

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2003D-0221]

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Center CDER
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Medical Devices; Immunology and Microbiology Devices; Classification of the Endotoxin Assay; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) published a final rule in the **Federal Register** of October 31, 2003 (68 FR 62007). The final rule classified the endotoxin assay into class II (special controls). The agency classified the device into class II (special controls) in order to provide reasonable assurance of safety and effectiveness of the device. FDA is amending the agency's regulations to redesignate the section number listed in the Code of Federal Regulations (CFR) from § 866.3610 to § 866.3210.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496 ext. 1111.

SUPPLEMENTARY INFORMATION: FDA has found that the endotoxin assay regulation does not reflect the correct section number listed in the CFR. Accordingly, FDA is amending the regulation in § 866.3610 (21 CFR 866.3610) to correct the error by redesignating the section number from § 866.3610 to 866.3210.

List of Subjects in 21 CFR Part 866

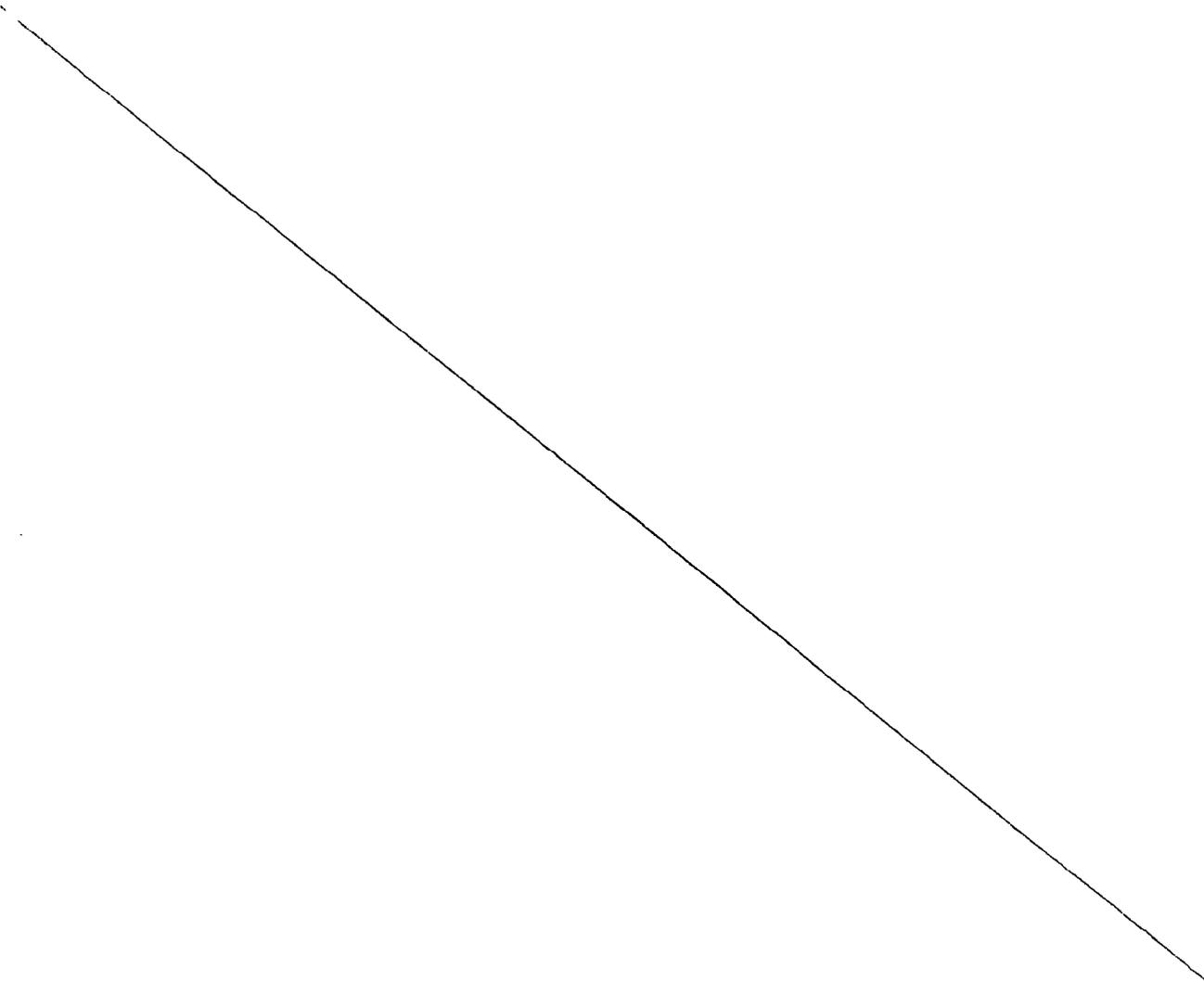
Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.



§ 866.3610 [Redesignated as § 866.3210]

- 2. Section 866.3610 is redesignated as § 866.3210.

Dated: 8/26/05
August 26, 2005.

Linda S. Kahan

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Center for Devices and Radiological Health.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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