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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 5**

**Delegations of Authority and Organization; Redlegation to Officials Within the Center for Biologics Evaluation and Research**

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the statements of redelegations of authority to reflect a new redelegation that enables the Director and Deputy Directors of the Center for Biologics Evaluation and Research (CBER) to issue license suspension notifications under the authority given to the Commissioner of Food and Drugs (the Commissioner). This amendment is intended to reflect those redelegations.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:** FDA is amending the redelegations of authority statement in § 5.67 (21 CFR 5.67) by revising the section heading and adding an authority to certain FDA officials. In order to ensure efficient program operations, the Commissioner has further redelegated this authority to the Center Director and the Deputy Center Directors, CBER, the authority to issue license suspensions under section 351(a)(2)(A) of the Public Health Service Act (42 U.S.C.

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262(a)(2)(A)), as amended. The Commissioner's authority is currently codified under 21 CFR 5.10(a)(5) and the associated regulation is currently codified under 21 CFR 601.6. This authority may not be further redelegated at this time.

### **List of Subjects in 21 CFR Part 5**

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

### **PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION**

1. The authority citation for 21 CFR part 5 continues to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242i, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1997 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.67 is amended by revising the section heading and the introductory paragraph, and by adding paragraph (e) to read as follows:

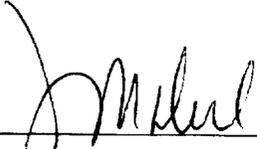
**§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.**

The Center Director and Deputy Center Directors, Center for Biologics Evaluation and Research are authorized to issue:

\* \* \* \* \*

(e) Notice of license suspensions under § 601.6 of this chapter.

Dated: 8/25/99  
August 25, 1999



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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