4160-01-P

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:

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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.

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