Issued in Kansas City, Missouri, on January 6, 1997.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to functions performed by the Center for Drug Evaluation and Research (CDER). This amendment updates the titles of CDER delegates and organizational components to reflect the organizational restructuring. This action is intended to ensure the accuracy and consistency of the regulations.

EFFECTIVE DATE: January 17, 1997.

FOR FURTHER INFORMATION CONTACT:

Rixie L. Scott, Center for Drug Evaluation and Research (HFD–54), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0494, or

Donna G. Page, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: CDER recently underwent a major organizational restructuring. The Center level structure was approved by the Commissioner of Food and Drugs and published in the Federal Register of October 13, 1995 (60 FR 53379). Most of the authorities delegated to the center officials are amended in this document to reflect new titles and organization placement under the restructuring.

This document revises the delegations of authority contained in part 5 (21 CFR part 5) relating to the functions assigned to CDER.

Further redelegation of the authorities delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

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; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.22 is amended by revising paragraphs (a)(13)(i) through (a)(13)(v) and by adding new paragraphs (a)(13)(vi) through (a)(13)(viii) to read as follows:

§ 5.22 Certification of true copies and use of Department seal.

(a) * * *

(13)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Management, CDER.

(iii) The Director and Deputy Director, Office of Compliance, CDER.

(iv) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, and the Director and Deputy Director of the Office of Epidemiology and Biostatistics, Office of Review Management, CDER.

(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology and Biopharmaceutics, Office of Pharmaceutical Science, CDER.

(vi) The Chief, Freedom of Information Staff, Office of Training and Communications, CDER.

(vii) The Directors of the Divisions of Labeling and Nonprescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, Office of Compliance, CDER.

(viii) The Director and Deputy Director, Division of Bioequivalence, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

* * * * *

3. Section 5.23 is amended by revising paragraph (b) to read as follows:

§ 5.23 Disclosure of official records.

* * * * *

(b) The Chief, Product Information Management Branch, Division of Database Management, Office of Management, Center for Drug Evaluation and Research (CDER), is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

* * * * *

4. Section 5.25 is amended by revising paragraph (a)(6) to read as follows:

§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.

(a) * * *

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

* * * * *

5. Section 5.26 is amended by revising paragraph (g) to read as follows:

§ 5.26 Service fellowships.

* * * * *

(g) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), and the Director and Deputy Director, Office of Management, CDER.

* * * * *

6. Section 5.30 is amended by revising paragraphs (a)(2) and (c)(3) to read as follows:

§ 5.30 Hearings.

(a) * * *

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

* * * * *

(c) * * *

(3) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; the

Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

* * * * *

7. Section 5.31 is amended by revising paragraphs (a)(2)(i) through (a)(2)(iii), (b)(1) through (b)(3), (c)(1), (d)(1), (d)(2), (e)(4), the introductory text of paragraph (f)(2), (f)(3), and (f)(5)(ii); by removing paragraph (a)(2)(iv); and by adding new paragraph (d)(3) to read as follows:

§ 5.31 Petitions under part 10.

(a) * * *

(2)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) * * *

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) * * *

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

* * * * *

(d) * * *

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e) * * *

(4) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER, are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

* * * * *

(f) * * *

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug product matters in program areas where they have been delegated final approval authority in the following sections of this part:

* * * * *

(3) The Director and Deputy Director, Division of Bioequivalence, 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.

* * * * *

(5) * * *

(ii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

* * * * *

8. Section 5.33 is amended by revising paragraph (c) to read as follows:

§ 5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug.

* * * * *

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

9. Section 5.37 is amended by revising paragraphs (a)(5)(i) and (a)(5)(ii) and by adding new paragraphs (a)(5)(iii) and (a)(5)(iv) to read as follows:

§ 5.37 Issuance of reports of minor violations.

(a) * * *

(5)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Compliance, CDER.

(iii) The Associate Director for Medical Policy, CDER.

(iv) The Director, Division of Drug Marketing, Advertising, and Communications, Office of Drug Evaluation I, Office of Review Management, CDER.

* * * * *

10. Section 5.38 is amended by revising paragraphs (a)(1) through (a)(6) to read as follows:

§ 5.38 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs.

(a) * * *

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Director and Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER.

* * * * *

11. Section 5.44 is amended by revising paragraphs (a)(1)(iii) and (b)(1)(iii) to read as follows:

§ 5.44 Export of unapproved drugs.

(a) * * *

(1) * * *

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

* * * * *

(b) * * *

(1) * * *

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

* * * * *

12. Section 5.45 is amended by revising paragraph (f)(2) to read as follows:

§ 5.45 Imports and exports.

* * * * *

(f) * * *

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

13. Section 5.54 is amended by revising paragraph (c) to read as follows:

§ 5.54 Determinations that medical devices present unreasonable risk of substantial harm.

* * * * *

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

14. Section 5.55 is amended by revising paragraph (c) to read as follows:

§ 5.55 Orders to repair or replace, or make refunds for, medical devices.

* * * * *

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

15. Section 5.56 is amended by revising paragraph (c) to read as follows:

§ 5.56 Recall authority.

* * * * *

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

* * * * *

16. Section 5.57 is amended by revising paragraph (d) to read as follows:

§ 5.57 Temporary suspension of a medical device application.

* * * * *

(d) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

* * * * *

17. Section 5.58 is amended by revising paragraphs (c)(1)(i) through (c)(1)(iii) and by removing paragraph (c)(1)(iv) to read as follows:

§ 5.58 Orphan products.

* * * * *

(c) * * *

(1) * * *

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

* * * * *

18. Section 5.60 is amended by removing paragraphs (a)(10) and (b)(9), by redesignating paragraphs (a)(11) through (a)(13) as paragraphs (a)(10) through (a)(12), and (b)(10) through (b)(12) as paragraphs (b)(9) through (b)(11), by revising paragraphs (a)(7) through (a)(9), and paragraphs (b)(6) through (b)(8) to read as follows:

§ 5.60 Required and discretionary postmarket surveillance.

(a) * * *

(7) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(8) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(9) The Director and Deputy Director, Office of Compliance, CDER.

* * * * *

(b) * * *

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(7) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(8) The Director and Deputy Director, Office of Compliance, CDER.

* * * * *

19. Section 5.70 is revised to read as follows:

§ 5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.

The Director, Deputy Center Director for Review Management, and Deputy Director, Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87–781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act.

20. Section 5.71 is amended by revising paragraphs (a)(2), (b)(1), (b)(2), (c)(1), and (c)(2) to read as follows:

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) * * *

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) * * *

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

* * * * *

(c) * * *

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

* * * * *

21. Section 5.72 is amended by revising paragraph (a) to read as follows:

§ 5.72 Authority to approve and to withdraw approval of a charge for investigational new drugs.

* * * * *

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

* * * * *

22. Section 5.73 is amended by revising paragraphs (a) through (d) and by adding new paragraphs (e) and (f) to read as follows:

§ 5.73 Certification of insulin.

* * * * *

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

(d) The Director and Deputy Director, Office of Compliance, CDER.

(e) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(f) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug

Compliance and Surveillance, Office of Compliance, CDER.

23. Section 5.74 is amended by revising paragraphs (a) and (b) and by adding new paragraphs (c) and (d) to read as follows:

§ 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.

* * * * *

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

(d) The Director and Deputy Director, Office of Compliance, CDER.

24. Section 5.75 is amended by revising paragraphs (a) through (c) to read as follows:

§ 5.75 Designation of official master and working standards for antibiotic drugs.

* * * * *

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

25. Section 5.76 is amended by revising paragraphs (a) through (d) to read as follows:

§ 5.76 Certification of antibiotic drugs.

* * * * *

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

(c) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(d) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

26. Section 5.78 is amended by revising paragraphs (a)(1) and (a)(2) and adding new paragraphs (a)(3) through (a)(7) to read as follows:

§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.

(a) * * *

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director, Office of Drug Evaluation I, Office of Review Management, CDER.

(3) The Director, Office of Drug Evaluation IV, Office of Review Management, CDER.

(4) The Director and Deputy Director, Division of Oncologic Drug Products, Office of Drug Evaluation I, Office of Review Management, CDER.

(5) The Director and Deputy Director, Division of Anti-Infective Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.

(6) The Director and Deputy Director, Division of Anti-Viral Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.

(7) The Director and Deputy Director, Office of Compliance, CDER.

* * * * *

27. Section 5.80 is amended by revising paragraphs (a)(1)(i), (a)(1)(ii), (b), (c)(1)(i) and (c)(1)(ii), (d)(1) through (d)(3), the first sentence in paragraph (e), and paragraph (f) and by removing paragraphs (a)(1)(iii), (c)(1)((iii), and (c)(1)(iv) to read as follows:

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) * * *

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

* * * * *

(b) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(c) * * *

(1) * * *

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors and Deputy Directors of the divisions in Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(d) * * *

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) Associate Director for Chemistry, Office of Pharmaceutical Science, CDER.

(e) The Director, Division of Labeling and Program Support, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in § 314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. * * *

(f) The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in § 314.70(b)(1), (b)(2)(ii) through (b)(2)((x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in § 5.10(a) and paragraphs (a) and (b) of this section.

28. Section 5.82 is amended by revising paragraph (a) to read as follows:

§ 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

* * * * *

29. Section 5.93 is amended by revising paragraphs (a) and (b) to read as follows:

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

* * * * *

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

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

30. Section 5.94 is amended by revising paragraphs (b)(1) through (b)(3) and by removing paragraph (b)(4) to read as follows:

§ 5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

* * * * *

(b) * * *

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

Dated: December 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–1202 Filed 1–16–97; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

Alaska, Indiana, Iowa, Kentucky, Minnesota, South Carolina, Utah, Virgin Islands and Wyoming State Plans; Approval of Plan Supplements; Changes in Level of Federal Enforcement

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule.

SUMMARY: This document amends OSHA's regulations to reflect the Assistant Secretary's decision approving amendments to nine (9) State plans to exclude coverage of the field sanitation standard and the temporary labor camp standard as it applies in agriculture (with the exception of temporary labor camps for employees engaged in egg, poultry or red meat production, or the post-harvest processing of agricultural or horticultural commodities) from their State Plans. The States of Alaska, Indiana, Iowa, Kentucky, Minnesota, South Carolina, Utah, Virgin Islands, and Wyoming have elected to follow the jurisdictional transfer of authority as effected by Secretary of Labor's Orders 5–96 and 6–96, published in the Federal Register on January 2, 1997, between the Employment Standards Administration (ESA) and OSHA with regard to these two OSHA standards. OSHA is hereby amending pertinent sections of its regulations on approved State plans to reflect this relinquishment of State jurisdiction and transfer of OSHA enforcement authority to ESA in these nine (9) States and to notify affected employers and employees of this action. In fourteen (14) other States operating OSHA-approved State plans, enforcement of the field sanitation and temporary labor camp standards in agriculture will not transfer to ESA and will continue as a State responsibility. (These States are: Arizona, California, Hawaii, Maryland, Michigan, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, Tennessee, Vermont, Virginia and Washington). In all other States under Federal OSHA jurisdiction, ESA will now exercise responsibility for enforcement in agriculture of the OSHA field sanitation and temporary labor camp standards, except as noted.

EFFECTIVE DATE: February 3, 1997.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N3637, 200 Constitution Avenue NW., Washington, DC 20210, (202) 219–8148.

SUPPLEMENTARY INFORMATION:

A. Introduction

Section 18 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 667, provides that States which wish to assume responsibility for developing and enforcing their own occupational safety and health standards may do so by submitting and obtaining Federal approval of a State plan. State plan approval occurs in stages which include initial approval under section 18(b) of the Act and, ultimately, final approval under section 18(e). Pursuant to section 18(e) OSHA previously announced in the Federal Register final state plan approval and relinquishment of concurrent Federal jurisdiction for each of the following nine States: Alaska, Indiana, Iowa, Kentucky, Minnesota, South Carolina, Utah, Virgin Islands, and Wyoming. Through amendments to their State plans, these nine States have excluded coverage of the field sanitation (29 CFR 1928.110) and temporary labor camp (29 CFR 1910.142) standards in agriculture (with the exception of temporary labor camps for employees engaged in egg, poultry or red meat production, or the post-harvest processing of agricultural or horticultural commodities) from their State plans. As provided in Secretary of Labor's Orders 5–96 and 6–96, effective February 3, 1997, (62 FR 107–113, January 2, 1997) this authority has been subsequently transferred from the Occupational Safety and Health Administration (OSHA) to the Employment Standards Administration (ESA). Therefore, the applicable subparts of 29 CFR Part 1952 are being revised to effect this change in coverage and enforcement jurisdiction.

B. Background

Following a one year pilot project and pursuant to Secretary's Orders 5–96 and 6–96 (62 FR 107–113), an exchange of specific authorities and responsibilities has been effected between the Assistant Secretary for Occupational Safety and Health and Assistant Secretary for