Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0577; FRL–9984–21]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before November 19, 2018.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov;* or Robert McNally, Biopesticides and Pollution Prevention Division (7511P), main telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to 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 preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included

in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petitions so that the public has an opportunity to comment on these requests for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petitions may be obtained through the petition summaries referenced in this unit.

A. Amended Tolerance For Inerts

PP IN–11139. (EPA–HQ–OPP–2018–0243). Monsanto Company, 1300 I Street, NW, Washington, DC 20005, requests to amend tolerances 40 CFR 180.471 for residues of furilazole (3-dichloroacetyl-5-(2-furanyl)-2,2-dimethyloxazolidine; CAS Reg. No. 121776–33–8) when used as an inert ingredient (herbicide safener) in or on the raw agricultural commodities corn, sweet, forage at 0.01 ppm, corn, sweet, kernel plus cob with husks removed at 0.01 parts per million (ppm), and, corn, sweet, stover at 0.01 ppm. The gas liquid chromatography/mass spectrometry with selected ion monitoring method is used to measure and evaluate the chemical furilazole. *Contact:* RD.

B. Amended Tolerances for Non-Inerts

1. *PP 8E8684.* (EPA–HQ–OPP–2018–0514). Interregional Research Project Number 4 (IR–4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540, proposes upon establishment of the tolerances referenced in this document under ''New Tolerances'' for PP 8E8684, to remove existing tolerances in 40 CFR 180.585 for residues of the herbicide pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1H-pyrazol-3-yl]-4-fluorophenoxy] acetate, and its acid metabolite, E–1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on cotton, undelinted seed at 0.04 ppm; fruit, stone, group 12 at 0.01 ppm; grape at 0.01 ppm; nut, tree, group 14 at 0.01 ppm; olive at 0.01 ppm; and pistachio at 0.01 ppm. *Contact:* RD.

2. *PP 8E8689.* (EPA–HQ–OPP–2018–0560). IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540, proposes upon establishment of the tolerances referenced in this document under ''New Tolerances'' for PP 8E8689, to remove existing tolerances in 40 CFR 180.553 for residues of the fungicide fenhexamid (N–2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide in or on the raw agricultural commodities: Bushberry subgroup 13B at 5.0 ppm; caneberry subgroup 13A at 20.0 ppm, cilantro, leaves at 30.0 ppm, fruit, stone, group 12, except plum, prune, fresh, postharvest at 10.0 ppm; grape at 4.0 ppm; juneberry at 5.0 ppm; kiwifruit, postharvest at 15.0 ppm; leafy greens subgroup 4A, except spinach at 30.0 ppm; lingonberry at 5.0 ppm; salal at 5.0 ppm; strawberry at 3.0 ppm; and vegetable, fruiting, group 8, except nonbell pepper at 2.0 ppm. The ''Method for the Determination of KBR 2738 (TM–402) Residues in Plant Material by HPLC'' is used to measure and evaluate the chemical fenhexamid. *Contact:* RD.

C. New Tolerance Exemptions for Inerts (Except PIPs)

1. *IN–11109.* (EPA–HQ–OPP–2018–0201). Exponent, Inc. (1150 Connecticut Ave, Suite 1100, NW, Washington, DC 20036) on behalf of Croda, Inc. (315 Cherry Lane, New Castle, DE 19720) requests to establish an exemption from the requirement of a tolerance for residues of C1–C4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers (C1–C4 Linear and Branched Chain AD–GDAE) cluster (D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-(CAS Reg. No. 5306–85–4), D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-ethyl- (CAS Reg. No. 30915–81–2), D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-propyl) (CAS Reg. No.107644–13–3), D-glucitol, 1,4:3,6-dianhydro-2,5-bis-O-(1-methylethyl) -,(iso-propyl diether) (CAS Reg. No. 103594–41–8), D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-butyl-(CAS Reg. No. 103594–41–9), D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(1-methylpropyl)-, (CAS Reg. No. not assigned) and D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(2-methylpropyl)-, (CAS Reg. No. not assigned) when used as an inert ingredient (solvent, co-solvent, viscosity modifier and adjuvant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910, applied in/on animals under 40 CFR 180.930, in antimicrobial formulations used in food contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a) and in antimicrobial formulations used for dairy processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(b). The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

2. *PP IN–11126.* (EPA–HQ–OPP–2018–0191). Spring Trading Company on behalf of Clariant, 4000 Monroe Rd., Charlotte, NC 28205, requests to establish an exemption from the requirement of a tolerance for residues of N,N-Dimethylnonanamide (CAS Reg. No. 6225–08–7) when used as a pesticide inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and in pesticide formulations applied to animals under 40 CFR 1280.930. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

3. *PP IN–11175.* (EPA–HQ–OPP–2018–0545). SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192, on behalf of Eden Research plc, 6 Priory Court, Priory Court Business Park, Poulton, Cirencester GL7 5JB, United Kingdom, requests to establish an exemption from the requirement of a tolerance for residues of cell walls of Saccharomyces cerevisiae when used as a pesticide inert ingredient in pesticide formulations applied to growing crops only under 40 CFR 180.920. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

4. *PP IN–11189.* (EPA–HQ–OPP–2018–0546). Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001, on behalf of Synthomer USA LLC, requests to establish an exemption from the requirement of a tolerance for residues of Polyvinyl acetate—polyvinyl alcohol copolymer (CAS Reg. No. 25213–24–5) when used as a pesticide inert ingredient in pesticide formulations under 40 CFR 180.960. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

D. New Tolerances for Non-Inerts

1. *PP 8E8684.* (EPA–HQ–OPP–2018–0514). IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180.585 for residues of the herbicide pyraflufen-ethyl, including its metabolites and degradates in or on the raw agricultural commodities (RACs). Compliance with the plant commodity tolerance levels specified below is to be determined by measuring only the sum of the parent

pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1H-pyrazol-3-yl]-4-fluorophenoxy] acetate, and its acid metabolite, E–1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the following RACs: Cottonseed subgroup 20C at 0.04 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.01 ppm; fruit, stone, group 12–12 at 0.01 ppm; hop, dried cones at 0.02 ppm; nut, tree, group 14–12 at 0.01 ppm; tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.01 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. Available analytical methodology involves multiple-step extractions of the chemical residues from plants and using Gas Chromatograph-Mass Spectrometry (GC–MS) to measure and evaluate pyraflufen-ethyl residues. *Contact:* RD.

2. *PP 8E8689.* (EPA–HQ–OPP–2018–0560). IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180.553 for residues of the fungicide fenhexamid (N–2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide in or on the raw agricultural commodities: Arugula at 30.0 ppm; berry, low growing, subgroup 13–07G at 3.0 ppm; bushberry subgroup 13–07B at 5.0 ppm; caneberry subgroup 13–07A at 20.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 4.0 ppm; fruit, stone, group 12–12, except plum, prune, fresh, postharvest at 10.0 ppm; garden cress at 30.0 ppm; kiwifruit, fuzzy at 30.0 ppm; leafy greens subgroup 4–16A, except spinach at 30.0 ppm; onion, bulb, subgroup 3–07A at 2.0 ppm; onion, green, subgroup 3–07B at 30.0 ppm; upland cress at 30.0 ppm; and vegetable, fruiting, group 8–10, except nonbell pepper at 2.0 ppm. The ''Method for the Determination of KBR 2738 (TM–402) Residues in Plant Material by HPLC'' is used to measure and evaluate the chemical fenhexamid. *Contact:* RD.

Authority: 21 U.S.C. 346a.

Dated: October 1, 2018.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2018–22659 Filed 10–17–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS–4187–P]

RIN 0938–AT87

Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Federal Health Insurance Programs for the Aged and Disabled by amending the Medicare Parts A, B, C and D programs, as well as the Medicaid program, to require direct-to-consumer (DTC) television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC, or ''list price'') of that drug or biological product. We are proposing this regulation to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also expenditures borne by Medicare and Medicaid, both of which are significant problems.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 17, 2018.

ADDRESSES: In commenting, please refer to file code CMS–4187–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4187–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4187–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cheri Rice, (410) 786–6499.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

A. Purpose

The purpose of this proposed rule is to reduce the price to consumers of prescription drugs and biological products. This rule would require direct-to-consumer (DTC) television advertisements for prescription drug and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product. We are proposing this regulation to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also unreasonable expenditures borne by Medicare and Medicaid, both of which are significant problems.

Markets operate more efficiently when consumers have relevant information about a product, including its price, as well as alternative products and their prices, before making an informed decision whether to buy that product or, instead, a competing one. Consumers price shop when looking to purchase a new car, a new house, or even a new coffee maker. Price shopping is the mark of rational