

**§ 1263.3 Requirements for consumer products containing button cell or coin batteries.**

Each consumer product containing button cell or coin batteries shall comply with ANSI/UL 4200A, *Standard for Safety for Products Incorporating Button Batteries or Coin Cell Batteries*, approved on August 30, 2023. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: [cpssc-os@cpssc.gov](mailto:cpssc-os@cpssc.gov). For information on the availability of this material at NARA, visit <https://www.archives.gov/federal-register/cfr/ibr-locations> or email [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov). A free, read-only copy of the standard is available for viewing on UL's website at <https://www.ulstandards.com/IBR/logon.aspx>. You may also obtain a copy from Underwriters Laboratories, Inc (UL), 333 Pfingsten Road, Northbrook, IL 60062, or through UL's website: [www.UL.com](http://www.UL.com).

**Alberta E. Mills,**

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023-20333 Filed 9-20-23; 8:45 am]

**BILLING CODE 6355-01-P**

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1263

[CPSC Docket No. 2023-0004]

### Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** In February 2023, as required by Reese's Law, the U.S. Consumer Product Safety Commission (CPSC or Commission) issued a notice of proposed rulemaking (NPR) to establish performance and labeling requirements for consumer products containing button cell or coin batteries, and requirements for labeling of button cell or coin battery packages, to eliminate or adequately reduce the risk of injury from ingestion of button cell or coin batteries by children six years old and

younger. Elsewhere in this issue of the **Federal Register**, the Commission is publishing a direct final rule to incorporate by reference a voluntary standard as the mandatory standard for consumer products containing button cell or coin batteries. The Commission issues this final rule to complete Reese's Law requirements for warning labels on the packaging of button cell or coin batteries. Button cell or coin battery packaging subject to this final rule must be certified as compliant with these warning label requirements.

**DATES:** This rule is effective September 21, 2024. Button cell or coin battery packaging manufactured or imported after September 21, 2024, must comply with this final rule.

**FOR FURTHER INFORMATION CONTACT:**

William Cusey, Small Business Ombudsman, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone 301-504-7945; email: [sbo@cpssc.gov](mailto:sbo@cpssc.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background and Statutory Authority<sup>1</sup>

On February 9, 2023, pursuant to Reese's Law (Pub. L. 117-171, 15 U.S.C. 2056e), the Commission published an NPR to establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries. 88 FR 8692. Consistent with section 2(a) of Reese's Law, the NPR proposed performance and labeling requirements for consumer products containing button cell or coin batteries<sup>2</sup> and labeling requirements for button cell and coin battery packaging. 15 U.S.C. 2056(a).

CPSC received 38 comments during a 30-day comment period ending in March 2023; four of the comments were duplicates. CPSC received two late-filed comments; one is out-of-scope for this rulemaking. We also received nine comments in response to an April 11,

<sup>1</sup> To implement requirements in Reese's Law for labeling of button cell or coin battery packaging, on September 8, 2023, the Commission voted (4-0) to publish this final rule. The Chair, and Commissioners Trumpka and Feldman, issued statements in connection with their vote, available at: [https://www.cpsc.gov/s3fs-public/RCA-Reese-s-Law-Implementation-UL-4200A-2023-DFR-for-Button-Cell-or-Coin-Batteries-and-Draft-FR-to-Amend-Part-1263.pdf?VersionId=V56MNzyWa\\_iXqZQIKCyOIRtjl9lcoFit](https://www.cpsc.gov/s3fs-public/RCA-Reese-s-Law-Implementation-UL-4200A-2023-DFR-for-Button-Cell-or-Coin-Batteries-and-Draft-FR-to-Amend-Part-1263.pdf?VersionId=V56MNzyWa_iXqZQIKCyOIRtjl9lcoFit).

<sup>2</sup> The Notes of Reese's Law, 15 U.S.C. 2056e, define the phrase "consumer product containing button cell or coin batteries" as "a consumer product containing or designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately."

2023 Paperwork Reduction Act (PRA) notice. 88 FR 21652. Most of the public comments concerned performance and labeling requirements for consumer products, which are addressed in the direct final rule, published elsewhere in this issue of the **Federal Register**, establishing 16 CFR part 1263. That direct final rule incorporates by reference ANSI/UL 4200A, *Standard for Safety for Products Incorporating Button Batteries or Coin Cell Batteries*, approved on August 30, 2023 (UL 4200A-2023), as the mandatory standard for consumer products containing button cell or coin batteries.

UL 4200A-2023 does not contain warning label requirements for button cell or coin battery packaging. Accordingly, in this final rule, pursuant to section 2(a)(2)(A) and 2(b) of Reese's Law, we review and respond to the public comments related to warning labels for packaging of button cell or coin batteries and finalize a rule for such warning labels. 15 U.S.C. 2056e(a)(2)(A) and (b). As explained in section I.D of this preamble, based on the comments, the final rule contains several modifications to requirements for battery package labeling from the NPR.<sup>3</sup>

#### A. Reese's Law

President Biden signed Reese's Law on August 16, 2022. 15 U.S.C. 2056e. The purpose of Reese's Law is to protect children six years old and younger against hazards associated with the ingestion of button cell or coin batteries during reasonably foreseeable use or misuse conditions. 15 U.S.C. 2056e(a)(1). Section 5 of Reese's Law broadly defines a "button cell or coin battery" as "(A) a single cell battery with a diameter greater than the height of the battery; or (B) any other battery, regardless of the technology used to

<sup>3</sup> The information in this final rule is based on information and analysis provided in the August 31, 2023, Staff Briefing Package: Draft Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (Staff's Final Rule Briefing Package), available at: <https://www.cpsc.gov/s3fs-public/Reeses-Law-Implementation-Commission-Determination-Regarding-UL-4200A-2023-and-Draft-DFR-for-Button-Cell-or-Coin-Batteries-and-2-Draft-FR-to-Amend-Part-1263-Labeling-Requirements-for-Button-Cell-or-Coin-Batte.pdf?VersionId=PyTbnom1OemA3BWl9Z11ONzTlyqbcthw>, and on the January 11, 2023, Staff Briefing Package: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (Staff's NPR Briefing Package), available at: <https://www.cpsc.gov/s3fs-public/NoticeofProposedRulemakingSafetyStandardandNotificationRequirementsforButtonCellorCoinBatteriesandConsumerProductsContainingSuchBatteries.pdf?VersionId=kDinNeydtkkt3T8RRtzn4u1GTXPRIjEl>.

produce an electrical charge, that is determined by the Commission to pose an ingestion hazard.”<sup>45</sup> Notes to 15 U.S.C. 2056e.

Section 2(a)(2) of Reese’s Law mandates that the Commission establish, by rulemaking, warning label requirements for consumer products containing button cell or coin batteries, and for packaging of button cell or coin batteries. The warning labels required by section 2(a)(2) of Reese’s Law must (1) clearly identify the hazard of ingestion, and (2) instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice. 15 U.S.C. 2056e(b).

In a companion rulemaking document, published elsewhere in this issue of the **Federal Register**, the Commission determines that UL 4200A–2023 meets the performance and labeling requirements of section 2(a) of Reese’s Law, and issues a direct final rule to incorporate by reference UL 4200A–2023 as the mandatory standard for consumer products containing button cell or coin batteries. As the scope of UL 4200A–2023 is on consumer products, it does not require the warnings mandated by Reese’s Law for the packaging of button cell or coin batteries. 15 U.S.C. 2056e(a)(2)(A). Accordingly, we issue this final rule to establish warning label requirements for packaging of button cell or coin batteries to complete implementation of section 2 of Reese’s Law.

Section 2(g) of Reese’s Law provides that any time after the promulgation of a final consumer product safety standard under section 2(a), the Commission may initiate a rulemaking

in accordance with 5 U.S.C. 553 to modify the requirements of the standard or revised standard. 15 U.S.C. 2056e(g). Any rule promulgated under section 2(g) of Reese’s Law will also be treated as a consumer product safety rule promulgated under section 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2058). *Id.*

Section 3 of Reese’s Law requires special packaging, meaning child-resistant packaging, for button cell or coin batteries. These requirements, codified in the Notes to 15 U.S.C. 2056e, are self-implementing, and do not require CPSC to issue a rule. Section 3 of Reese’s Law was effective by operation of the statute on February 12, 2023.

Section 4 of Reese’s Law, Notes to 15 U.S.C. 2056e, states that the special packaging requirements in section 3(a) do not apply with respect to button cell or coin batteries that are in compliance with the marking and packaging provisions of the ANSI Safety Standard for Portable Lithium Primary Cells and Batteries (ANSI C18.3M). This exemption does not apply to the requirements for battery package labeling in section 2 of Reese’s Law, which this final rule implements.

#### *B. Updated Incident Data*

Based on information in the National Electronic Injury Surveillance System (NEISS), the NPR reflected staff’s estimate that from 2011–2021, approximately 54,300 emergency room visits were associated with human ingestion, impaction, or insertion of button cell or coin batteries. The data show that these incidents occur most often with children aged 4 years or younger. Ingestion of a button battery has caused severe injuries and deaths: based on data in the Consumer Product Safety Risk Management System (CPSRMS), the NPR identified 25 fatalities from 2016 through 2021. 88 FR 8696–98.

Since the NPR, 2 additional deaths of children in the United States associated with ingestion of button or coin cell

batteries have been added to the CPSRMS database, for the years 2020–2021. Moreover, reporting to CPSC through May 1, 2023, indicates another 5 more recent deaths of children—3 in 2022 and 2 in the first three months of 2023. Combining all reported deaths since 2011, CPSC staff has identified 32 reported deaths in the United States from button cell or coin battery ingestion for the period January 1, 2011 through March 31, 2023. *See* Tab B of Staff’s Final Rule Briefing Package.

Additionally, Tab C of Staff’s Final Rule Briefing Package updates incident data from the National Capital Poison Center (NCPC). Since the NPR, from June 2022 through May 2023, the NCPC reported 2 additional child deaths due to ingestion of button cell or coin batteries. Both cases were from lithium button cell or coin batteries impacted in the esophagus; one battery was impacted for 25 days, the other for 3 days. The children died of hematemesis and sepsis, respectively. This brings the total fatal cases tracked by NCPC to 71 since 1977. Also, since the NPR, from June 2022 through May 2023, NCPC reported 13 additional cases of severe injury from button cell or coin battery ingestion, bringing the total since 1977 to 280.

#### *C. Description of Battery Packaging Labeling Requirements in the NPR*

The NPR proposed a rule to address the battery ingestion hazard for children six years of age or younger. Children can potentially gain access to button cell or coin batteries from battery packaging and be exposed to the ingestion hazard. Six out of 119 fatal and nonfatal incident narratives in the CPSRMS refer to loose batteries or battery packaging hazards, and staff estimates that at least 7 percent of NEISS incidents involve loose batteries or batteries liberated from the packaging. Figure 1 shows examples of button cell or coin batteries that, when packaged, are subject to this final rule.

<sup>44</sup> The definitions in section 5 of Reese’s Law are codified in the notes to 15 U.S.C. 2056e.

<sup>45</sup> This final rule focuses on addressing button cell and coin batteries under part (A) of the definition because other batteries where the diameter is less than the height, such as AAA cylindrical batteries, do not pose the same type or degree of ingestion hazard as button cell or coin batteries.




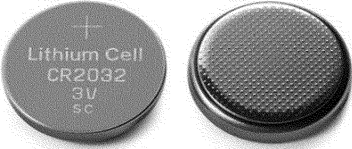
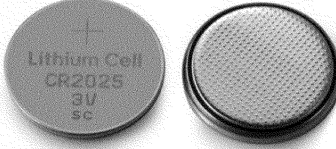
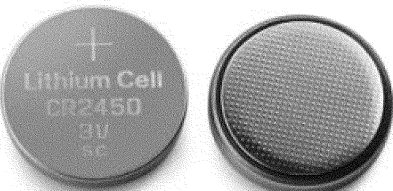
		
LR44 button cell, 11.6mm (0.45 inch) diameter x 5.4mm (0.21 inch) thick	LR754 button cell, 7.9 mm (0.31 inch) diameter, 5.4mm (0.21 inch) thick	LR626 button cell, 6.8 mm (0.26 inch) diameter, 2.6mm (0.10 inch) thick
		
CR2032, 20mm (0.787 inch) diameter	CR2025, 20mm (0.787 inch) diameter	CR2450, 24mm (0.945 inch) diameter

Figure 1. Example button cell and coin batteries.

The NPR assessed warnings requirements in several voluntary standards, and preliminarily concluded that none of the voluntary standards were adequate to meet the requirements in Reese’s Law. Tab C of Staff’s NPR Briefing Package. 88 FR 8704–05. Table 11 in the NPR summarizes the Commission’s assessment of warnings requirements in voluntary standards for button cell and coin battery packaging, finding that none of the voluntary standards adequately address warnings on battery packaging in accordance with Reese’s Law. 88 FR 8705.

Because none of the voluntary standards were deemed to meet the requirements in Reese’s Law, the Commission proposed warnings requirements for button cell and coin battery packaging and packaging of

batteries included separately with consumer products, explaining that labeling of button cell or coin battery packaging is intended to reduce the likelihood of loose batteries being liberated from these products and to warn caregivers of the battery ingestion hazards to children. 88 FR 8706–09. The proposed requirements followed the format requirements in ANSI Z535.4, *Product Safety Signs and Labels*, and were based on warnings found in ANSI C18.3M, ASTM F963, UL 4200A–2020, and other voluntary standards. *Id.*

The NPR also defined two terms relevant to placement of warning labels. The “principal display panel” is the display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries that is most

likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package. The “secondary display panel” means a display panel for a retail package of a button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

The NPR proposed a warning for the principal display panel of the battery packaging, shown in Figure 2, to meet the requirements in section 2 of Reese’s Law.

**⚠ WARNING**

- **INGESTION HAZARD: DEATH** or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- **KEEP** new and used batteries **OUT OF REACH OF CHILDREN**
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.




Figure 2. Warning of Ingestion Hazard for Battery Packaging.

The NPR proposed that battery packaging include the following warning statements:

- “INGESTION HAZARD: DEATH or serious injury can occur if ingested.” This sentence identifies the hazard of ingestion, as required by section 2(b)(1) of Reese’s Law.
- “A swallowed button cell or coin battery can cause Internal Chemical

Burns in as little as 2 hours.” This sentence provides warning label requirements, as stated in Reese’s Law; an effective warning should have an explanation of how and why ingestion of a button cell or coin battery is hazardous.

- “KEEP new and used batteries OUT OF REACH OF CHILDREN.” This sentence implements language in

section 2(b)(2) of Reese’s Law. In addition, use of the icon recognized for keeping items out of children’s reach is intended to quickly convey the required message and direct the reader’s attention to the label.

- “Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.” This sentence implements language in

section 2(b)(2) of Reese's Law and informs the consumer what actions should be taken if a button cell or coin battery is ingested or inserted into any part of the body. The warning includes the term "inserted" because insertions into the nose can be aspirated into the trachea and lead to ingestion, with the same risk of injury as oral ingestion.

The NPR proposed that the icon incorporated with the warning must be at least 8 mm (0.31 in.) in diameter for visibility, and that text size be calculated per Table 1 in the regulation text (Table 12 in the NPR preamble at 88 FR 8706). The NPR also stated that if space prohibits the full warning with the icon shown in Figure 2 in accordance with the formatting

requirements of Table 1 of the regulation text, packaging is required to use the "Keep out of Reach" icon (Figure 3) on the principal display panel and the warning text must be placed on the secondary display panel, as shown in Figure 4. 88 FR 8707. The icon must be at least 20 mm (0.79 in.) in diameter for visibility.



Figure 3. "Keep Out of Reach" Icon

**WARNING** **INGESTION HAZARD • DEATH** or serious injury can occur • A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours** • **KEEP** new and used batteries **OUT OF REACH OF CHILDREN** • **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 4. Warning Text Without Icon.

To address the hazard of button cell or coin batteries that become loose or separated from packaging, and to provide critical safety-related information should an ingestion incident occur, the NPR proposed that the following information implementing section 2(b)(2) of Reese's Law be placed on the secondary display panel of the packaging:

(1) "Keep in original package until ready to use." This statement instructs consumers to leave the batteries in child-resistant packaging as a means of keeping new batteries out of the reach of children.

(2) "Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash." This statement instructs consumers on how to prevent ingestion hazards from used batteries by keeping used batteries out of the reach of children, including out of household trash.

(3) "Call a local poison control center for treatment information." This statement makes more actionable the guidance to "immediately seek medical attention" as described in section 2(b)(2) of Reese's Law, and provides consumers with a resource for obtaining medical advice suitable to their situation. 88 FR 8707.

#### D. Changes Adopted in the Final Rule

Based on the consideration of comments received and analysis in Staff's Final Rule Briefing Package, the labeling requirements for button cell or

coin battery packaging are being finalized as proposed, with three modifications:

- **Warning label colors:** The final rule clarifies that specific colors on warning labels, in accordance with ANSI Z535, are required only if the label is present in more than one color, to allow flexibility in warning label designs and align with existing requirements in relevant voluntary standards.

- **Warning label letter size:** The final rule clarifies that the minimum text size for warning labels must be based on the product display panel size.

- **Treatment information:** To provide specific guidance to consumers on an available contact for treatment information, the final rule requires that button battery packaging display the National Battery Ingestion Hotline phone number. Additionally, the final rule replaces the warning statement "Call a local poison control center for treatment information" with the more actionable presentation of the National Battery Ingestion Hotline phone number.

#### E. Scope of Battery Packaging Subject to the Final Rule

This rule finalizes the warning label requirements for packaging of button cell or coin batteries, including batteries packaged separately with consumer products. Although section 4 of Reese's Law, Notes to 15 U.S.C. 2056e, states that the special packaging requirements in section 3(a) do not apply with respect to button cell or coin batteries that are in compliance with the marking and

packaging provisions of the ANSI Safety Standard for Portable Lithium Primary Cells and Batteries (ANSI C18.3M), this exemption does not apply to the labeling requirements of this rule. Therefore, all packages of button cell or coin batteries that fall within the definition of a "button cell or coin battery," except batteries listed in § 1263.1(d) (currently zinc-air batteries), must comply with the warning label requirements in this rule. Consistent with the NPR, the final rule does not require warning labels on zinc-air batteries. These requirements are consistent with ANSI C18.3M; battery packaging can comply with both the labeling requirements in ANSI C18.3M and this final rule.

#### F. Assessment of Labeling Requirements for Packaging of Button Cell or Coin Batteries in Existing Voluntary Standards

None of the voluntary standards addressing warning labels on button cell or coin battery packaging have been updated since publication of the NPR. Accordingly, and for the reasons further discussed in Part II below, the Commission adopts the NPR's assessment that no existing voluntary standard meets the warning label requirements that section 2 of Reese's Law establishes for battery packaging.

## II. Comments on the NPR

Below we summarize and respond to the comments received in response to the NPR that relate to the proposed

requirements for battery package labeling.

*Comments in Response to Questions on Marking and Labeling Requirements*

*A. Whether all button cell or coin battery packaging should include the warning on the principal display panel.*

*Comment 1:* Several commenters, including a coalition of medical and consumer organizations, the Battery Association of Japan (BAJ), Energizer, Duracell, Landsdowne Labs, National Electrical Manufacturers Association (NEMA), and the Consumer Technology Association (CTA), support warning labels on the packaging of button cell and coin battery packaging. The coalition of medical and consumer organizations and Duracell support the use of a conspicuous warning label on the principal display panel, whereas others (BAJ, Energizer, CTA, Information Technology Industry Council (ITI)) request flexibility in the warning label location and the placement of the “KEEP OUT OF REACH” icon, citing limitations of battery packaging size. Seven commenters support warning label placement as allowed by current voluntary standards, as such standards do not mandate the warning label location. BAJ suggests, however, that the icon be accompanied by the warning “KEEP OUT OF REACH” because the icon may not be well known.

*Response 1:* Reese’s Law requires warning labels on the packaging of button cell or coin batteries and minimum content requirements. Existing voluntary standards (IEC 60086–4 & –5) do not set forth location requirements, or specify that warnings be on the back of the packaging (ANSI C18.3). Existing voluntary standards often do not specify the content of the warning label. While the use of an icon is permissible in voluntary standards, icon use is based on the diameter of the battery.

Consistent with Reese’s Law and the ANSI standard, the final rule requires battery packaging to identify the hazard, explain how to avoid the hazard, and requires that warnings be conspicuous on the front of the packaging where it is more likely to be seen. The final rule requires a warning label on all button cell and coin battery packages within the scope of the rule, regardless of battery chemistry or battery size. The warning’s content also outlines options for a condensed warning label in the form of an icon on the front with additional text to be placed on the back, to accommodate limited space on the battery packaging. The “KEEP OUT OF REACH” text is not required to

accompany the icon; however, manufacturers may choose to include the text voluntarily to clarify the icon’s meaning. The final rule does not include any changes to the warning on the front of the battery packaging as a result of these comments.

*B. Whether the requirement for the “Keep Out of Reach” icon to be at least 20 mm in diameter for visibility purposes, when alone on the front of battery packaging, provides a sufficient warning of the ingestion hazard.*

*Comment 2:* Renata SA comments that the 6 mm minimum icon size requirements in the IEC 60086–4 voluntary standard are adequate. BAJ commented that the icon sizes of minimum 20 mm and minimum 8 mm are not necessary because “based on the market results so far” a minimum size of 6 mm icon is sufficient.

*Response 2:* We do not have the details of the “market results so far” that BAJ references to determine whether the 6 mm icon is sufficiently attention-getting for consumers, recognized by consumers, and adhered to by industry. Based on an evaluation of existing battery packaging, staff assesses in Tab D of Staff’s Final Rule Briefing Package that the recommended sizes of icons in the proposed rule are feasible and likely to get the attention of the consumer. After reviewing a number of battery packages, staff advises that the 20 mm diameter icon is sufficiently large to be visible to most consumers, and sufficiently small to fit on existing battery packaging. The final rule contains no changes in response to these comments.

*C. Whether the Commission should require ingestion warnings on zinc-air button cell or coin battery packaging.*

*Comment 3:* Three commenters (Duracell, Energizer, and NEMA) agree that warning labels on zinc-air batteries are not needed regarding the ingestion hazard, citing low risk of injury. Landsdowne Labs Inc., a coalition of medical and consumer organizations, and Dr. Ian Jacobs (Director at the Center for Pediatrics Airway Disorders at the Children’s Hospital of Philadelphia) support warning labels on packaging for zinc-air batteries, because they pose an insertion hazard. BAJ states that labeling on zinc-air batteries should be a recommendation, rather than a requirement, and that if zinc-air batteries are labeled, then they should use the word CAUTION instead of WARNING. Dr. Jacobs and Dr. Jatana (Director of Pediatric Otolaryngology in the Department of Otolaryngology Head and Neck Surgery at Nationwide Children’s Hospital and Wexner Medical Center at Ohio State University)

state that zinc-air batteries pose a risk of injury when inserted into the ear canals and nasal cavities, and should be labeled accordingly.

*Response 3:* Tab C of Staff’s Final Rule Briefing Package reviews the literature and the incident data regarding ingestion of zinc-air batteries. Staff advises that labeling of zinc-air batteries for an ingestion hazard is unnecessary, and may cause consumer confusion, because zinc-air batteries are not associated with an ingestion hazard.

*D. Comments addressing silver-oxide battery chemistries.*

*Comment 4:* The Permanent European Horological Committee (CPHE), Federation of the Swiss Watch Industry (FH), American Watch Association (AWA), and Renata SA state that silver-oxide batteries should be excluded from a Commission rule implementing Reese’s Law because of the lack of data on fatal incidents with these batteries and children’s inability to access them from watches. Duracell states that silver-oxide batteries should contain different warnings than lithium batteries because they are lower voltage. Switzerland asks whether silver oxide batteries could be excluded from the rule.

*Response 4:* Based on the medical literature, staff does not recommend that silver-oxide batteries be removed from the scope of the final rule. As reviewed in Tab C of Staff’s Final Rule Briefing Package, Jatana *et al.* (2017) found in testing using an animal model that silver-oxide button or coin cell batteries caused severe esophageal injuries.

*Comments in Response to Questions on Other Topics Posed in the NPR*

*E. Whether a later or an earlier effective date would be appropriate to comply with the proposed requirements and to provide specific information to support such a later or an earlier effective date.*

*Comment 5:* Commenters differed in their recommendations for an effective date, from the proposed 180 days (consumer advocates) to up to 3 years (manufacturer associations). Multiple manufacturers, trade associations, and Switzerland provided comments stating that a longer effective date is required to provide compliant products to the U.S. market. A few commenters provided detailed timelines of the necessary activities (product redesign, testing, certification sourcing, supply chain management, *etc.*), which ranged from 12 months to 36 months in total. A commenter also explained that additional time is required to accredit third party laboratories for a large variety of product types. Energizer and NEMA request that battery

manufacturers be allowed to sell their existing stock of child-resistant packaging and labels that were purchased to comply with section 3 of Reese's Law.

*Response 5:* Arguments made by manufacturers for a longer effective date relate primarily to performance and labeling requirements for consumer products, and not to battery package labeling. For example, battery packaging is not a children's product that requires third party testing; manufacturers can self-certify compliance to labeling requirements. However, the Commission recognizes that warning label requirements may compel manufacturers to revise or reprint existing packaging, and manufacturers may want to consult outside laboratories regarding compliance. Nevertheless, changes to labeling of battery packaging does not require extensive product redesign. To provide time for battery manufacturers to comply with this final rule, the Commission is establishing an effective date of one year after publication in the **Federal Register**, the low end of the time frame sought by commenters for the NPR's proposals, generally.

*F. Comments addressing the use of color in the requirements for marking and labeling.*

*Comment 6:* Several commenters (JEITA, Duracell, Gramin, HCPS and CTA) state that the use of color on packing, instructions, or manuals, and on some consumer products would be challenging and, in most cases, add costs to the manufacturing and printing process, particularly to those materials that do not already incorporate color. Duracell and Technet also stress that other product safety standards (e.g., ASTM F963, ANSI C18.3, or ANSI Z535 series) do not mandate the use of colors and accept black and white printing or contrasting colors to the background it is printed on. Commenters state, however, that if color is used for the signal panel, colors should conform to ANSI Z535.1 safety colors that correspond to the safety message. The Toy Association and RILA state that the use of color may not be reasonable for printing on certain product materials, for example, colored or textured plastics.

*Response 6:* Applying color to some materials (e.g., consumer product packaging, manuals, or other collateral material) that do not already contain color may present a burden to some manufacturers. ANSI Z535.4 provides flexibility for special circumstances that limit the use of colors while preserving the visibility and noticeability of the label by requiring contrast. To address

commenter concerns, the final rule requires the use of color when the subject materials already use printed color processing; otherwise, the use of either black and white or contrasting colors is acceptable. The use of color is not specified in Reese's Law, and with this modification the label or icon will visually align with other information on the display while still being noticeable due to its contrast or color.

*G. Comments addressing text size, icons, and alternative symbols for marking and labeling.*

*Comment 7:* Renata Batteries, ITI, The Toy Association, RILA, BAJ, and Duracell express cost concerns with increased packaging dimensions required to accommodate larger warning labels and font sizes, especially for small products. Another commenter states that the minimum letter size requirements for packaging warnings may reduce the prominence of other warnings on product packaging.

*Response 7:* The NPR proposed that font size requirements for both on-product and on-packaging warning labels be determined based on the size of the principal display panel (e.g., the front face) of the package or the product display panel (e.g., surface area on, near, or in the battery compartment). Reese's Law requires that warning labels clearly identify the hazard of ingestion, and this requirement is met when warning labels are displayed prominently on the principal display panel. For very large products or packages with principal display panels exceeding 400 inch<sup>2</sup>, the required letter size could be larger than standard font sizes usually referenced in other standards. The required letter size in the final rule is proportional to the display panel size and allows easy visibility and noticeability of the label. The minimum letter size is otherwise comparable to font sizes in other standards, and therefore of similar prominence when displayed on the same panel. The largest packaging will have ample room for additional warnings that are of comparable size to the requirements in the final rule. This level of prominence is appropriate to inform consumers which products contain button cell or coin batteries and to adequately reduce the risk of injury from ingestion.

*H. Whether the requirement to provide other information related to the safety of button cell or coin batteries is sufficient to address the risk of ingestion and other hazards associated with button cell or coin batteries.*

*Comment 8:* One commenter (Billie Jo Burr) states that labeling should provide consumers with the nationwide poison

control center phone number to ease the process of obtaining assistance quickly.

*Response 8:* We agree with the commenter that providing consumers with an appropriate contact phone number will provide an actionable step that will ease the process of obtaining assistance quickly if a caregiver suspects a button cell or coin battery ingestion. The National Battery Ingestion Hotline (NBIH) is dedicated solely to addressing battery ingestions, and is therefore an immediate and practical resource available to consumers who suspect a battery ingestion. The final rule adds the contact number for the NBIH, currently 1-(800) 498-8666, on the required warning labels for battery packaging.

*Comments Addressing the Paperwork Reduction Act*

Tab A of Staff's Final Rule Briefing Package and the companion direct final rule to establish in 16 CFR part 1263 a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries, published elsewhere in this issue of the **Federal Register**, provide CPSC's final rule PRA burden estimate for battery package labeling, and summarize and respond to comments related to CPSC's PRA burden estimate in the NPR.

### III. Description of the Final Rule

This final rule adds to 16 CFR part 1263 warning label requirements for packaging of button cell or coin batteries, including such batteries packaged separately with a consumer product. Primarily, the final rule adds § 1263.4, requirements for labeling of button cell or coin battery packaging. We also add several provisions in the scope and definitions to fully implement and explain the required warnings.

The final rule amends the last sentence in the NPR's proposed § 1263.1(a) to state that part 1263 establishes warning label requirements for "packaging of button cell or coin batteries, including button cell or coin batteries packaged separately with a consumer product," to ensure that the scope of the rule reflects requirements for battery package labeling. The final rule also amends § 1263.1(b) to add a one-year effective date for battery packaging labeling, as explained in section V of this preamble.

Final rule § 1263.2 adds two definitions for the "principal display panel" and the "secondary display panel." Section 1263.4 uses these definitions to explain requirements for the placement of battery package labeling.

Final rule § 1263.4 adds requirements for warning labels for button cell or coin battery packaging, including for such batteries packaged separately with a consumer product. The NPR's warning label requirements are explained in section I.C of this preamble. They are being finalized with the three modifications explained in section I.D of this preamble.

#### IV. Testing, Certification, and Notice of Requirements

Section 14(a) of the CPSA includes requirements for certifying that consumer products comply with applicable mandatory standards. 15 U.S.C. 2063(a). Section 14(a)(1) addresses required certifications for non-children's products, and sections 14(a)(2) and (a)(3) address certification requirements specific to children's products. Packages of button cell and coin batteries are unlikely to ever be children's products and therefore do not require third party testing. Manufacturers can self-certify compliance with the labeling requirements in this final rule.

Section 14(a)(1) of the CPSA requires every manufacturer (which includes importers per 15 U.S.C. 2052(a)(11)) of a non-children's product that is subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other law enforced by the Commission, to certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a)(1). Section 14(g) of the CPSA contains content and availability requirements for certificates. 15 U.S.C. 2063(g).

#### V. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule must be at least 30 days after publication of a final rule. 5 U.S.C. 553(d). In the NPR, the Commission proposed that a final rule containing (1) performance and warning label requirements for consumer products containing button cell or coin batteries, and (2) warning label requirements for button cell or coin battery packaging, would become effective 180 days after publication of a final rule in the **Federal Register**. Section II.E of this preamble describes comments from multiple manufacturers and trade associations stating that a longer effective date is required to supply compliant products to the U.S. market. Commenters provided detailed timelines of the necessary activities to become compliant, including time for product redesign, testing, certification sourcing, supply chain management,

and other issues, with the timeline ranging from 12 months to 36 months in total. A commenter also explained that additional time is required to accredit third party laboratories for a large variety of product types.

The Commission recognizes that the rule's warning label requirements may require manufacturers to revise or reprint existing packaging. However, battery packaging is not a children's product that requires third party testing. Manufacturers can self-certify compliance to labeling requirements. Also, changes to labeling of battery packaging do not require extensive product redesign; revising labeling on battery packaging will not require a lengthy timeframe. To provide time for battery manufacturers to comply with this final rule, the Commission establishes an effective date of one year after publication in the **Federal Register**, the low end of the time frame suggested by commenters with respect to the full set of requirements proposed in the NPR.

#### VI. Environmental Considerations

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have "little or no potential for affecting the human environment," and therefore, do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c)(1). Safety standards providing labeling requirements for packaging of button cell or coin batteries fall within this categorical exclusion.

#### VII. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* However, a regulatory flexibility analysis is not required if an agency certifies that a rule will not have a significant impact on a substantial number of small businesses. Tab H of Staff's Final Rule Briefing Package contains an economic analysis for this final rule establishing labeling requirements for packaging of button cell or coin batteries. Based on the information in that analysis, the Commission certifies that this final rule

will not have a significant impact on a substantial number of small businesses.

#### VIII. Paperwork Reduction Act

This final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). For convenience and clarity to stakeholders, section XII of the preamble for the direct final rule "Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries," published elsewhere in this issue of the **Federal Register**, contains the PRA analysis for both rules implementing Reese's Law, including this rule addressing the labeling of packaging of button cell or coin batteries.

CPSC has submitted the information collection requirements of this final rule for button cell or coin battery package labeling to OMB for review in accordance with PRA requirements. See 44 U.S.C. 3507(d).

#### IX. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the Federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances.

Section 2(a) of Reese's Law requires the Commission to issue a "consumer product safety standard for button cell or coin batteries and consumer products containing button cell or coin batteries," and section 2(c) of Reese's Law states that a consumer product safety standard promulgated under subsection (a) shall be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058). Therefore, the preemption provision of section 26(a) of the CPSA applies to all consumer products that fall within the scope of this final rule issued under section 2 of Reese's Law. 15 U.S.C. 2056e.

#### X. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and



certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a “major rule.” The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a “major rule.” Pursuant to the CRA, OIRA designated this rule as not a “major rule,” as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

#### List of Subjects in 16 CFR Part 1263

Administrative practice and procedure, Batteries, Consumer protection, Imports, Infants and children, Labeling, Law enforcement.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

#### PART 1263—SAFETY STANDARD FOR BUTTON CELL OR COIN BATTERIES AND CONSUMER PRODUCTS CONTAINING SUCH BATTERIES

■ 1. The authority citation for part 1263 continues to read as follows:

**Authority:** 15 U.S.C. 2052, 2056e.

■ 2. Amend § 1263.1 by adding sentences at the end of paragraphs (a) and (b) to read as follows:

##### § 1263.1 Scope, purpose, effective date, and exemption.

(a) \* \* \* Additionally, this part establishes warning label requirements

for packaging of button cell or coin batteries, including button cell or coin batteries packaged separately with a consumer product.

(b) \* \* \* Packages of button cell or coin batteries manufactured or imported after September 21, 2024, must meet the labeling requirements for battery packaging in § 1263.4.

\* \* \* \* \*

■ 3. Amend § 1263.2 by adding the definitions of “Principal display panel” and “Secondary display panel” in alphabetical order to read as follows:

##### § 1263.2 Definitions.

\* \* \* \* \*

*Principal display panel* means the display panel for a retail package of button cell or coin batteries that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.

*Secondary display panel* means a display panel for a retail package of button cell or coin batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

■ 4. Add § 1263.4 to read as follows:

##### § 1263.4 Requirements for labeling of button cell or coin battery packaging.

(a) *General requirements for labeling of button cell or coin battery packaging.*

(1) All warning statements must be

clearly visible, prominent, legible, and permanently marked.

(2) Warning statements must be in contrasting color to the background onto which the warning statement is printed.

(3) Warning statements must be in English.

(4) The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.

(5) The signal word “WARNING” and safety alert symbol must be in black letters on an orange background unless this would conflict with paragraphs (a)(1) and (2) of this section or only one color is present, in which case, the signal word and safety alert symbol must contrast to the background on which they are printed. The signal word must appear in sans serif letters in upper case only.

(6) Certain text in the message panel must be in bold and in capital letters as shown in the example warning labels (figure 1 to paragraph (b)(1) and figure 3 to paragraph (b)(2)) to get the attention of the reader.

(7) For labels that are required to be on the packaging of button cell and coin batteries, text size must be dependent on the area of the principal display panel. Text size must be determined based on table 1 to this paragraph (a)(7).

TABLE 1 TO PARAGRAPH (a)(7)—LETTER SIZE FOR RECOMMENDED WARNING LABELS

[Information based on 16 CFR 1500.19(d)(7)]

Letter size measurements in inches								
Display area: inches <sup>2</sup>	0–2	+2–5	+5–10	+10–15	+15–30	+30–100	+100–400	+400
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2
Statement of Hazard .....	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4
Other Text .....	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32
Letter size measurements in cm (for reference only)								
Display area: cm <sup>2</sup>	0–13	+13–32	+32–65	+65–97	+97–194	+194–645	+645–2,581	+2,581
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270
Statement of Hazard .....	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635
Other Text .....	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397


(b) *Warning label requirements for button cell or coin battery packaging.* (1) The principal display panel of the packaging must include the warning

label in figure 1 to this paragraph (b)(1). The icon must be at least 8 mm (0.3 inches) in diameter. The text must state

the following warnings as shown in figure 1 to this paragraph (b)(1).



Figure 1 to Paragraph (b)(1)

<b>⚠ WARNING</b>	
<ul style="list-style-type: none"><li>• <b>INGESTION HAZARD: DEATH</b> or serious injury can occur if ingested.</li><li>• A swallowed button cell or coin battery can cause <b>Internal Chemical Burns</b> in as little as <b>2 hours</b>.</li><li>• KEEP new and used batteries <b>OUT OF REACH OF CHILDREN</b></li><li>• <b>Seek immediate medical attention</b> if a battery is suspected to be swallowed or inserted inside any part of the body.</li><li>• For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].</li></ul>	

(2) If space prohibits the full warning label shown in figure 1 to paragraph (b)(1), place the icon shown in figure 2 to this paragraph (b)(2) on the principal

display panel with the text shown in figure 3 to this paragraph (b)(2) on the secondary display panel. The icon must be at least 20 mm in diameter. The text

must state the following warnings as shown on figure 3 to this paragraph (b)(2).

Figure 2 to Paragraph (b)(2)

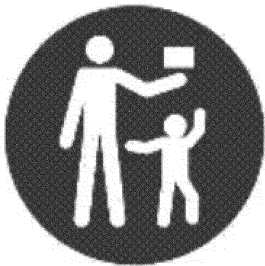


Figure 3 to Paragraph (b)(2)

<b>⚠ WARNING</b>	<b>INGESTION HAZARD • DEATH</b> or serious injury can occur • A swallowed button cell or coin battery can cause <b>Internal Chemical Burns</b> in as little as <b>2 hours</b> • KEEP new and used batteries <b>OUT OF REACH OF CHILDREN</b> • <b>Seek immediate medical attention</b> if a battery is suspected to be swallowed or inserted inside any part of the body • For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].
------------------	--

(3) The following safety-related statements must be addressed on the principal display panel or secondary display panel:  
(i) Keep in original package until ready to use.

(ii) Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash.  
(4) For button cell or coin battery packaging included separately with a

consumer product, only paragraphs (b)(1) and (2) of this section apply.

**Alberta E. Mills,**  
*Secretary, Consumer Product Safety Commission.*  
[FR Doc. 2023–20334 Filed 9–20–23; 8:45 am]  
**BILLING CODE 6355–01–P**