

trifluoromethylnicotinamide (IUPAC)] and its metabolites, TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] and TFNG [N(4-trifluoromethylnicotinoyl)-glycine] in or on the raw agricultural commodity crop group 10–10, citrus at 1.5 parts per million (ppm). Adequate enforcement methodology is available to enforce the tolerance expression for flonicamid and its metabolites in/on appropriate raw agricultural commodities and processed commodities are available for the established and proposed tolerances. *Contact:* Carmen Rodia, (703) 306–0327, rodia.carmen@epa.gov.

2. *PP 6E8466.* (EPA–HQ–OPP–2016–0029). Gowan Company, P.O. Box 5569, Yuma, AZ 85366–5569, requests to establish an import tolerance for residues of fenazaquin, [3-[2-[4-(1,1-dimethylethyl) phenyl] ethoxy] quinazoline] in/on the raw agricultural commodity for tea at 9 ppm and pineapple at 0.2 ppm. The analytical method for the analysis of fenazaquin in/on tea was conducted by GC–MS in selected ion monitoring mode. The analytical method used for the determination of fenazaquin in or on pineapple was conducted by UPLC employing mass spectrometric detection (LC–MS/MS). *Contact:* Carmen Rodia, (703) 306–0327, rodia.carmen@epa.gov.

3. *PP 6F8468.* (EPA–HQ–OPP–2016–0416). BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528, requests to establish a tolerance for residues of the insecticide afidopyropen, [(3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3-(cyclopropanecarbonyloxy)-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,2,3,4,4a,5,6,6a,12a,12b-decahydro-11H,12H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropanecarboxylate, its metabolites, and degradates, in or on the raw agricultural commodities almond hulls at 0.15 ppm; apple, wet pomace at 0.05 ppm; citrus oil at 0.3 ppm; cotton, gin byproducts at 2 ppm; cotton, undelinted seed at 0.1 ppm; fruit, citrus, group 10–10 at 0.15 ppm; fruit, pome, group 11–10 at 0.03 ppm; fruit, stone, group 12–12 at 0.03 ppm; nut, tree, group 14–12 at 0.01 ppm; plum, prune at 0.06 ppm; soybean, aspirated fractions at 0.4 ppm; soybean, forage at label restriction ppm; soybean, hay at label restriction ppm; soybean, seed at 0.01 ppm; vegetable, brassica, head and stem group 5–13 at 0.5 ppm; vegetable, cucurbit, group 9 at 0.7 ppm; vegetable, fruiting, group 8–10 at 0.15 ppm; vegetable, leaf petioles, subgroup 22B at 3 ppm; vegetable, leafy, subgroup 4–13A at 2 ppm; vegetable leafy, subgroup 4–

13B at 5 ppm; and vegetable tuberous and corm, subgroup 1C at 0.01 ppm.

An independently validated analytical method has been submitted for analyzing residues of parent afidopyropen (BAS 440 I) plus metabolite M440I007 with appropriate sensitivity in all crop and processed commodities. An independently validated analytical method has been submitted for analyzing residues of parent afidopyropen (BAS 440 I) plus metabolite M440I001, M440I003, and M440I060 in animal meat, fat and liver and egg and for BAS 440 I and metabolites M440I001, M440I005, and M440I060 in milk with appropriate sensitivity in the event tolerances are established. A multi-residue method using modified AOAC Official method 2007.01 for the determination of residues of afidopyropen (BAS 440 I) and metabolite M440I007 in plant matrices was successfully validated. *Contact:* Carmen Rodia, (703) 306–0327, rodia.carmen@epa.gov.

4. *PP 6E8463.* (EPA–HQ–OPP–2007–0099). Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808–2951, requests to establish an import tolerance for residues of flubendiamide, N²-[1,1-dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N¹-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in/on the processed commodity dried tea at 60 ppm. Independently validated, analytical methods for crop matrices have been submitted for measuring flubendiamide. Typically, plant matrices samples are extracted, concentrated, and quantified by LC/MS/MS using deuterated internal standards. *Contact:* Carmen Rodia, (703) 306–0327, rodia.carmen@epa.gov.

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

Dated: August 5, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2016–19239 Filed 8–11–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2000–0006; FRL–9950–61–Region 2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Jackson Steel Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent for deletion.

SUMMARY: The Environmental Protection Agency (EPA), Region 2, is issuing this Notice of Intent to Delete (NOID) the Jackson Steel Site, located in the Village of Mineola, Nassau County, New York, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan. EPA and the State of New York, through the New York State Department of Environmental Conservation (NYSDEC), have determined that other than the ongoing operation and maintenance of the vapor intrusion mitigation systems at the daycare center, periodic vapor intrusion monitoring, ensuring that the institutional controls are in place and effective, and five-year reviews, all appropriate response actions under CERCLA have been completed at the Site and that the soil on the Site and the groundwater beneath the Site no longer pose a threat to public health or the environment.

DATES: Comments must be received by *September 12, 2016*.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–2000–0006, by mail to Joel Singerman, Chief, Central New York Remediation Section, Emergency and Remedial Response Division, U.S. Environmental Protection Agency, Region 2, 290 Broadway, 20th Floor, New York, NY, 10007–1866. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the “Addresses” section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Joel Singerman at the address noted in the **ADDRESSES** section; by telephone at 212–

637-4258; or by email at singerman.joel@epa.gov.

SUPPLEMENTARY INFORMATION: In the “Rules and Regulations” Section of today’s **Federal Register**, EPA is publishing a direct final Notice of Deletion (NOD) of the Site without a prior NOID because EPA views this as a noncontroversial revision and anticipates no adverse comment. EPA has explained its reasons for this deletion in the preamble to the direct final NOD. If EPA receives no adverse comment(s) on this deletion action, EPA will proceed with the deletion without further action on this NOID. If EPA receives adverse comment(s), EPA will withdraw the direct final NOD, and it will not take effect. EPA will, as appropriate, address all public comments in a subsequent final NOD based on this NOID. EPA will not institute a second comment period on this NOID. Any parties interested in commenting must do so at this time.

For additional information, see the direct final NOD, which is located in the “Rules” section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601-9675; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: August 2, 2016.

Judith A. Enck,

Regional Administrator, EPA Region.

[FR Doc. 2016-19142 Filed 8-11-16; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AA90

340B Drug Pricing Program; Administrative Dispute Resolution

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Health Resources and Services Administration (HRSA) implements section 340B of the Public Health Service Act (PHSA), which is referred to as the “340B Drug Pricing Program” or the “340B Program.” This proposed rule will apply to all drug

manufacturers and covered entities that participate in the 340B Program. The proposed rule sets forth the requirements and procedures for the 340B Program’s administrative dispute resolution process.

DATES: Submit written comments on or before October 11, 2016.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906-AA90, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow instructions for submitting comments. This is the preferred method for the submission of comments.

- *Email:* 340BNPRMADR@hrsa.gov. Include 0906-AA90 in the subject line of the message.

- *Regular, express, or overnight mail:* CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

All submitted comments will be available to the public in their entirety. All comments received may be posted without change to <http://www.regulations.gov>, including any personally identifiable or confidential business information that is included in a comment.

FOR FURTHER INFORMATION CONTACT:

CAPT Krista Pedley, Director, OPA, HSB HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301-594-4353.

SUPPLEMENTARY INFORMATION: The President encourages Federal agencies through Executive Order 13563 to develop balanced regulations by encouraging broad public participation in the regulatory process and an open exchange of ideas. Accordingly, the Department of Health and Human Services (HHS or the Department) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any data to support your positions. If you have questions before submitting comments, please see the **FOR FURTHER INFORMATION CONTACT** field above for the name and contact information of the subject-matter expert involved in the development of this proposal. We will consider all written comments received during the comment period before issuing a final rule.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please contact HRSA’s Regulations Officer at: Room 13N82, 5600 Fishers Lane, Rockville, MD 20857; or by telephone at 301-443-1785, to obtain this information in an accessible format. This is not a toll free telephone number.

Please visit <http://www.HHS.gov/regulations> for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

I. Background

Section 602 of Public Law 102-585, the “Veterans Health Care Act of 1992,” enacted section 340B of the PHSA entitled “Limitation on Prices of Drugs Purchased by Covered Entities,” which was codified at 42 U.S.C. 256b. The 340B Program permits covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. REP. No. 102-384(II), at 12 (1992). The Secretary of the HHS delegated the authority to operate section 340B of the PHSA to the Administrator of HRSA. Pursuant to this delegation of authority, HRSA established and administers the 340B Program. Operationally, the 340B Program is housed within HRSA’s Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA). Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, as amended. Section 340B of the PHSA instructs HHS to enter into pharmaceutical pricing agreements (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS that comply with section 340B of the PHSA if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data reported by manufacturers to the Centers for Medicare & Medicaid Services (CMS).

Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111-152), hereinafter referred to as the “Affordable Care Act,” added section 340B(d)(3) of the PHSA, which requires the Secretary of HHS (or the Secretary) to promulgate a regulation establishing