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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to correct position titles for delegates in the Center for Drug Evaluation and Research (CDER). This action is necessary to ensure the continued accuracy of the regulations.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is correcting its regulations in subpart B of part 5 (21 CFR part 5) in two sections that reflect incorrect position titles for delegates within CDER. In the **Federal Register** of January 17, 1997 (62 FR 2554), FDA amended the regulations for delegations of authority to update titles of CDER delegates and organizational components to reflect organizational restructuring. In two instances, the position titles for the Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science (OPS), CDER were inadvertently changed to reflect the Director and Deputy Director, Division of Bioequivalence,

OGD, OPS, CDER. Previously, the Director and Deputy Director, OGD, OPS, CDER held those authorities. The Director and Deputy Division Director of Bioequivalence titles should be removed.

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, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

§ 5.22 [Amended]

2. Section 5.22 *Certification of true copies and use of Departmental seal* is amended by removing paragraph (a) (13) (viii).

3. Section 5.31 is amended by revising paragraph (f) (3) to read as follows:

§ 5.31 Petitions under part 10.

(f) * * *

(3) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, except for those drug products listed in § 314.440(b) of this chapter, are authorized

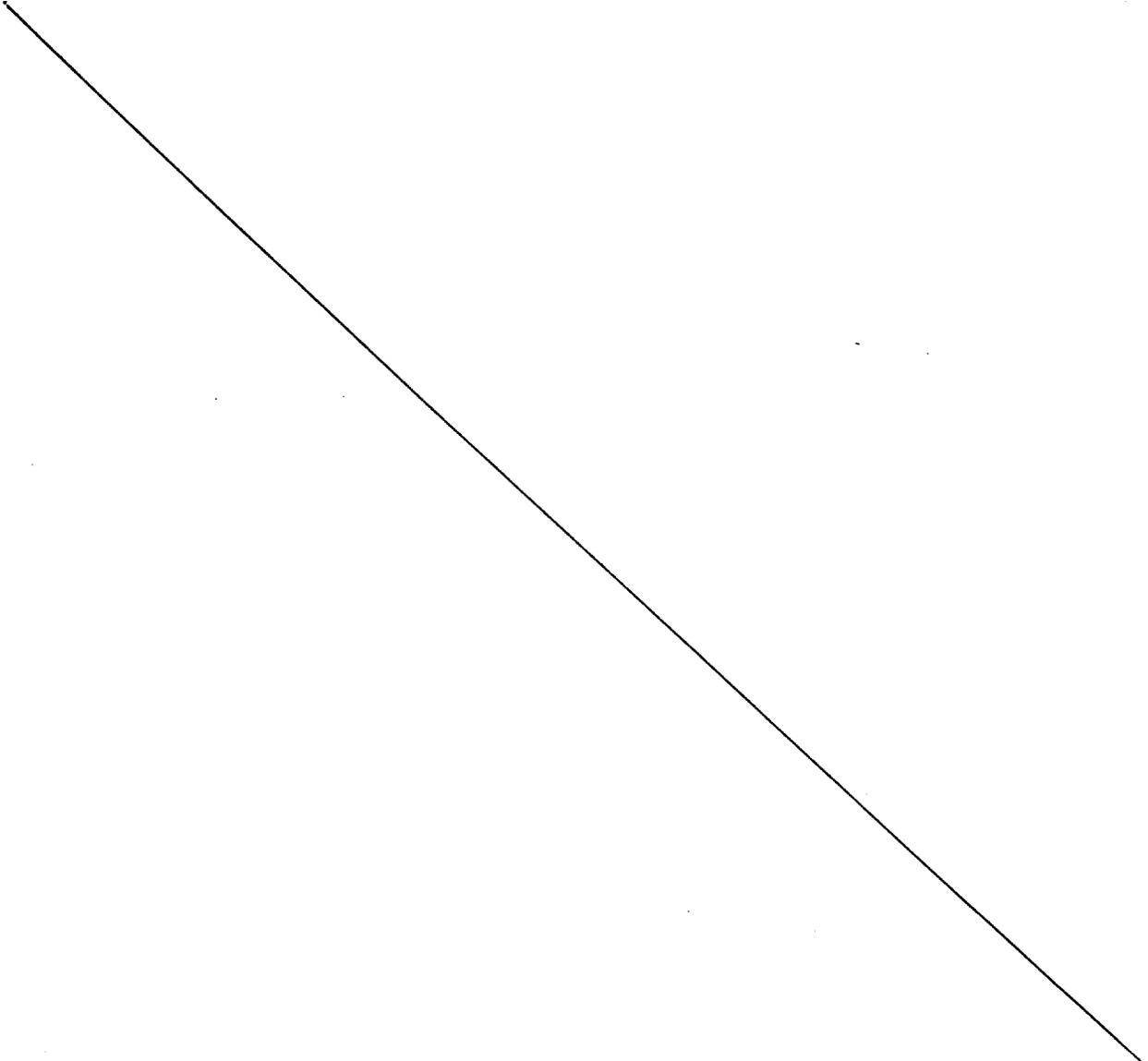
to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

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4. Section 5.93 is amended by revising paragraph (b) to read as follows:

§ 5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

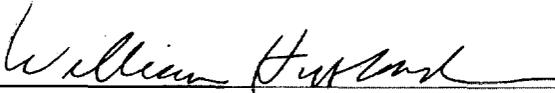
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(b) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

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Dated: September 7, 1999



William K. Hubbard
Senior Associate Commissioner for Policy, Planning and Legislation

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