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Display Date 8-10-04
Publication Date 8-11-04
Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0287]

21 CFR Parts 1, 5, 26, 203, 207, and 314

Change of Names and Addresses; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect name and address changes for the Office of Compliance, Center for Drug Evaluation and Research (CDER). This action is editorial in nature and is intended to provide accuracy and clarity to the agency's regulations.

EFFECTIVE DATE: [*Insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Mary C. Hennessey, Office of Compliance, Center for Drug Evaluation and Research (HFD–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8910.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR parts 1, 5, 26, 203, 207, and 314 to reflect name and address changes for certain divisions of the Office of Compliance, CDER. The name changes are the result of a reorganization in CDER's Office of Compliance to improve coordination and communication and to enhance the office's capacity to implement risk management approaches to compliance activities. The address changes are due to the relocation of CDER's Office of Compliance.

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Under this reorganization, the following organizational changes are reflected in the amendments made by this final rule:

• The name of the former Division of Labeling and Nonprescription Drug Compliance has been changed to the Division of New Drugs and Labeling Compliance,

• The name of the former Division of Prescription Drug Compliance and Surveillance has been changed to the Division of Compliance Risk Management and Surveillance, and

• Information sent to or obtained from the Drug Listing Branch is now maintained and distributed by CDER's Records Repository Team.

The amendments also include:

• The new mailing address of the Office of Compliance, CDER, and

• The new mailing addresses of specific divisions within the Office of Compliance (CDER) and for the Records Repository Team.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because these amendments are nonsubstantive.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 5

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

21 CFR Part 26

Animal drugs, Biologics, Drugs, Exports, Imports.

21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 5, 26, 203, 207, and 314 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

§ 1.101 Notification and recordkeeping.

SR per Karen Thompson @ OFR 8-9-04

■ 2. Section 1.101 is amended by revising paragraph (d)(2)(ii) to read as follows:

* * * * *

(d) * * *

(2) * * *

(ii) For human drug products—Division of New Drugs and Labeling Compliance (HFD–310), Office of Compliance, Center for Drug Evaluation and

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

SL per K. Thornton at CFR 3-9-04

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

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

■ 4. Section 5.1100 is amended under the heading "CENTER FOR DRUG EVALUATION AND RESEARCH.[1]" by removing the entries

"Office of Compliance.[6]

Division of Manufacturing and Product Quality.

Division of Prescription Drug Compliance and Surveillance.

Division of Labeling and Non-Prescription Drug Compliance." and by adding in its place the entries

"Office of Compliance.[1]

Division of New Drugs and Labeling Compliance (HFD–310).

Division of Manufacturing and Product Quality (HFD–320).

Division of Compliance Risk Management and Surveillance (HFD–330)."

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

■ 5. The authority citation for 21 CFR part 26 continues to read as follows:

Authority: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

■ 6. Section 26.21 is amended in "APPENDIX E TO SUBPART A OF PART 26 ~~ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO–WAY ALERT SYSTEM~~" is amended under the heading "B. For the United States:" in the entry for "Human Drugs" by removing the phrase "MPN I, 7520 Standish Pl., Rockville, MD 20855–2737, phone: 301–594–0054, fax: 301–594–2114" and by adding in its place the phrase "5600 Fishers Lane, Rockville, MD 20857, phone: 301–827–8910, fax: 301–827–8901".

SR per K. Thornton at OFR 8-9-04

PART 203—PRESCRIPTION DRUG MARKETING

■ 7. The authority citation for 21 CFR part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

§ 203.12 [Amended]

■ 8. Section 203.12 is amended in the first sentence by removing the phrase "7520 Standish Pl., Rockville, MD 20855" and by adding in its place the phrase "5600 Fishers Lane, Rockville, MD 20857".

§ 203.37 [Amended]

■ 9. Section 203.37 is amended by revising the first sentence of paragraph (e) to read as follows:

* * * * *

(e) *Whom to notify at FDA.* Notifications and reports concerning prescription human drugs shall be made to the Division of Compliance Risk Management and Surveillance (HFD–330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. * * *

§ 203.70 [Amended]

■ 10. Section 203.70 is amended in paragraph (b)(1) by removing the phrase "7500 Standish Pl., Rockville, MD 20855" and by adding in its place the phrase "5600 Fishers Lane, Rockville, MD 20857".

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

■ 11. The authority citation for 21 CFR part 207 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

§ 207.7 [Amended]

■ 12. Section 207.7 is amended in paragraph (d) by removing the phrase "Drug Listing Branch (HFD–334)" and by adding in its place the phrase "Records Repository Team (HFD–143)".

§ 207.22 [Amended]

■ 13. Section 207.22 is amended in paragraph (a) by removing the phrase "Drug Listing Branch (HFD–334)" and by adding in its place the phrase "Records Repository Team (HFD–143)"; and in paragraph (b) by removing the phrase "Drug Listing Branch (HFD–334)" and by adding in its place the phrase "Records Repository Team (HFD–143)".

■ 14. Section 207.37 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA–2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Records Repository Team (HFD–143), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857. In addition, copies of these forms for establishments located within a particular geographic area are available for inspection at FDA district offices responsible for that geographical area. Copies of forms submitted by foreign drug establishments are available for inspection at the Division of Manufacturing and Product Quality, Foreign Inspection Team (HFD–325), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Upon request and receipt of a stamped, self-addressed envelope, the Records Repository Team, the Foreign Inspection Team, or the appropriate FDA district office will verify registration numbers or provide the location of a registered establishment. The mailing address for the Foreign Inspection Team is: Division of Manufacturing and Product Quality, Office of Compliance, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 15. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.81 [Amended]

■ 16. Section 314.81 is amended in paragraph (b)(3)(iii)(*b*) by removing the phrase "Drug Listing Branch (HFD–334)" and by adding in its place the phrase "Records Repository Team (HFD–143)".

§ 314.200 [Amended]

■ 17. Section 314.200 is amended in the second sentence of paragraph (a)(3) by removing the phrase "Division of Drug Labeling Compliance (HFD–310)" and by adding in its place the phrase "Division of New Drugs and Labeling Compliance (HFD–310), Office of Compliance".

Dated: AUG 3 2004

August 3, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S

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Dawn P. Hawkins