

§ 558.342 Melengestrol.

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(d) * * *

(3) Liquid or dry combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be labeled in accordance with § 558.311(d).

(4) Liquid or dry combination Type B or C medicated feeds containing melengestrol acetate and monensin must be labeled in accordance with § 558.355(d).

(5) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(d).

(6) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

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Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-06704 Filed 3-31-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 821

[Docket No. FDA-2021-N-0246]

Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its medical device regulations to make an editorial nonsubstantive change and replace a reference to an obsolete office with updated information. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective April 1, 2021.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993-0002, 301-796-5837.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's Center for Devices and Radiological Health (CDRH) has reorganized to create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs (84 FR 22854, May 20, 2019; 85 FR 18439, April 2, 2020). The newly formed Office of Product Evaluation and Quality (OPEQ) combined the former Office of Compliance, the Office of Device Evaluation, the Office of Surveillance and Biometrics, and the Office of In Vitro Diagnostics and Radiological Health, with a focus on a Total Product Lifecycle (TPLC) approach to medical device oversight. Within OPEQ there are Offices of Health Technology that focus on the TPLC review of specific types of medical devices as well as cross-cutting offices focusing on specific policy and programmatic needs including the Office of Regulatory Programs and the Office of Clinical Evidence and Analysis. As part of this technical amendment, we are making changes to correct a reference to an obsolete office and to correctly identify the positions with authority to make decisions on exemptions and variances from tracking orders. This change is nonsubstantive and editorial in nature.

II. Description of the Technical Amendments

The regulations specified in this rule have been revised to make a non-substantive editorial change to correct "Director of the Office of Regulatory Program" to "Director or Principal Deputy Director of the Office of Product Evaluation and Quality" and replace a reference to "Director, Office of Compliance" with "Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality." The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). Section 553 of the Administrative Procedure Act (APA) exempts "rules of agency organization, procedure, or practice" from proposed rulemaking (*i.e.*, notice and comment rulemaking) (5 U.S.C. 553(b)(3)(A)). Rules are also exempt when an Agency finds "good cause" that notice and

comment rulemaking procedures would be "impracticable, unnecessary, or contrary to the public interest" (5 U.S.C. 553(b)(3)(B)).

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA's revisions make technical or non-substantive changes that pertain solely to the CDRH reorganization and do not alter any substantive standard. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as "provided by the agency for good cause found and published with the rule" (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 821

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 821 is amended as follows.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

■ 1. The authority citation for part 821 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

■ 2. In § 821.2, revise paragraphs (b) introductory text and (c) to read as follows:

§ 821.2 Exemptions and variances.

* * * * *

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

* * * * *

(c) An exemption or variance is not effective until the Director or Deputy Directors, CDRH, or the Director or Principal Deputy Director of the Office of Product Evaluation and Quality,

CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

Dated: March 25, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021-06681 Filed 3-31-21; 8:45 am]

BILLING CODE 4164-01-P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4908

RIN 1212-AB52

Rescission of Pension Benefit Guaranty Corporation Rule on Guidance

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule; rescission of regulations.

SUMMARY: On August 26, 2020, the Pension Benefit Guaranty Corporation (PBGC) published a final rule on guidance implementing an Executive order entitled “Promoting the Rule of Law Through Improved Agency Guidance Documents,” and providing policy and requirements for issuing, modifying, withdrawing, and using guidance; making guidance available to the public; a notice and comment process for significant guidance; and taking and responding to petitions about guidance. In accordance with the “Executive Order on Revocation of Certain Executive Orders Concerning Federal Regulation,” issued by President Biden on January 20, 2021, this final rule rescinds PBGC’s rule on guidance.

DATES: This final rule is effective April 1, 2021.

FOR FURTHER INFORMATION CONTACT: Hilary Duke (duke.hilary@pbgc.gov), Assistant General Counsel for Regulatory Affairs, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026; 202-229-3839. (TTY users may call the Federal Relay Service toll-free at 800-877-8339 and ask to be connected to 202-229-3839.)

SUPPLEMENTARY INFORMATION:

I. Discussion

On August 26, 2020, the Pension Benefit Guaranty Corporation (PBGC) published a final rule on procedures for PBGC guidance documents implementing E.O. 13891, “Promoting the Rule of Law Through Improved

Agency Guidance Documents,” signed by President Trump on October 9, 2019. As required by the E.O., this rule contained policy and requirements for issuing, modifying, withdrawing, and using guidance; making guidance available to the public; a notice and comment process for significant guidance; and taking and responding to petitions about guidance (85 FR 52481).

On January 20, 2021, President Biden issued E.O. 13992, “Revocation of Certain Executive Orders Concerning Federal Regulation” which, among other things, revoked E.O. 13891 and directed agencies to promptly take steps to rescind any orders, rules, regulations, guidelines, or policies, or portions thereof, implementing or enforcing the Executive orders. In accordance with E.O. 13992, PBGC is issuing this final rule, which rescinds the rule on procedures for PBGC guidance documents published at 85 FR 52481.

II. Final Rule

PBGC has determined that this rule is suitable for final rulemaking. The revisions to PBGC’s policies and requirements surrounding guidance are purely internal matters of agency management, as well as the agency’s organization, procedure, and practice. Accordingly, as with the August 2020 final rule, PBGC is not required to engage in a notice and comment process to issue this rule under the Administrative Procedure Act. See 5 U.S.C. 553(a)(2), 553(b)(A). Furthermore, because this rule is procedural rather than substantive, the normal requirement of 5 U.S.C. 553(d) that a rule not be effective until at least 30 days after publication in the **Federal Register** is inapplicable. PBGC also finds good cause to provide an immediate effective date for this rule because it imposes no obligations on parties outside the federal government and therefore no advance notice is required to enable employers or other private parties to come into compliance.

List of Subjects in 29 CFR Part 4908

Administrative practice and procedure, Employee benefit plans, Organization and functions (Government agencies), Pension insurance.

PART 4908—[REMOVED]

■ For the reasons discussed in the preamble, and under the authority of section 4002(b)(3) of the Employee Retirement Income Security Act of 1974 (ERISA), which authorizes PBGC to issue regulations to carry out the purposes of title IV of ERISA, and E.O.

13992, PBGC amends title 29, chapter XL, subchapter L of the Code of Federal Regulations by removing part 4908.

Issued in Washington, DC.

Gordon Hartogensis,

Director, Pension Benefit Guaranty Corporation.

[FR Doc. 2021-06734 Filed 3-31-21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0155]

RIN 1625-AA87

Security Zone; Cleveland Harbor, Cleveland, OH

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone for navigable waters surrounding the Port of Cleveland, First Energy Stadium, The Rock and Roll Hall of Fame, and Voinovich Bicentennial Park from east of the Cuyahoga River entrance to west of the Voinovich Bicentennial Park and outward from shore, including inlets, to the navigation channel as marked by navigation buoys, but not including the channel. The security zone is needed to protect the public, participants, and spectators of the 2021 NFL Draft from terrorist and similar criminal acts, accidents, or other incidents detrimental to public safety. Entry of persons, vessels or objects into this zone when under enforcement is prohibited unless specifically authorized by the Captain of the Port Buffalo or her representative.

DATES: This rule is effective from 8 a.m. on April 29, 2021, through 11:59 p.m. on May 1, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0155 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Natalie Smith, Waterways Management Division, U.S. Coast Guard Marine Safety Unit Cleveland; telephone 216-937-6007, email D09-SMB-MSUCleveland-WWM@uscg.mil.