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

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:


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. 1227.1 Scope.

1227.2 Requirements for carriages and strollers.


§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 700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm. You may inspect a copy of 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]

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 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. Filers may consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.

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 'Filer Manual' link available on the EDGAR Filing Web site. Instruct filers to use the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.

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 'Filer Manual' link available on the EDGAR Filing Web site. Instruct filers to use the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.

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). It follows that the requirements of the Regulatory Flexibility Act do not apply.

The effective date for the updated Filer Manual and the rule amendments is March 10, 2014. In accordance with the APA, 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, Sections 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934, Section 319 of the Trust Indenture Act of 1939, and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.

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 RULES FOR ELECTRONIC FILINGS

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

Authority: 15 U.S.C. 77t, 77g, 77h, 77m, 77n, 77s(a), 77s(b), 77s(c), 77s(d), 77s(e), 77s(f), 77s(h), 77s(i), 77s(j), 77s(k), 77s(m), 77s(n), 77s(o), 77s(p), 77s(q), 77s(r), 77s(s), 77s(t), 77s(u), 77s(v), 77s(w), 77s(x), 77s(y), 77s(z), 77s(aa), 77s(bb), 77s(cc), 77s(dd), 77s(ee), 77s(ff), 77s(gg), 77s(hh), 77s(ii), 77s(jj), 77s(kk), 77s(ll), 77s(mm), 77s(nn), 77s(oo), 77s(pp), 77s(qq), 77s(rr), 77s(ss), 77s(tt), 77s(uu), 77s(vv), 77s(ww), 77s(xx), 77s(yy), 77s(zz), and 77s(aa) et seq., and 18 U.S.C. 1350.

2. Section 232.301 is revised to read as follows:


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

1 5 U.S.C. 553(b).
3 5 U.S.C. 553(d).
4 5 U.S.C. 77t, 77g, 77h, 77m, and 77s(a).
5 15 U.S.C. 78c, 78m, 78n, 78o, 78w, and 78ll.
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.