whether the product's labeling meets the requirements of the FHSA.

VII. Effect on State and Local Laws

In general, the preemption language in section 18(b)(1)(A) of the FHSA provides that if a hazardous substance or its packaging is subject to a cautionary labeling requirement under the FHSA designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to a hazardous substance or packaging that is designed to protect against the same risk of illness or injury, unless the cautionary labeling requirement is identical to the labeling requirement under the FHSA. 15 U.S.C. 1261n. As mentioned, this document provides guidance to industry. This guidance does not have binding legal force, does not constitute a rule, and thus, does not have preemptive effect. However, the underlying duty to label a hazardous household product arises from the FHSA. This underlying statutory obligation preempts state and local non-identical cautionary labeling requirements that are designed to protect against the same risk of injury or illness.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2018–05580 Filed 3–20–18; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA–2008–N–0424]

Immediately in Effect Guidance for Industry; Compliance Policy for Combination Product Postmarketing Safety Reporting; 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 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 FDA regulations that addresses combination product postmarketing safety reporting. This guidance is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on March 21, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2008–N–0424 for ''Compliance Policy for Combination Product Postmarketing Safety Reporting.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Combination Products, Food and Drug Administration, Bldg. 32, Rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Office of Combination

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: