criteria, and advances in knowledge showing scientific concerns with the logic underpinning the criteria as constructed in 1994, the Agency cannot utilize the proposed criteria as a basis for this rulemaking. EPA is therefore withdrawing this proposal.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP–300369. See also related dockets identified by the docket ID numbers OPP–300370 and OPP–300371.

Authority: 7 U.S.C. 136 *et seq.,* 21 U.S.C. 346.

Dated: April 25, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–09206 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0291; FRL–9976–34]

Receipt of a Pesticide Petition Filed for Residues of Diquat in or on Crop Group 6C, Dried Shelled Pea and Bean (Except Soybean); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction.

SUMMARY: EPA issued a notice in the **Federal Register** of September 15, 2017, announcing the initial filing of a pesticide petition 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 June 6, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2017–0291, 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, Director, Registration Division (RD) (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

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).

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 Does this Correction Do?

This notice is being issued to correct PP 7E8571. (EPA–HQ–OPP–2017–0291) in FR Doc. 2017–19692, published in the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL–9965–43) is corrected as follows:

PP 7E8571. (EPA–HQ–OPP–2017–0291). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419, requests to establish a tolerance in 40 CFR 180.226 for residues of the herbicide, diquat (6,7-dihydrodipyrido [1,2-a:2′1′-c] pyrazinediium), and its metabolites in or on Crop Group 6C, dried shelled pea and bean (except soybean) at 0.9 parts per million (ppm). The Method GRM012.03A is used to measure and evaluate the chemical residues of diquat dibromide in commodities. Contact: RD.

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

Dated: April 26, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2018–09648 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AB18

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking; further delay of effective date.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act, referred to as the ''340B Drug Pricing Program'' or the ''340B Program.'' HHS is soliciting comments on further delaying the

effective date of the January 5, 2017, final rule that sets forth the calculation of the ceiling price and application of civil monetary penalties, and applies to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. HHS proposes to further delay the effective date of the final rule published in the **Federal Register** from July 1, 2018, to July 1, 2019. HHS proposes this action to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking.

DATES: Submit comments on or before May 22, 2018.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB18, 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: 340BCMPNPRM@hrsa.gov.* Include 0906–AB11in the subject line of the message.
- *Mail:* Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.

All comments submitted will be available to the public in their entirety. Please do not submit confidential commercial information or personally identifying information that you do not want in the public domain.

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:

I. Background

HHS published a notice of proposed rulemaking (NPRM) on June 17, 2015, to implement civil monetary penalties (CMPs) for manufacturers that knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity regarding the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis; and to establish the requirement that a manufacturer charge $.01 (penny pricing) for each unit of a drug when the ceiling price calculation equals zero (80 FR 34583, June 17, 2015). After review of the initial comments, HHS reopened the comment period (81 FR 22960, April 19, 2016) to invite additional comments on the following areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers use when estimating the ceiling price for a new covered outpatient drug; and the definition of the ''knowing and intentional'' standard to be applied when assessing a CMP for manufacturers that overcharge a covered entity.

On January 5, 2017, HHS published a final rule in the **Federal Register** (82 FR 1210, January 5, 2017); comments from both the original comment period established in the NPRM and the reopened comment period announced in the April 19, 2016, notice were considered in the development of the final rule. The provisions of that final rule were to be effective March 6, 2017; however, HHS issued a subsequent final rule (82 FR 12508, March 6, 2017) delaying the effective date to March 21, 2017, in accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, titled ''Regulatory Freeze Pending Review.'' [1]

To provide affected parties sufficient time to make needed changes to facilitate compliance, and because questions were raised, HHS issued an interim final rule (82 FR 14332, March 20, 2017) to delay the effective date of the final rule to May 22, 2017. HHS solicited additional comments on whether that date should be further extended to October 1, 2017. After careful consideration of the comments received, HHS delayed the effective date of the January 5, 2017, final rule to October 1, 2017 (82 FR 22893, May 19, 2017).

HHS later solicited comment on delaying the effective date of the January 5, 2017, final rule to July 1, 2018 (82 FR 39553, August 21, 2017). After consideration of the comments received, HHS delayed the effective date of the January 5, 2017, final rule to July 1, 2018 (82 FR 45511, September 29, 2017).

II. Proposal To Delay the Effective Date of the Final Rule

HHS proposes to further delay the effective date of the January 5, 2017, final rule as HHS intends to engage in additional or alternative rulemaking on these issues, and as discussed in more detail on page 5, the Department believes it would be counterproductive to effectuate the final rule prior to issuance of additional or alternative rulemaking on these issues. HHS is in the process of developing new comprehensive policies to address the rising costs of prescription drugs. Those policies will address drug pricing in government programs, such as Medicare Parts B & D, Medicaid, and the 340B discount drug program. Accordingly, we are proposing to delay the effective date of the final rule entitled ''340B Drug Pricing Ceiling Price and Manufacturer Civil Monetary Penalties Regulation.'' See 82 FR 1210 (Jan. 5, 2017).

This rule is currently scheduled to go into effect on July 1, 2018; we are proposing to delay further the effective date to July 1, 2019. We do not believe that this delay will adversely affect any of the stakeholders in a meaningful way. The final rule implements both penny pricing and a provision in the Affordable Care Act contemplating civil money penalties for those who fail to provide the proper 340B discounts to covered entities. The so-called penny pricing provision would allow manufacturers to charge $0.01 for a drug with when the ceiling price calculation results in a zero amount. As discussed in the January 5, 2017 final rule, a small number of manufacturers have informed HHS over the last several years that they charge more than $0.01 for a drug with a ceiling price below $0.01. However, this is a long-standing HHS policy, and HHS believes the majority of manufacturers currently follow the practice of charging a $0.01. Therefore, the delay of this portion of the regulation would not result in a significant economic impact.

Delaying implementation of the 340B-specific CMPs should have no adverse effect given that other more significant remedies are available to entities that believe that they have not been provided the full discount that they are entitled to receive under the program. This proposed delay, though, will save the healthcare sector compliance costs, as described in the January 5, 2017 issuance of the final rule.

HHS believes that the proposed delay would allow necessary time to consider more fully the substantial questions of fact, law, and policy identified by the Department during its review of the rule pursuant to the aforementioned ''Regulatory Freeze Pending Review,'' memorandum. Requiring manufacturers to make targeted and potentially costly changes to pricing systems and business procedures to comply with a rule that is under further consideration would be disruptive.

[1] See: *https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.*

As background, the January 20, 2017, Executive Order entitled, ''Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal,'' specifically instructs HHS and all other heads of executive offices to utilize all authority and discretion available to delay the implementation of certain provisions or requirements of the Patient Protection and Affordable Care Act.[2] The January 5, 2017, final rule is based on changes made to the 340B Program by the Patient Protection and Affordable Care Act. HHS is proposing to further delay the effective date of the January 5, 2017, final rule to July 1, 2019, to more fully consider the regulatory burdens that may be posed by this final rule.

At this time, HHS seeks public comment regarding the impact of delaying the effective date of the final rule, published January 5, 2017, for an additional 12 months from the current effective date of July 1, 2018, to Ju1y 1, 2019, while a more deliberate rulemaking process is undertaken. HHS is soliciting public comments for a shortened 15-day period because parties have had ample opportunity to comment on the two prior delays of the effective date of the underlying 340B regulation, and the impact of this delay on the regulated community is de minimis. Given the prior opportunities to comment on the underlying proposed regulation and the delays, we do not envision receiving any novel comments. Moreover, we believe that the delay of the CMP authority can be issued without the opportunity for public comment because it delays the effective date of a regulatory restriction. HHS encourages all stakeholders to provide comments on this proposed rule.

III. Regulatory Impact Analysis

HHS has examined the effects of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (Pub. L. 96–354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB).

HHS does not believe that the proposal to further delay the effective date of the January 5, 2017, final rule will have an economic impact of $100 million or more, and therefore, this NPRM has not been designated as an ''economically significant'' proposed rule under section 3(f)(1) of the Executive Order 12866. The economic impact of having no rule in place related to the policies addressed in the final rule is believed to be minimal.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This action's designation as regulatory or deregulatory will be discussed in the final rule and be informed by comments received in response to this proposed rule.

The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief for small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

For purposes of the RFA, HHS considers all health care providers to be small entities either by meeting the Small Business Administration (SBA) size standard for a small business, or by being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $7 million to $35.5 million. As of January 1, 2018, over 12,800 covered entities participate in the 340B Program, representing safety-net health care providers across the country. HHS has determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small manufacturers; therefore, we are not preparing an analysis of impact for this RFA. HHS estimates that the economic impact on small entities and small manufacturers would be minimal. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' In 2017, the threshold level was approximately $148 million. HHS does not expect this rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This proposed rule would not ''have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and

[2] See: *https://www.gpo.gov/fdsys/pkg/FR-2017-01-24/pdf/2017-01799.pdf.*

responsibilities among the various levels of government.''

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This proposed rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. This proposed rule would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

Dated: May 1, 2018.

George Sigounas,

Administrator, Health Resources and Services Administration.

Approved: May 2, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–09711 Filed 5–4–18; 8:45 am]

BILLING CODE 4165–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 2, 90

[WP Docket No. 07–100; FCC 18–33]

4.9 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In 2002, the Commission allocated the 4940–4990 MHz (4.9 GHz) band for fixed and mobile use and designated the band for public safety broadband communications. Since then, the band has experienced relatively light usage compared to the heavy use of other public safety bands. In this document, the Commission proposes several rule changes and seeks comment on alternatives with the goal of promoting increased public safety use of the band while opening up the spectrum to additional uses that will encourage a more robust market for equipment and greater innovation. The Commission proposes rules on channel aggregation, aeronautical mobile use, frequency coordination, site-based licensing, regional planning, and technical rule changes with the goal of promoting increased use of the band. The Commission seeks comment on alternatives such as expanding eligibility, spectrum leasing, sharing, and redesignating the band for commercial use.

DATES: Submit comments on or before July 6, 2018. Submit reply comments August 6, 2018.

ADDRESSES: You may submit comments, identified by WP Docket No. 07–100 by any of the following methods:

- *Federal Communications Commission's website: http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- *Hand or Messenger Delivery:* 445 12th St., SW, Room TW–A325, Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Thomas Eng, Policy and Licensing Division, Public Safety and Homeland Security Bureau, Federal Communications Commission, 445 12th Street SW, Washington, DC 20554, at (202) 418–0019, TTY (202) 418–7233, or via email at *Thomas.Eng@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Sixth Further Notice of Proposed Rulemaking (*Sixth FNPRM*) in WP Docket No. 07–100, adopted on March 22, 2018 and released as FCC 18–33 on March 23, 2018. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY–A257, Washington, DC 20554. Alternative formats (computer diskette, large print, audio cassette, and Braille) are available to persons with disabilities or by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at (202) 418–0530, TTY (202) 418–0432. This document is also available on the Commission's website at *http://www.fcc.gov.*

Comments

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). See *Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1 (1998).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

Introduction

The Commission has allocated and designated 50 megahertz of spectrum in the 4.9 GHz band (4940–4990 MHz) to public safety. Although nearly 90,000 public safety entities are eligible under our rules to obtain licenses in the band, there were only 2,442 licenses in use in 2012 and only 3,174 licenses in use nearly six years later in 2018. With no more than 3.5% of potential licensees using the band, we remain concerned that, as the Commission stated in 2012, the band has ''fallen short of its potential.''

Public safety entities have offered several reasons why the band has seen less use than expected. One reason cited is the difficulty of acquiring equipment and the cost of deployment. According