hundreds of millions of Americans, and that participants in every single industry the Department regulates, including Plaintiffs, must plan their futures and operations without knowing what regulations will govern their businesses in these notoriously complex regulatory arenas. *See* Complaint, ¶¶ 2, 95–122. While HHS does not concede that Plaintiffs would establish irreparable harm in litigation, HHS agrees that it is appropriate to postpone the effective date of the SUNSET final rule to preserve the status quo and to ensure that HHS has time to evaluate the rule before it takes effect to avoid the possibility of confusion among the regulated community. All of these potential consequences would be detrimental to the public health, underscoring that justice requires a postponement of the SUNSET final rule's effective date pursuant to 5 U.S.C. 705.

We further conclude that extending the effective date of the SUNSET final rule will create no countervailing harms because this delay merely continues the status quo. And because implementation of the regulatory review framework provided under the SUNSET final rule would be a complex and lengthy process, any purported benefits from the retirement of regulations under the new process would not accrue for several years. Accordingly, given the public health concerns and the harms from the implementation of the SUNSET final rule alleged by the Plaintiffs and echoed in the comments to the SUNSET proposed rule and the Withdrawal NPRM, and the dearth of countervailing harms from extending the effective date, the balance of equities and the public interest favor the extension of the stay of the effective date of the SUNSET final rule to preserve the status quo and allow for judicial review of its legality before any implementation.

Accordingly, HHS is issuing this further stay of the effective date of this final rule pending judicial review. This postponement applies to all of the regulations established under the SUNSET final rule. As noted above, the Complaint alleges that the SUNSET final rule suffers from a variety of defects, including procedural defects related to its promulgation. The Department believes it is appropriate to review the entire rule in light of the claims raised in the litigation, which it continues to actively evaluate in conjunction with its consideration of the comments to the Withdrawal NPRM and its efforts to develop a final rule. Thus, this postponement reaches the full rule, consistent with the Complaint's prayer for relief.

**Xavier Becerra,**

*Secretary.*

[FR Doc. 2022–04524 Filed 3–3–22; 8:45 am]

**BILLING CODE 4150–26–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 7

**[Docket No. FDA–2018–D–2074]**

### Initiation of Voluntary Recalls; Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry and FDA staff entitled ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' The guidance for industry and FDA staff provides guidance on timely initiation of voluntary recalls of FDA-regulated products. It also discusses preparations that firms in a distribution chain should consider making to ensure timely responses to a recall communication. In addition, the guidance discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed products in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other laws administered by FDA. This guidance finalizes the draft guidance of the same title issued on April 24, 2019.

**DATES:** The announcement of the guidance is published in the **Federal Register** on March 4, 2022.

**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–2018–D–2074 for ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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 Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4141, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Peter Fox, Office of Regulatory Affairs, Office of Strategic Planning and Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4146, Rockville, MD 20857, 240–402–1857, *Peter.Fox@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' The guidance for industry and FDA staff provides guidance on timely initiation of voluntary recalls of FDA-regulated products. The guidance discusses what preparations firms in a distribution chain, including manufacturers and distributors, should consider making to establish recall initiation procedures; to ensure timely identification of, and response to, product problems that might lead to a recall; and to promptly issue recall communications and press releases or other public notices. It also discusses preparations that firms in a distribution chain should consider making to ensure timely responses to recall communications. In addition, the guidance discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed products in violation of the FD&C Act and other laws administered by FDA.

This guidance finalizes the draft guidance of the same title issued on April 24, 2019 (84 FR 17112). FDA considered comments received on the draft guidance as the guidance was finalized. In addition to editorial changes made to improve clarity, changes from the draft to the final guidance include the addition of the terms *correction* and *market withdrawal* to the terminology section, the addition of language encouraging the use of electronic communications for conveying voluntary recall communications about FDA-regulated products, and the deletion of section IV (''References'').

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The 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.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 7.46, 7.49, and 7.59 have been approved under OMB control number 0910–0249; section 417 of the FD&C Act (21 U.S.C. 350f) has been approved under OMB control number 0910–0643; section 761 of the FD&C Act (21 U.S.C. 379aa–1) has been approved under OMB control number 0910–0291; 21 CFR 107.240 has been approved under OMB control number 0910–0188; 21 CFR part 117 has been approved under OMB control number 0910–0751; and 21 CFR part 507 has been approved under OMB control number 0910–0751.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.regulations.gov.*

Dated: February 28, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–04704 Filed 3–3–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF JUSTICE

### Office of the Attorney General

### 28 CFR Part 0

**[Docket No. OAG 175; AG Order No. 5536–2022]**

## Revisions to Approval of Civil Consent Decrees With State and Local Governmental Entities

**AGENCY:** Office of the Attorney General, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises the regulations of the Department of Justice (''Department'') to restore the traditional process regarding the approval procedures to be used when a civil action against a State or local governmental entity is to be resolved by consent decree.

**DATES:** This rule is effective March 4, 2022.

**FOR FURTHER INFORMATION CONTACT:** Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530, telephone (202) 514–8059 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

## I. Discussion

*A. Overview*

This rule implements the April 16, 2021 Memorandum of Attorney General Merrick B. Garland titled ''Civil Settlement Agreements and Consent Decrees with State and Local Governmental Entities'' (the ''April 2021 Memorandum''), available at *https://www.justice.gov/ag/page/file/1387481/download.* Specifically, this rule withdraws the changes made to the Department's regulations by the rule ''Approval of Civil Consent Decrees With State and Local Governmental Entities'' published on December 28, 2020 (85 FR 84229).

The April 2021 Memorandum also specifically rescinded the Memorandum issued by former Attorney General Jefferson B. Sessions III, entitled ''Principles and Procedures for Civil Consent Decrees and Settlement