidance at a later date that includes those reserved sections. The sections that we are announcing are as follows:

- Section A: Who Must Register?
- Section D: When Must You Register or Renew Your Registration?
- Section E: How and Where Do You Register or Renew Your Registration?
- Section F: What Information is Required in the Registration?

- Section G: What Optional Items are Included in the Registration?

- Section H: How and When Do You Update Your Facility's Registration Information?

- Section I: How and When Do You Cancel Your Facility's Registration Information?

- Section J: What Other Registration Requirements Apply?

- Section K: What are the Consequences of Failing to Register, Renew, Update, or Cancel Your Registration?

- Section L: What Does Assignment of a Registration Number Mean?

- Section M: Is Food Registration Information Available to the Public?

- Section N: Waiver Request

- Section O: General Registration Questions

- Section P: Suspension of Registration

- Section Q: Compliance Dates

We intend to announce the availability for public comment of the remaining sections of the draft guidance in a revised draft guidance.

This edition of the draft guidance also revises information in existing questions and answers, removes some questions and answers, and makes editorial changes (e.g., we reorganized existing questions and answers) to improve clarity. For the revised questions and answers, we are not adding a date indicating when the questions and answers were revised. As in the previous editions, the following indicators are used to help users identify revisions: (1) The guidance is identified as a revision of a previously issued document; (2) the revision date appears on the cover of the guidance; (3) the edition number of the guidance is included in its title; and (4) questions and answers that have been added are identified as such in the body of the guidance. In addition, we indicated certain sections in the draft guidance as "Reserved."

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of

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.

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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