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* 16. Food and Drug Administration Supplemental Review of Topical Tranilast, April 25, 2016.

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List of Subjects in 21 CFR Part 216

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 216 is amended as follows:

PART 216—HUMAN DRUG COMPOUNDING

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353a, 353b, 355, and 371.

■ 2. Add § 216.23 to subpart B to read as follows:

§ 216.23 Bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act.

(a) The following bulk drug substances can be used in compounding under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act.

(1) Brilliant Blue G, also known as Coomassie Brilliant Blue G–250.

(2) Cantharidin (for topical use only).

(3) Diphenylcyclopropenone (for topical use only).

(4) N-acetyl-D-glucosamine (for topical use only).

(5) Squaric acid dibutyl ester (for topical use only).

(6) Thymol iodide (for topical use only).

(b) After balancing the criteria set forth in paragraph (c) of this section, FDA has determined that the following bulk drug substances will not be included on the list of substances that can be used in compounding set forth in paragraph (a) of this section:

(1) Oxitriptan.

(2) Piracetam.

(3) Silver Protein Mild.

(4) Tranilast.

(c) FDA will use the following criteria in evaluating substances considered for inclusion on the list set forth in paragraph (a) of this section:

(1) The physical and chemical characterization of the substance;

(2) Any safety issues raised by the use of the substance in compounded drug products;

(3) The available evidence of the effectiveness or lack of effectiveness of a drug product compounded with the substance, if any such evidence exists; and

(4) Historical use of the substance in compounded drug products, including information about the medical condition(s) the substance has been used to treat and any references in peer-reviewed medical literature.

(d) Based on evidence currently available, there are inadequate data to demonstrate the safety or efficacy of any drug product compounded using any of the drug substances listed in paragraph (a) of this section, or to establish general recognition of the safety or effectiveness of any such drug product. Any person who represents that a compounded drug made with a bulk drug substance that appears on this list is FDA approved, or otherwise endorsed by FDA generally or for a particular indication, will cause the drug to be misbranded under section 502(a) and/or 502(bb) of the Federal Food, Drug, and Cosmetic Act.

Dated: February 11, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019–02367 Filed 2–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

32 CFR Part 162

[Docket ID: DOD–2018–OS–0084]

RIN 0790–AK46

Productivity Enhancing Capital Investment (PECI)

AGENCY: Under Secretary of Defense (Personnel and Readiness), DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the DoD regulation issued to explain to contractors how the Productivity Enhancing Capital Investment (PECI) program could be used by DoD components to fund projects that improve productivity. This rule implemented an Executive Order which has since been revoked. The associated internal programs were discontinued, and internal guidance was cancelled. The content of this part is obsolete.

DATES: *Effective Date:* This rule is effective on February 19, 2019.

FOR FURTHER INFORMATION CONTACT: Dana F. Kline, 703–695–4506, *dana.f.kline.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: It has been determined that publication of this CFR part removal for public comment is

impracticable, unnecessary, and contrary to public interest because it is based on removing obsolete information. This rule implemented Executive Order 12637, ''Productivity Improvement Program for the Federal Government,'' which was revoked by Executive Order 13048, ''Improving Administrative Management in the Executive Branch,'' on June 10, 1997. The DoD-level program was discontinued in 2010, and the corresponding internal DoD guidance was canceled. Any associated reporting was sunset thereafter. The content of the rule is obsolete and should be removed.

This rule is not significant under Executive Order (E.O.) 12866, Regulatory Planning and Review, therefore, the requirements of E.O. 13771, Reducing Regulation and Controlling Regulatory Costs do not apply.

List of Subjects in 32 CFR Part 162

Armed forces, Arms and munitions, Government contracts.

PART 162—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 162 is removed.

Dated: February 12, 2019.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 2019–02619 Filed 2–15–19; 8:45 am]

BILLING CODE 5001–06–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 32, 54, and 65

[WC Docket Nos. 10–90, 14–58, 07–135, CC Docket No. 01–92; FCC 18–176]

Connect America Fund, ETC Annual Reports and Certifications, Establishing Just and Reasonable Rates for Local Exchange Carriers, Developing a Unified Intercarrier Compensation Regime

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) continues its efforts to bridge the digital divide. The Commission addresses the challenges that rate-of-return carriers face by taking steps to promote broadband deployment, ensure the efficient use of resources, and provide sufficient and predictable support necessary to increase broadband deployment. The Commission also denies three petitions seeking reconsideration of its decision directing the Wireline Competition Bureau (Bureau) to offer additional support up to $146.10 per-location to all carriers that accepted the revised offers of model-based support.

DATES: Effective March 21, 2019, except for the amendments to §§ 54.313 and 54.316, which contain information collection requirements that have not been approved by OMB—the FCC will publish a document in the **Federal Register** announcing the effective date of those amendments awaiting OMB approval—and except for the amendments to §§ 32.1410, 32.2680, 32.2681, 32.2682, 32.3400, 32.3410, 32.4130, 32.4200, 32.4300, 32.7500, 54.643, and 65.450, which are effective January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Suzanne Yelen, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order and Order on Reconsideration in WC Docket Nos. 10–90, 14–58, 07–135, CC Docket No. 01–92; FCC 18–176, adopted on December 12, 2018 and released on December 13, 2018. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW, Washington, DC 20554 or at the following internet address: *https://docs.fcc.gov/public/attachments/FCC-18-176A1.pdf.* The Further Notice of Proposed Rulemaking (FNPRM) that was adopted concurrently with the Report and Order and Order on Reconsideration will be published elsewhere in this issue of the **Federal Register**.

I. Introduction

1. In the Report and Order, the Commission continues its efforts to bridge the digital divide. According to the Commission's most recently available data, about 30% of rural Americans lack access to fixed, terrestrial high-speed internet of at least 25 Mbps download/3 Mbps upload (25/3 Mbps), the Commission's current speed benchmark, which reflects consumer demand for high-speed broadband services. In urban areas, that number is 2%. The gap between broadband access in rural and urban areas is unacceptable. The Commission must do better. The Commission has made progress in bringing broadband service to rural Americans living in areas served by our nation's largest telecommunications companies, and will realize additional gains as the winners of the Connect America Fund (CAF) Phase II auction begin to deploy 25/3 Mbps or higher speed service to approximately 713,176 locations. But the rules governing smaller, community-based providers—rate-of-return carriers—have not kept pace, making it more difficult for these carriers to bring 25/3 Mbps service to rural America. The Report and Order addresses the challenges that rate-of-return carriers face by taking steps to promote broadband deployment, ensure the efficient use of resources, and provide sufficient and predictable support necessary to increase broadband deployment.

2. By improving access to modern communications services, the Commission can help provide individuals living in rural America with the same opportunities that those in urban areas enjoy. Broadband access is critical to economic opportunity, job creation, education, and civic engagement. And as important as these benefits are in America's cities, they can be even more important in America's more remote small towns and rural and insular areas. Rural Americans deserve to reap the same benefits of the internet—and not run the risk of falling yet further behind.

3. The Report and Order marks a significant next step in closing the digital divide. The Commission recognizes that access to 25/3 Mbps broadband service is not a luxury for urban areas, but important to Americans wherever they live. To that end, the Commission adopts additional measures toward its goal of expanding the availability of affordable broadband service to rural America. First, the Commission makes another model offer to those rate-of-return carriers currently receiving Alternative Connect America Cost Model (A–CAM) support for additional funding if they commit to building out to additional locations at speeds of 25/3 Mbps. Second, the Commission makes a new model offer to those on legacy support in return for specifically tailored obligations to build out broadband networks providing speeds of 25/3 Mbps. Third, for those rate-of-return carriers remaining on legacy support that do not take the new model offer, the Commission adopts a new budget based on uncapped 2018 claims that will be increased by inflation annually, as well as new deployment obligations that require speeds of 25/3 Mbps rather than 10/1 Mbps. Fourth, the Commission adopts measures to mitigate the regulatory burden on providers and encourage the