disseminating any record about an individual, to ensure that the record is accurate, relevant, timely, and complete;

(g) Maintain no record describing how an individual exercises his or her First Amendment rights unless such maintenance is expressly authorized by statute or by the individual about whom the record is maintained or is pertinent to and within the scope of an authorized law enforcement activity;

(h) When required by the Privacy Act, maintain an accounting in the specified form of all disclosures of records by the agency to persons, organizations, or agencies;

(i) Maintain and use records with care in order to prevent the unauthorized or inadvertent disclosure of a record to anyone; and

(j) Notify the appropriate agency official of any record that contains information that the Privacy Act does not permit the agency to maintain.

§ 304.33 Preservation of records.

The agency will preserve all correspondence pertaining to the requests that it receives under this subpart, as well as copies of all requested records, until disposition or destruction is authorized by title 44 of the United States Code or the National Archives and Records Administration's General Records Schedule 14. Records will not be disposed of while they are the subject of a pending request, appeal, or lawsuit under the Act.

§ 304.34 Other rights and services.

Nothing in this subpart shall be construed to entitle any person, as of right, to any service or to the disclosure of any record to which such person is not entitled under the Privacy Act.

Dated: March 30, 2011.

Shawne C. McGibbon,

General Counsel.

[FR Doc. 2011–7976 Filed 4–4–11; 8:45 am]

BILLING CODE 6110–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1303

[CPSC Docket No. CPSC–2008–0033]

Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies—Lead Paint

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of requirements; revision of testing terms.

SUMMARY: The U.S. Consumer Product Safety Commission ("CPSC," "Commission," or "we") is amending the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing to the lead paint ban regulations. We are taking this action to require CPSC and/or ASTM published test methods to be referenced by a third party conformity assessment body in the scope of its accreditation.

DATES: *Effective date:* The revised requirements are effective April 5, 2011.

Comment date: Comments in response to this notice of requirements should be submitted by May 5, 2011. Comments on this notice should be captioned, "Third Party Testing for Certain Children's Products; Requirements for Accreditation of Third Party Conformity Assessment Bodies—Lead Paint."

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2008–0033, by any of the following methods:

Electronic Submissions: Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through *http://www.regulations.gov.*

Written Submissions: Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions) preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. Do not submit confidential business information, trade secret information, or other sensitive or protected information (such as a Social Security Number) electronically; if furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Robert "Jay" Howell, Assistant Executive Director for he Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; e-mail: *rhowell@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 14(a)(3)(B)(i) of the Consumer Product Safety Act (CPSA), as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110–314, directed the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies to test children's products for conformity with the Commission's regulations at 16 CFR part 1303, *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint* (the lead paint ban). In the **Federal Register** of September 22, 2008, the Commission published a notice of requirements for accreditation of third party conformity assessment bodies to test children's products for conformity with the lead paint ban under 16 CFR part 1303 (73 FR 54564).

In response to the September 22, 2008 notice of requirements, the International Laboratory Accreditation Cooperation (ILAC) and the American Association for Laboratory Accreditation (A2LA) submitted letters asking us to specify test methods to ensure that accreditation bodies are able to determine the acceptable technologies and methods for lead analyses. The September 22, 2008 notice of requirements stated that the accreditation must be to the International Standards Organization (ISO)/International Electrotechnical Commission (IEC) Standard ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," and that the scope of the accreditation must include testing to the requirements of 16 CFR part 1303. However, these requirements for accreditation did not reference a specific test method, although the CPSC staff's test method (CPSC–CH–E1003–09) was made available on the CPSC Web site at: *http://www.cpsc.gov/about/cpsia/CPSC-CH-E1003-09.pdf.* Therefore, to require certain test methods that are acceptable to the CPSC for testing for lead in paint, we are amending the notice of requirements to state that the scope of the third party conformity assessment body's accreditation shall specify certain test methodologies.

The Commission is revising the September 22, 2008 notice of requirements to require reference of specific test methods for CPSC acceptance of accreditation of third party conformity assessment bodies to assess conformity with 16 CFR part

1303. One or more of the following test methods must be referenced: The existing CPSC Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings, CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1 and/or, ASTM F2853–10, "Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams."

Test Method CPSC–CH–E1003–09 was revised in Test Method CPSC–CH–E1003–09.1 to reflect ministerial edits and remove the statement that the rules for accreditation for lead in paint testing do not explicitly require the use of a particular standard operating procedure. Additionally, the following statement was added. "Adjustments may be necessary to achieve total digestion for certain paints and should be based on sound chemistry knowledge and appropriate acids for the sample material being analyzed." It is still based on standard test procedures, such as ASTM International (formerly the American Society for Testing and Materials) ASTM E1645, ASTM E1613–04, and Association of Official Analytical Chemists (AOAC) standard AOAC 974.02. This test method will be made available on the CPSC Web site at: *http://www.cpsc.gov/about/cpsia/CPSC–CH–E1003–09_1.pdf.*

In addition to the CPCS's test methods, CPSC staff finds that ASTM F2853–10, "Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams." which uses a specific type of X-Ray Fluorescence (XRF) technology, may be used as a test method and is as effective, precise, and reliable as method CPSC–CH–E1003–09 posted on the CPSC Web site. The standard is available on the ASTM Web site at: *http://www.astm.org/Standards/F2853.htm.* Supporting data about the associated interlaboratory research report has been filed with ASTM and can be obtained by contacting ASTM and requesting Research Report RR:F40–1001. Our findings are based on a study conducted in August 2009, as updated in December 2010, which evaluates the effectiveness, precision, and reliability of XRF methods and other alternative methods for measuring lead in paint or other surface coatings when used in children's products. The studies on XRF are published on the CPSC's Web site at: *http://www.cpsc.gov/ABOUT/Cpsia/leadinpaintmeasure.pdf* and *http://www.cpsc.gov/ABOUT/Cpsia/leadinpaintmeasure_update.pdf.* XFR methods and equipment other than those specified in ASTM F2853–10 are not considered effective for testing in paint and surface coatings for the purpose of determining conformity with 16 CFR part 1303 at this time. We are working with the National Institute of Standards and Technology (NIST) to develop and release a lead in paint standard reference material (SRM) 2569, consisting of a thin, uniform film with thickness and lead concentrations appropriate to testing of painted surfaces, and which would be suitable for validating ASTM F2853–10. This SRM may become available in 2011. We also are aware that other commercial reference materials are now available that may be suitable for validating ASTM F2853–10.

Many third party conformity assessment bodies operate on a two year cycle for review and renewal of accreditation. Accordingly, in order to give third party conformity assessment bodies sufficient time to amend their scope documents to reflect the specific test methods accepted by the Commission, CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1 and/or ASTM F2853–10, CPSC-accepted third party conformity assessment bodies that are listed on the CPSC Web site as approved to 16 CFR part 1303 (without reference to a test method) will have two years from the date of publication of this notice in the **Federal Register** to reapply and be accepted by the CPSC for CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1 and/or ASTM F2853–10 for testing to the lead in paint regulation at 16 CFR part 1303. After that date, previously accepted third party conformity assessment bodies that test for 16 CFR part 1303 must have been accepted by the CPSC for one or more of the required test methods to maintain CPSC-accepted status. All accreditations must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation—Mutual Recognition Arrangement (ILAC–MRA) and the scope of the accreditation must include:

- 16 CFR part 1303 (CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1), and/or
- 16 CFR part 1303 (ASTM F2853–10).

New applicants seeking CPSC acceptance of accreditation to test to 16 CFR part 1303 will have the option to apply without reference to a specific test method under 16 CFR part 1303 or to apply to the CPSC for acceptance to test to 16 CFR part 1303 according to one or more test methods for up to one year after publication of this notice in the **Federal Register**. After one year from the publication of this notice in the **Federal Register**, the option for third party conformity assessment bodies to apply for CPSC-acceptance of accreditation to 16 CFR part 1303 without reference to a CPSC required test method will not be permitted.

To make it easier for interested parties to understand the nature of the revisions, we are republishing the notice of requirements in its entirety for readability. The republished notice incorporates several nonsubstantive changes or grammatical changes, such as replacing the term "laboratory" with "third party conformity assessment body." These changes were made to make the notice of requirements consistent with other recent notices of requirements published in the **Federal Register**. *See, e.g., Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6X and 7 Through 14: Requirements for Accreditation of Third Party Conformity Assessment Bodies,* (75 FR 70911 (November 19, 2010)); *Third Party Testing for Certain Children's Products; Youth All-Terrain Vehicles: Requirements for Accreditation of Third Party Conformity Assessment Bodies,* (75 FR 52616 (August 27, 2010)).

II. Accreditation Requirements

The notice of requirements that appeared in the **Federal Register** on September 22, 2008 (73 FR 5456) is amended to read as follows:

A. Baseline Third Party Conformity Assessment Body Accreditation Requirements

For a third party conformity assessment body to be CPSC-accepted as accredited to test children's products for conformity with the lead paint ban and 16 CFR part 1303, it must be accredited to ISO/IEC 17025–2005 by an accreditation body that is a signatory to the ILAC–MRA, and the accreditation must be registered with, and accepted by, the Commission. A listing of ILAC–MRA signatory accreditation bodies is available on the Internet at: *http://ilac.org/membersbycategory.html.* The scope of the accreditation must include 16 CFR part 1303 (CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1) and/or 16 CFR part 1303 (ASTM F2853–10).

The Commission will maintain on its Web site an up-to-date listing of third party conformity assessment bodies whose accreditations it has accepted and the scope of each accreditation.

Once the Commission adds a third party conformity assessment body to that list, the third party conformity assessment body may commence testing of children's products to support the manufacturer's certification that the product complies with 16 CRF part 1303.

B. Additional Accreditation Requirements for Firewalled Conformity Assessment Bodies

In addition to the baseline accreditation requirements in Section II.A of this document above, firewalled conformity assessment bodies seeking accredited status by the CPSC must submit to the Commission copies, in English, of their training documents, showing how employees are trained to notify the Commission immediately and confidentially of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the third party conformity assessment body's test results. This additional requirement applies to any third party conformity assessment body in which a manufacturer or private labeler of a children's product to be tested by the third party conformity assessment body owns an interest of 10 percent or more. While the Commission is not addressing common parentage of a third party conformity assessment body and a children's product manufacturer at this time, it will be vigilant to see whether this issue needs to be addressed in the future.

As required by section 14(f)(2)(D) of the CPSA, the Commission must accept formally, by order, the application from a third party conformity assessment body before the third party conformity assessment body can become accredited by the CPSC as a firewalled conformity assessment body.

C. Additional Accreditation Requirements for Governmental Conformity Assessment Bodies

In addition to the baseline accreditation requirements of part II.A of this document above, the CPSIA permits accreditation of a third party conformity assessment body owned or controlled, in whole or in part, by a government if:

- To the extent practicable, manufacturers or private labelers located in any nation are permitted to choose conformity assessment bodies that are not owned or controlled by the government of that nation;
- The third party conformity assessment body's testing results are not subject to undue influence by any other person, including another governmental entity;
- The third party conformity assessment body is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited;
- The third party conformity assessment body's testing results are accorded no greater weight by other governmental authorities than those of other accredited third party conformity assessment bodies; and
- The third party conformity assessment body does not exercise undue influence over other governmental authorities on matters affecting its operations or on decisions by other governmental authorities controlling distribution of products based on outcomes of the third party conformity assessment body's conformity assessments.

The Commission will accept the accreditation of a governmental third party conformity assessment body if it meets the baseline accreditation requirements of part II.A of this document above and meets the additional conditions stated here. To obtain this assurance, CPSC staff will engage the governmental entities seeking accreditation.

III. How does a third party conformity assessment body apply for acceptance of its accreditation?

The Commission has established an electronic accreditation acceptance and registration system accessed via the Commission's Internet site at: *http://www.cpsc.gov/about/cpsia/labaccred.html.* The applicant provides, in English, basic identifying information concerning its location, the type of accreditation it is seeking, and electronic copies of its accreditation certificate and scope statement by its ILAC–MRA signatory accreditation body, and firewalled third party conformity assessment body training document(s), if relevant.

Commission staff will review the submission for accuracy and completeness. In the case of baseline third party conformity assessment bodies and government-owned or government-operated conformity assessment bodies, when that review and any necessary discussions with the applicant are completed satisfactorily, the third party conformity assessment body in question is added to the CPSC's list of accredited third party conformity assessment bodies at: *http://www.cpsc.gov/about/cpsia/labaccred.html.* In the case of a firewalled conformity assessment body seeking accredited status, when the CPSC staff's review is complete, the CPSC staff transmits its recommendation on accreditation to the Commission for consideration. (A third party conformity assessment body that ultimately may seek acceptance as a firewalled third party conformity assessment body also initially can request acceptance as a third party conformity assessment body accredited for testing of children's products other than those of its owners.) If the Commission accepts a CPSC staff recommendation to accredit a firewalled conformity assessment body, the firewalled conformity assessment body will be added to the CPSC's list of accredited third party conformity assessment bodies. In each case, the Commission will notify the third party conformity assessment body electronically of acceptance of its accreditation. All information to support an accreditation acceptance request must be provided in the English language.

Once the Commission adds a third party conformity assessment body to the list, the third party conformity assessment body then may begin testing children's products to support certification of compliance with 16 CFR part 1303, for which it has been accredited.

New applicants for CPSC acceptance of accreditation to 16 CFR part 1303 will have the option to apply to the CPSC without reference to a specific test method or to apply for CPSC acceptance to include a specific reference to 16 CFR part 1303 (CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1) and/or 16 CFR part 1303 (ASTM F2853–10) for up to one year after publication of this notice in the **Federal Register**. After one year, the option to apply for accreditation to 16 CFR part 1303 without reference to a CPSC required test method will not be permitted.

CPSC-accepted third party conformity assessment bodies for 16 CFR part 1303 without a reference to one of the specified test methods have up to two years from the date of publication of this notice in the **Federal Register** to reapply and become accepted by the CPSC for 16 CFR part 1303 (CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1) and/or 16 CFR part 1303 (ASTM F2853–10). To maintain CPSC-accepted status, third party conformity assessment bodies that are CPSC-accepted for 16 CFR part 1303 without reference to one of the required test methods must reapply with, and be accepted by, the CPSC within the two-year period, irrespective of whether the scope document from their accreditation body that was supplied with their

earlier CPSC application included a reference to one of the required test methods. Previously CPSC-accepted third party conformity assessment bodies for 16 CFR part 1303 (including those that had one of the specified test methods in their accreditation scope document that was supplied with their earlier CPSC application) must reapply to maintain CPSC acceptance because the CPSC did not record references to test methods. If accepted, the third party conformity assessment body will remain on the list of accepted third party conformity bodies whose accreditations the CPSC has accepted for 16 CFR part 1303.

IV. Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing to 16 CFR Part 1303

The September 22, 2008 **Federal Register** Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1303 of Title 16, Code of Federal Regulations established that each manufacturer (including the importer) or private labeler of children's products subject to the lead paint ban must have products that are manufactured after December 21, 2008 tested by a laboratory accredited (by the CPSC) and must issue a certificate of compliance with the lead paint ban based upon that testing.

This amended notice of requirements published today addresses only the CPSC acceptance criteria for a third party conformity assessment body for testing to the lead paint ban at 16 CFR part 1303. This amended notice does not affect the already-established criteria for CPSC acceptance of certificates of compliance. A product manufacturer's certificate of compliance to 16 CFR part 1303 must be based on testing by a third party conformity assessment body that is posted on the CPSC Web site as accepted for 16 CFR part 1303 at the time the product is tested. The Commission will accept a certificate of compliance with 16 CFR part 1303, Ban of Lead-Containing Paint for a children's product based on testing performed by an accredited (CPSC-accepted) third party conformity assessment body (including a government-owned or government-controlled conformity assessment body, or a firewalled conformity assessment body) if the testing was conducted on a date for which the third party conformity assessment body was listed as accepted by the CPSC for testing to the lead paint ban at 16 CFR part 1303.

Dated: March 30, 2011.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2011–7905 Filed 4–4–11; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2011–N–0003]

Oral Dosage Form New Animal Drugs; Robenacoxib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of robenacoxib tablets in cats for the control of postoperative pain and inflammation.

DATES: This rule is effective April 5, 2011.

FOR FURTHER INFORMATION CONTACT: Amy L. Omer, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8336, *e-mail: amy.omer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141–320 that provides for the veterinary prescription use of ONSIOR (robenacoxib) Tablets in cats for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration. The NADA is approved as of March 8, 2011, and the regulations are amended in 21 CFR part 520 by adding § 520.2075 to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Add § 520.2075 to read as follows:

§ 520.2075 Robenacoxib.

(a) *Specifications.* Each tablet contains 6 milligrams (mg) robenacoxib.

(b) *Sponsors.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer 0.45 mg per pound (/lb) (1 mg/kilogram (kg)) once daily.

(2) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats weighing at least 5.5 lb (2.5 kg) and at least 6 months of age; for up to a maximum of 3 days.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 31, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–8053 Filed 4–4–11; 8:45 am]

BILLING CODE 4160–01–P