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Certifier	Jan Winkler

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 56**

[Docket No. 98N-0144]

**Biological Products Regulated Under Section 351 of the Public Health Service Act;  
Implementation of Biologics License; Elimination of Establishment License and  
Product License; Technical Amendment**

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

**ACTION:** Final rule; technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the biologics regulations to correct inadvertent errors. This action is necessary to ensure the accuracy and consistency of the regulations.

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

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, 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:** FDA has discovered that errors have inadvertently become incorporated into the agency's regulations for biologics. In the **Federal Register** of October 20, 1999 (64 FR 56441), a final rule incorrectly revised § 56.102 (21 CFR 56.102) in paragraph (b)(11) instead of correctly revising paragraph (b)(10). Section 56.102 (b)(10) and (b)(11) were affected by this inadvertent error. This document corrects those errors.

**List of Subjects in 21 CFR Part 56**

Human research subjects, Reporting and recordkeeping requirements, Safety.

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Human research subjects, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR part 56 is amended as follows:

**PART 56—INSTITUTIONAL REVIEW BOARDS**

1. The authority citation for 21 CFR part 56 continues to read as follows:

**Authority:** 21 U.S.C. 321, 346, 346a, 348, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

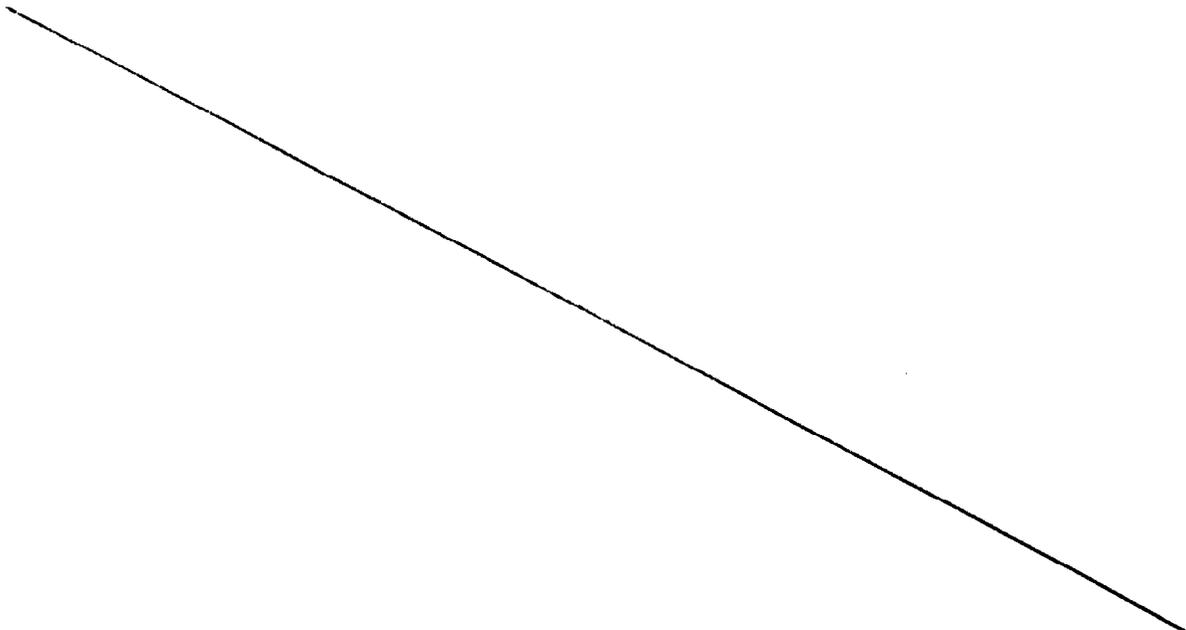
2. Section 56.102 is amended by revising paragraphs (b)(10) and (b)(11) to read as follows:

**§ 56.102 Definitions.**

\* \* \* \* \*

(b) \* \* \*

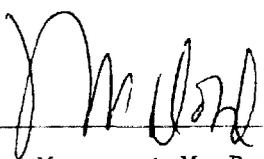
(10) An application for a biologics license, described in part 601 of this chapter.



(11) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in part 601 of this chapter.

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Dated: 8/4/00  
August 4, 2000



Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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