requirements of PDMA, PDA, or this part, remains responsible for creating and maintaining all requests, receipts, forms, reports, and records required under PDMA, PDA, and this part.

* * * * *

■ 11. In § 203.37, revise paragraph (e) to read as follows:

§ 203.37 Investigation and notification requirements.

* * * * *

(e) *Whom to notify at FDA.* Notifications and reports concerning samples of human prescription drugs or biological products that are regulated by the Center for Drug Evaluation and Research shall be made via email to *PDMAREPORTS@fda.hhs.gov.* Alternatively, reports and correspondence concerning such samples may be made via regular mail to the Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, ATTN: PDMA Reports. Notifications and reports concerning samples of human prescription biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002.

Subpart E [Removed and Reserved]

■ 12. Remove and reserve subpart E, consisting of § 203.50.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–01927 Filed 2–3–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. FDA–2011–N–0446]

Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment; Withdrawal

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

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of the proposed rule ''Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment,'' published in the **Federal Register** on July 14, 2011. FDA is taking this action because the proposed changes are duplicative of another FDA proposed rulemaking, which is also being published in this issue of the **Federal Register**, that is intended to conform with newly established definitions and requirements set out by the Drug Supply Chain Security Act of 2013 (DSCSA).

DATES: The proposed rule published July 14, 2011 (76 FR 41434), is withdrawn as of February 4, 2022.

ADDRESSES: For access to the docket, 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.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Center for Drug Evaluation and Research, Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–9362, *AaronWeisbuch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. The DQSA contains two titles: Title I, the Compounding Quality Act, and Title II, the DSCSA (Pub. L. 113–54). The DSCSA amended Chapter V of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding Subchapter H (Pharmaceutical Distribution Supply Chain), sections 581 through 585 (21 U.S.C. 360eee through 360eee–4), and by amending section 503(e) of the FD&C Act (21 U.S.C. 353(e)). As amended, sections 503(e) and 583 of the FD&C Act require the Secretary to establish national prescription drug wholesale distributor licensure standards. In addition, section 582 of the FD&C Act establishes prescription drug product tracing requirements for wholesale distributors and their trading partners.

On July 14, 2011, FDA proposed to remove § 203.50(a) (21 CFR 203.50(a)). Before that rulemaking was finalized, the DSCSA was enacted. Section 204 of the DSCSA amended section 503(e)(1) through (3) of the FD&C Act with additional and different requirements for wholesale distributors. The DSCSA also added new requirements for wholesale distributors, including phased-in prescription drug tracing requirements in section 582(c) of the FD&C Act. Because of the changes to requirements for wholesale distributors under the DSCSA, the Agency's proposed rule published on July 14, 2011, to remove § 203.50(a), was never finalized.

In its proposed rulemaking entitled ''Certain Requirements Regarding Prescription Drug Marketing,'' published elsewhere in this issue of the **Federal Register**, FDA will propose a rule that will seek to amend part 203 (21 CFR part 203) to remove provisions no longer in effect and incorporate conforming changes following enactment of the DSCSA. In the proposed rulemaking, the Agency will clarify provisions to avoid potential confusion with the new standards for wholesale distribution established by the DSCSA. The amendments to part 203 in the proposed rule will include the removal of § 203.50 in its entirety, rendering the proposed rule published July 14, 2011, removing § 203.50(a), obsolete.

II. Withdrawal of the Proposed Rule

As result of these efforts, FDA is withdrawing the proposed rule ''Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment,'' published in the **Federal Register** of July 14, 2011.

The withdrawal of this proposed rule does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposal. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, this proposed rule is only intended to address the withdrawal of the proposed rule on ''Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment,'' published in the **Federal Register** of July 14, 2011, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rule, visit the Agency's website at *https://www.fda.gov* for any current information on the matter.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–01928 Filed 2–3–22; 8:45 am]

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