

comments received regarding revocation of the definition of unblockable drain covers," dated March 30, 2012.

Commission staff's summary and response to these comments follow:

1. Cost of compliance (142 comments) and dire financial circumstances (131 comments).

*Comment:* Members of the American Hotel & Lodging Association, the Illinois Department of Health, and others assert that the cost of retrofitting pools again would put an undue burden on them and cite to the impact of the poor economy on their operating revenues and the loss of revenue that will be incurred while the pools are closed for the modifications that will be required to bring them into compliance. Commenters in this category also mention the respondents' "dire financial circumstances" as a reason against the revocation of the Commission's April 27, 2010 definition of "unblockable drain."

*Response:* Commission staff agrees that there may be financial hardship, but only to those who relied upon the Commission's interpretive rule and installed an unblockable drain cover in lieu of installing a secondary system. Thus, Commission staff believes it seems reasonable to provide firms that relied on the Commission's prior interpretation the time to budget and plan for the expenditure needed to install a secondary system.

2. Apply prospectively (4 comments).

*Comment:* Commenters in this category cited the lack of injuries as a reason to apply the revocation only to facilities that are newly constructed or renovated in the future.

*Response:* Commission staff does not agree with prospective application to new construction or renovation. The law has required pools to be compliant with the VGBA for almost four years. Only firms that relied on the unblockable drain interpretive rule of April 27, 2010, and installed VGBA-compliant unblockable drain covers on or before October 11, 2011, are affected by the revocation decision. Thus, prospective application is overly broad, and applying it to firms that did not install VGBA-compliant unblockable drain covers on or before October 11, 2011, would not follow the statutorily mandated effective date, would create confusion, and would unduly complicate enforcement.

3. Comments Requesting Delay of Enforcement (2 comments).

*Comment:* Two commenters requested that the Commission delay the implementation of enforcement. One requested that the CPSC delay implementation of the enforcement of

the change for one year because they had relied upon the original interpretation and installed unblockable drain covers and now would have to go back and "re-do" their work, which they said would penalize them unfairly for their compliance with the prior interpretation. The commenter also noted that the unblockable drain covers were far more expensive than typical smaller fittings, and asserted that they represented a major investment on the basis that, once the covers were installed, additional equipment would not be required. The other commenter requested that the Commission delay the implementation date to January 1, 2013, or prior to 2013 operation dates for seasonal pools and spas. The commenter also stated that regulated pools and spas that had already invested to comply with the requirements of the VGBA would be required to add secondary anti-entrapment systems or make other modifications at considerable expense, in addition to expenditures necessary to comply with state law and U.S. Department of Justice pool and spa accessibility requirements.

*Response:* Commission staff agrees that those who relied upon the Commission's interpretive rule and installed an unblockable drain cover in lieu of installing a secondary system will now face additional expenditures to bring their pools into compliance with the VGBA. Thus, Commission staff believes that it seems reasonable to provide those who installed VGBA-compliant unblockable drain covers on or before October 11, 2011, time to budget and plan for the expenditure needed to install a secondary system.

4. Compliance Date Is Acceptable (1 comment).

*Comment:* One comment was received in support of the May 28, 2012, compliance date. The commenter, the National Multi Housing Council/National Apartment Association (NMHC/NAA), expressed the belief that if the Commission offered additional guidance to the regulated community to assist with compliance, the majority of their members could comply by the deadline; but NMHC/NAA urged the CPSC to reevaluate the progress being made by pool owners and adjust the deadline, if necessary.

*Response:* CPSC staff has a concern about the number of requests that may be received for assistance with compliance and whether the pool operator is seeking a plan review and not just limited advice about how to handle the revocation decision. The only circumstance in which staff believes there could be any need for compliance assistance due to the

revocation of the unblockable drain interpretive rule is with respect to pool operators who relied on the Commission's April 27, 2010 decision and installed VGBA-compliant unblockable drain covers on or before October 11, 2011. The guidance to those firms is that your unblockable drain cover is VGBA-compliant and does not need to be removed; but pool operators need to install a secondary anti-entrapment system to come into compliance, unless the pool uses a gravity drain system or the underlying drain is unblockable. Accordingly, if a pool operator installed an unblockable drain cover over a drain that is blockable, staff believes it is reasonable to allow them time to budget and plan for the expenditure required to install a secondary anti-entrapment system.

### C. Commission Determination

Upon being presented with the staff briefing package, the Commission voted to extend the compliance date to May 23, 2013. Only firms that relied on the unblockable drain interpretive rule of April 27, 2010, and installed VGBA-compliant unblockable drain covers on or before October 11, 2011, will have until May 23, 2013, to install a secondary system, as necessary. Firms that did not rely on the unblockable drain interpretive rule of April 27, 2010, and did not install VGBA-compliant unblockable drain covers on or before October 11, 2011, should be compliant with the VGBA, and will not have additional time to come into compliance if they are not.

Dated: May 17, 2012.

**Todd A. Stevenson,**  
Secretary, Consumer Product Safety Commission.

[FR Doc. 2012-12335 Filed 5-23-12; 8:45 a.m.]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 600, 610, and 680

[Docket No. FDA-2011-N-0080]

RIN 0910-AG16

#### Amendments to Sterility Test Requirements for Biological Products; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule, correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a

final rule that appeared in the **Federal Register** of May 3, 2012. (77 FR 26162). The final rule provides manufacturers of biological products greater flexibility, as appropriate, and encourages use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products. The rule was published with an inaccurate citation in the codified section of the rule. This notice corrects that error.

**DATES:** Effective June 4, 2012.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2012-10649, appearing on page 26162 in the **Federal Register** of Thursday, May 3, 2012, the following correction is made:

**§ 680.3 [Corrected]**

1. On page 26175, in the second column, in Part 680 Additional Standards for Miscellaneous Products, in § 680.3 Tests, paragraph (c), in line 4, “§ 601.12” is corrected to read “§ 610.12”.

Dated: May 18, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-12594 Filed 5-23-12; 8:45 a.m.]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Indian Affairs**

**25 CFR Part 36**

[Docket ID: BIA-2012-0001]

RIN 1076-AF10

**Heating, Cooling, and Lighting Standards for Bureau-Funded Dormitory Facilities**

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** As required by the No Child Left Behind Act of 2001, the Secretary of the Interior has developed regulations using negotiated rulemaking that address heating, cooling, and lighting standards for Bureau-funded dormitory facilities. These regulations also make a technical change to remove an obsolete reference.

**DATES:** This rule is effective on May 24, 2012. Please submit written comments by June 25, 2012. The incorporation by

reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of May 24, 2012.

**ADDRESSES:** You may submit comments by any of the following methods:

—*Federal rulemaking portal:* <http://www.regulations.gov>. The rule is listed under the agency name “Bureau of Indian Affairs.” The rule has been assigned Docket ID: BIA-2012-0001. If you would like to submit comments through the Federal e-Rulemaking Portal, go to [www.regulations.gov](http://www.regulations.gov) and do the following. Go to the box entitled “Enter Keyword or ID,” type in “BIA-2012-0001,” and click the “Search” button. The next screen will display the Docket Search Results for the rulemaking. If you click on BIA-2012-0001, you can view this rule and submit a comment. You can also view any supporting material and any comments submitted by others.

—*Email:* [Regina.Gilbert@bia.gov](mailto:Regina.Gilbert@bia.gov). Include the number 1076-AF10 in the subject line of the message.

—*Fax:* (505) 563-3811. Include the number 1076-AF10 in the subject line of the message.

—*Mail:* Regina Gilbert, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1001 Indian School Road NW., Suite 312, Albuquerque, NM 87104. Include the number 1076-AF10 in the subject line of the message.

—*Hand delivery:* Regina Gilbert, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1001 Indian School Road NW., Suite 312, Albuquerque, NM 87104. Include the number 1076-AF10 in the subject line of the message.

We cannot ensure that comments received after the close of the comment period (see **DATES**) will be included in the docket for this rulemaking and considered. Comments sent to an address other than those listed above will not be included in the docket for this rulemaking.

**FOR FURTHER INFORMATION CONTACT:** Regina Gilbert, Office of Regulatory Affairs and Collaborative Action, Office of the Assistant Secretary—Indian Affairs, 1001 Indian School Road NW., Suite 312, Albuquerque, NM 87104; telephone (505) 563-3805; fax (505) 563-3811.

**SUPPLEMENTARY INFORMATION:**

I. Background

II. Description of Changes

III. Procedural Requirements

- A. Regulatory Planning and Review (E.O. 12866)

- B. Regulatory Flexibility Act  
C. Small Business Regulatory Enforcement Fairness Act  
D. Unfunded Mandates Reform Act  
E. Takings (E.O. 12630)  
F. Federalism (E.O. 13132)  
G. Civil Justice Reform (E.O. 12988)  
H. Consultation With Indian Tribes (E.O. 13175)  
I. Paperwork Reduction Act  
J. National Environmental Policy Act  
K. Information Quality Act  
L. Effects on the Energy Supply (E.O. 13211)  
M. Clarity of This Regulation  
N. Public Availability of Comments  
O. Determination To Allow Shortened Public Comment Period

**I. Background**

The U.S. Government is responsible for educating American Indian children. This Federal duty is executed by the Bureau of Indian Affairs within the Department of the Interior. The Bureau funds 183 schools serving American Indian children. In part because of the low population densities across much of Indian country, a number of these schools include dormitory (“home-living”) facilities. Many of these schools and associated facilities are in poor physical condition.

The No Child Left Behind Act of 2001 (107 Pub. L. 110: 115 Stat. 1425) (Act) included provisions intended to improve the quality of education provided at Bureau-funded schools, and the physical condition of the school facilities. The Act directed the Secretary of the Interior to establish a negotiated rulemaking committee, in accordance with the provisions of the Negotiated Rulemaking Act, to ensure maximum contribution by the affected Indian tribes in responding to the mandates of the Act.

In 2003, the Secretary established a negotiated rulemaking committee, which held a series of meetings to address the mandates of the Act (the 2003 committee). On April 28, 2005, final rules developed by the 2003 committee were published in the **Federal Register**, addressing six components of the Act’s mandates: defining adequate yearly progress; establishing geographic attendance areas for Bureau-funded schools; establishing a formula for the minimum amount necessary to fund Bureau-funded schools; establishing a system of uniform direct funding and support for Bureau-operated schools; providing guidelines to ensure the Constitutional and civil rights of Indian students; and establishing a method for administering grants to tribally controlled schools. 70 FR 22178.