4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2012-N-0165]

# Medical Devices; Immunology and Microbiology Devices; Classification of Norovirus Serological Reagents; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: In the Federal Register of March 9, 2012 (76 FR 14272), the Food and Drug Administration (FDA) classified norovirus serological reagents into class II (special controls) because special controls, in addition to general controls, will provide a reasonable assurance of safety and effectiveness of these devices. The document published with inadvertent errors in the Analysis of Impacts section. This document corrects those errors.

DATES: Effective April 9, 2012.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In FR Doc. 2012-5675 appearing on page 14272 in the Federal Register of Friday, March 9, 2012, the following corrections are made:

1. On page 14274, in the first column, in section VI. Analysis of Impacts, in the first paragraph, in the last sentence, correct the phrase "proposed rule" to read "final rule", and in the second paragraph, in the last sentence, correct the phrase "proposes to certify" to read "certifies".

2. On page 14274, in the second column, in the first full sentence, correct the phrase "proposed rule" to read "final rule".

Dated: March 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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