Products, Food and Drug Administration, 301–796–5616, *melissa.burns@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an immediately in effect guidance for industry entitled ''Compliance Policy for Combination Product Postmarketing Safety Reporting.'' This guidance describes FDA's compliance policy for combination product applicants and constituent part applicants and activities under 21 CFR part 4, subpart B, which was published in the **Federal Register** of December 20, 2016 (81 FR 92603) and addresses postmarketing safety reporting for combination products. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment, because we have determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). We made this determination because FDA needs to communicate its compliance policy in a timely manner given the upcoming compliance deadlines for certain provisions in 21 CFR part 4, subpart B, and the amount of time needed for firms to prepare for them. Although this guidance is immediately effective, it remains subject to comment in accordance with FDA's GGP regulation.

Published elsewhere in this issue of the **Federal Register,** FDA is announcing the availability of the draft guidance entitled ''Postmarketing Safety Reporting for Combination Products.''

This guidance represents the current thinking of 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 alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This 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 314.80(c) and (e), as well as for 21 CFR 314.81(b) are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The information collection provisions for 21 CFR 600.80 and 600.81 are approved under OMB control number 0910–0308. Those for 21 CFR 606.170 are approved under OMB control number 0910–0116. Those for 21 CFR 606.171 are approved under OMB control number 0910–0458. The information collection provisions for 21 CFR 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The information collection provisions for 21 CFR 806.10 and 806.20 are approved under OMB control number 0910–0359. The information collection provisions for §§ 4.102, 4.103, and 4.105 are approved under OMB control number 0910–0834.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: March 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05688 Filed 3–20–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

Requirements for Preparation, Adoption, and Submittal of Implementation Plans

CFR Correction

■ In Title 40 of the Code of Federal Regulations, Parts 50 to 51, revised as of July 1, 2017, on page 478, in Part 51, Appendix M, following *Reynolds Number.,* Equation 10 is reinstated to read as follows:

$$N_{re} = 8.64 \times 10^{5} \left[\frac{P_s M_w}{T_s} \right] \left[\frac{Q_s}{\mu} \right] \qquad \text{(Eq. 10)}$$

[FR Doc. 2018–05798 Filed 3–20–18; 8:45 am]

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0639; FRL–9974–63]

Aluminum tris (O-ethylphosphonate); Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends a tolerance for residues of aluminum tris (O-ethylphosphonate) in or on Fruit, citrus, group 10. Fosetyl-al is the common name for aluminum tris (O-ethylphosphonate). Tessenderlo Kerley, Inc requested the amended tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 21, 2018. Objections and requests for hearings must be received on or before May 21, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0639, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (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: