Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the standard for carriages and strollers. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the standard for carriages and strollers to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the standard for carriages and strollers will not have a significant impact on a substantial number of small entities.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1227

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008).

■ 2. Amend § 1112.15 by adding paragraph (b)(36) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b)(36) 16 CFR part 1227, Safety Standard for Carriages and Strollers.

* * * * *

■ 3. Add part 1227 to read as follows:

PART 1227—SAFETY STANDARD FOR CARRIAGES AND STROLLERS

Sec.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

§ 1227.1 Scope.

This part establishes a consumer product safety standard for carriages and strollers.

§ 1227.2 Requirements for carriages and strollers.

(a) Except as provided in paragraph (b) of this section, each carriage and stroller must comply with all applicable provisions of ASTM F833–13b, *Standard Consumer Safety Performance Specification for Carriages and Strollers,* approved on November 1, 2013. 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. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; *http://www.astm.org/cpsc.htm.* You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.*

(b) Comply with ASTM F833–13b standard with the following changes:

(1) Instead of complying with section 7.12.1 of ASTM F833–13b, comply with the following:

(i) 7.12.1 Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create an opening(s) size that is most likely to cause failure.

(ii) [Reserved]

(2) Instead of complying with section 7.12.3 of ASTM F833–13b, comply with the following:

(i) 7.12.3 If necessary, reattach/reposition tray(s) grab bar(s), then perform the torso probe test per 7.12.4. Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the opening(s) size that is most likely to cause failure.

(ii) [Reserved]

Dated: March 5, 2014.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2014–05065 Filed 3–7–14; 8:45 am]

BILLING CODE 6355–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–9554; 34–71643; 39–2496; IC–30972]

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the Commission) is adopting revisions to the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR) Filer Manual and related rules to reflect updates to the EDGAR system. The revisions are being made primarily to introduce new submission form types MA, MA–A, MA/A, MA–I, MA–I/A, and MA–W to support Registration of Municipal Advisors; updates to submission form types 8–K, 8–K/A, 10–K, 10–K/A, 10–KT, 10–KT/A, 10–D, 10–D/A, POS AM, 424B1, 424B2, 424B3, 424B4, 424B5, 424B7, and 424B8; and minor updates to Form 13F validations. The EDGAR system is scheduled to be upgraded to support this functionality on March 3, 2014.

DATES: *Effective Date:* March 10, 2014. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of March 10, 2014.

FOR FURTHER INFORMATION CONTACT: In the Office of Municipal Securities, for questions concerning Registration of Municipal Advisors contact Jessica Kane at (202) 551–3235; in the Division of Investment Management, for questions concerning Form 13F contact Heather Fernandez at (202) 551–6715; and in the Office of Information Technology, contact Vanessa Anderson at (202) 551–8800.

SUPPLEMENTARY INFORMATION: We are adopting an updated EDGAR Filer Manual, Volume I and Volume II. The Filer Manual describes the technical formatting requirements for the preparation and submission of electronic filings through the EDGAR system.[1] It also describes the

[1] We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993.

requirements for filing using EDGARLink Online and the Online Forms/XML Web site.

The revisions to the Filer Manual reflect changes within Volume I entitled EDGAR Filer Manual, Volume I: ''General Information,'' Version 16 (March 2014) and Volume II entitled EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 26 (March 2014). The updated manual will be incorporated by reference into the Code of Federal Regulations.

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.[2] Filers may consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.[3]

The EDGAR system will be upgraded to Release 14.0 on March 3, 2014 and will introduce the following changes: EDGAR will be updated to add new submission form types MA, MA–A, MA/A, MA–I, MA–I/A, and MA–W on the EDGAR Filing Web site. These submission form types can be accessed by selecting the 'File Municipal Advisor Forms' link available on the EDGAR Filing Web site. Instructions to file the Municipal Advisor Forms are included in two new sections of Chapter 9 (Preparing and Transmitting Online Submissions) of the ''EDGAR Filer Manual, Volume II: EDGAR Filing'' to guide filers through the filing process. See Release No. 34–70462 [4] for the compliance dates.

Submission form types 8–K, 8–K/A, 10–K, 10–K/A, 10–KT, 10–KT/A, 10–D, 10–D/A, POS AM, 424B1, 424B2, 424B3, 424B4, 424B5, 424B7, and 424B8 will be updated to collect Depositor CIK, Sponsor CIK, ABS Asset Class, and ABS Sub Asset Class information for filings where the primary registrant CIK is designated as an Asset-Backed Securities issuing entity (i.e., entities assigned the Standard Industrial Classification Code 6189).

Submission form types 13F–HR/A will be updated to allow a future date for the ''Date denied or on which confidential treatment expired'' field.

For EDGARLink Online application, recommended version for Firefox browser is being changed from 3.5 to 17.0 or higher. For all EDGAR Web sites, Microsoft Internet Explorer 7.0 or later is the recommended browser. Additionally, minor documentation only corrections were made to the Chapter 6, Interactive Data, sections 6.5.20 and 6.6.29.

Along with the adoption of the Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of today's revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Room 1543, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. We will post electronic format copies on the Commission's Web site; the address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml*.

Since the Filer Manual and the corresponding rule changes relate solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).[5] It follows that the requirements of the Regulatory Flexibility Act [6] do not apply.

The effective date for the updated Filer Manual and the rule amendments is March 10, 2014. In accordance with the APA,[7] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 14.0 is scheduled to become available on March 3, 2014. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the system upgrade.

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[8] Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[9] Section 319 of the Trust Indenture Act of 1939,[10] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[11]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for Part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.;* and 18 U.S.C. 1350.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: ''General Information,'' Version 16 (March 2014). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 26 (March 2014). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: ''N–SAR Supplement,'' Version 2 (August 2011). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Room 1543, Washington, DC

Release No. 33–6986 (April 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on September 25, 2013. *See* Release No. 33–9457 (October 2, 2013) [78 FR 60684].

[2] *See* Rule 301 of Regulation S–T (17 CFR 232.301).

[3] *See* Release No. 33–9457 in which we implemented EDGAR Release 13.3. For additional history of Filer Manual rules, please see the cites therein.

[4] *See* Release No. 34–70462 (September 20, 2013) [78 FR 67467 (November 12, 2013)].

[5] 5 U.S.C. 553(b).

[6] 5 U.S.C. 601–612.

[7] 5 U.S.C. 553(d)(3).

[8] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[9] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78o, 78w, and 78*ll.*

[10] 15 U.S.C. 77sss.

[11] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Electronic copies are available on the Commission's Web site. The address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml*. You can also inspect the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Dated: March 4, 2014.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2014–05057 Filed 3–7–14; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2014–N–0107]

Medical Devices; General and Plastic Surgery Devices; Classification of the Absorbable Lung Biopsy Plug

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the absorbable lung biopsy plug into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the absorbable lung biopsy plug's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective April 9, 2014. The classification was effective on December 19, 2012.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2532, Silver Spring, MD 20993–0002, 301–796–6274.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, July 9, 2012, 126 Stat. 1054), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2). If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 19, 2009, classifying the Bio-Seal Lung Biopsy Tract Plug System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On April 16, 2009, Angiotech submitted a request for classification of the Bio-Seal Lung Biopsy Tract Plug System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 19, 2012, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4755.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an absorbable lung biopsy plug will need to comply with the special controls named in this final order.

The device is assigned the generic name Absorbable Lung Biopsy Plug, and it is identified as a preformed (polymerized) absorbable lung biopsy plug intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. Upon deployment into the biopsy tract, the plug expands to fill the biopsy void and remains in place until resorbed.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures.