Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 822 is amended as follows:

PART 822—POSTMARKET SURVEILLANCE

■ 1. The authority citation for part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

■ 2. Revise § 822.8 to read as follows:

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send your submission 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. For devices regulated by the Center for Drug Evaluation and Research, send your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B, Ammendale Rd., Beltsville, MD 20705–1266. For devices regulated by the Center for Devices and Radiological Health, send your submission to the Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993–0002. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

■ 3. Amend § 822.12 by revising the first sentence to read as follows:

§ 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's website, the Food and Drug Administration main website, and from the Food and Drug Administration, Center for Devices and Radiological Health, Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. * * *

■ 4. Revise § 822.21 to read as follows:

§ 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?

You must receive our approval in writing before making changes in your plan that will affect the nature or validity of the data collected in accordance with the plan. To obtain our approval, you must submit the request to make the proposed change and revised postmarket surveillance plan to the applicable address listed in § 822.8. You may reference information already submitted in accordance with § 822.14. In your cover letter, you must identify your submission as a supplement and cite the unique document number that we assigned in our acknowledgment letter for your original submission, specifically identify the changes to the plan, and identify the reasons and justification for making the changes. You must report changes in your plan that will not affect the nature or validity of the data collected in accordance with the plan in the next interim report required by your approval order.

Dated: March 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

Income Taxes

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 26 of the Code of Federal Regulations, Part 1 (§§ 1.301 to 1.400), revised as of April 1, 2021, in § 1.362–4, revise paragraph (j) to read as follows:

§ 1.362–4 Basis of loss duplication property.

* * * * *

(j) *Effective/applicability date.* This section applies to transactions occurring after September 3, 2013, unless effected pursuant to a binding agreement that was in effect prior to September 3, 2013, and at all times thereafter. In addition, taxpayers may apply these regulations to transactions occurring after October 22, 2004. The introductory text and Example 11 of paragraph (h) of this section apply with respect to transactions occurring on or after March 28, 2016, and also with respect to transactions occurring before such date as a result of an entity classification election under § 301.7701–3 of this chapter filed on or after March 28, 2016, unless such transaction is pursuant to a binding agreement that was in effect prior to March 28, 2016 and at all times thereafter. In addition, taxpayers may apply such provisions to any transaction occurring after October 22, 2004.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

Income Taxes

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 26 of the Code of Federal Regulations, Part 1 (§§ 1.301 to 1.400), revised as of April 1, 2021, in § 1.351–3, revise paragraph (f) to read as follows:

§ 1.351–3 Records to be kept and information to be filed.

* * * * *

(f) *Effective/applicability date.* This section applies to any taxable year beginning on or after May 30, 2006. However, taxpayers may apply this section to any original Federal income tax return (including any amended return filed on or before the due date (including extensions) of such original return) timely filed on or after May 30, 2006. For taxable years beginning before May 30, 2006, see § 1.351–3 as contained in 26 CFR part 1 in effect on April 1, 2006. Paragraphs (a)(3) and (b)(3) of this section apply with respect to exchanges under section 351 occurring on or after March 28, 2016, and also with respect to exchanges under section 351 occurring before such date as a result of an entity classification election under § 301.7701–3 of this chapter filed on or after March 28, 2016, unless such exchange is pursuant to a binding agreement that was in effect