DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2003P–0564]

Display Date 8-28-06
Publication Date 3-1-06
Certifier R. LEDESMA
PDM

Microbiology Devices; Reclassification of Hepatitis A Virus Serological Assays; 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 February 9, 2006 (71 FR 6677). That document reclassified hepatitis A virus (HAV) serological assays from class III (premarket approval) into class II (special controls). That document inadvertently published with an error. This document corrects the error.

DATES: This rule is effective March 13, 2006.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION: In FR Doc. 06–1206, appearing on page 6677 in the **Federal Register** of Thursday, February 9, 2006, the following correction is made:

1. On page 6679, beginning in the first column, under section "VI. Analysis of Impacts," the second paragraph is corrected to read:

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities.

Reclassification of HAV serological assays from class III into class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with

respect to these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Dated: 2/21/06
February 21, 2006.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL