

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, Amundson 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

prior to March 28, 2016 and at all times thereafter.

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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 § 1.358-6, revise paragraph (f)(1) and revise the first sentence of paragraph (f)(3) to read as follows:

#### § 1.358-6 Stock basis in certain triangular reorganizations.

\* \* \* \* \*

(f) \* \* \*

(1) *General rule.* Except as otherwise provided in this paragraph (f), this section applies to triangular reorganizations occurring on or after December 23, 1994.

\* \* \* \* \*

(3) *Triangular G reorganization and special rule for triangular reorganizations involving members of a consolidated group.* Paragraph (e)(1) of this section shall apply to triangular reorganizations occurring on or after September 17, 2008. \* \* \*

\* \* \* \* \*

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## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Information Security Oversight Office

#### 32 CFR Part 2001

[FDMS No. NARA-22-0002; NARA-2022-021]

RIN 3095-AC06

#### Classified National Security Information

**AGENCY:** Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA).

**ACTION:** Direct final rule.

**SUMMARY:** We are revising our Classified National Security Information regulation to permit digital signatures that meet certain requirements on the Standard Form (SF) 312, which is the non-disclosure agreement required prior to accessing classified information. Due to agency needs during the COVID-19 pandemic and remote work situations, combined with developments in digital signatures since a regulatory prohibition on electronic signatures was implemented in 2010, it is both urgent and appropriate to make this administrative change at this time.

**DATES:** This rule is effective on May 9, 2022, unless we receive adverse comments by April 28, 2022 that warrant revising or rescinding this rulemaking.

**ADDRESSES:** You may submit comments, identified by RIN 3095-AC06, by the following method:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Search for RIN 3095-AC06 and follow the site's instructions for submitting comments.

We may publish any comments we receive without changes, including any personal information you include.

During the COVID-19 pandemic and remote work situation we cannot accept comments by mail or delivery because we do not have staff in the office.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at [regulation\\_comments@nara.gov](mailto:regulation_comments@nara.gov), or by telephone at 301.837.3151.

**SUPPLEMENTARY INFORMATION:** These regulations were last revised in 2010. At that time, these regulations included a prohibition against signing the Standard Form (SF) 312 electronically, due to concerns about integrity and legal enforceability of any form of electronic signature (e-signature) at the time. In the decade-plus since then, encryption and other measures for e-signatures have advanced and they are now regularly encouraged or required and deemed legally enforceable. In addition, Federal agencies are required to digitize services and forms and accelerate the use of e-signatures as much as possible (*see, e.g.*, 2018 21st Century Integrated Digital Experience Act (21st Century IDEA), 44 U.S.C. 3501 note).

Since the COVID-19 pandemic began in March 2020, numerous Federal agencies have had to engage in remote work to varying degrees and have had difficulty bringing new workers onboard who require access to classified information, due to the requirement for handwritten signatures on the SF 312. It

has been placing employees at risk of spreading the virus, as well as creating logistical and other difficulties. Multiple agencies have been consistently requesting the ability to allow e-signatures as a result, and the need became critical and urgent once the COVID-19 pandemic extended much longer than originally anticipated.

The advances in technical ability to ensure valid e-signatures, and legal acceptance of such signatures, is clearly the way of the future and necessary to support a modernized classified national security information system. However, the timing to make this change is more urgent now because of COVID-19 related health risks.

Under laws such as the Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504 note, the Uniform Electronic Transactions Act (UETA), a model act since adopted by 47 states and the District of Columbia (the remaining three states have comparable laws), and the Electronic Signatures in Global and National Commerce Act (ESIGN), 15 U.S.C. 7001, *et seq.*, an e-signature has the same legal weight as a handwritten signature and cannot be considered invalid simply due to being electronic. The laws establish criteria for valid e-signatures, along the following lines: Intent to sign, consent to do business electronically, association of the signature with the record, attribution to the person signing, and a record of the digital transactions. The United States practices an open-technology approach, meaning there's no law requiring use of a specific signing technology for an e-signature to be legally binding, as long as it meets the criteria.

However, for the purpose of e-signatures on the SF 312, ISOO has established certain requirements agencies must meet if they wish to allow such signatures. We require that agencies use digital signatures (rather than other forms of e-signature) on the SF 312 because digital signatures provide the requisite level of security and authenticity appropriate for these agreements. Digital signatures are a specific signature technology type of e-signature that allows users to sign documents and authenticate the signer. Digital signatures are based on a standard, accepted format, called public key infrastructure (PKI), to provide the highest levels of security and universal acceptance through use of a mathematical algorithm and other features. The mathematical algorithm acts like a cipher and encrypts the data matching the signed document. The resulting encrypted data is the digital signature, which is also marked with the