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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA-2009-N-0099]

Display Date 3-5-09
Publication Date 3-6-09
Commenter A. Corbin

New Drug Applications and Abbreviated New Drug Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its new drug application (NDA) and abbreviated new drug application (ANDA) regulations to update agency contacts for patent information and patent notifications and to correct an inaccurate cross-reference. This action is being taken to ensure accuracy and clarity in the agency's regulations.

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

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 6308, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3506.

SUPPLEMENTARY INFORMATION: FDA is amending its NDA and ANDA regulations in part 314 (21 CFR part 314) to update agency contacts for information and notifications pertaining to patents and to correct an inaccurate reference. To accommodate the ongoing relocation of FDA offices, users are directed to FDA's Web site to obtain the current address of the Office of Generic Drugs.

In §§ 314.52(a)(2) and 314.95(a)(2), FDA is updating the agency contact for obtaining the name and address of the NDA holder or designee for purposes

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of providing notice of a patent certification submitted under section 505(b)(2)(A)(iv) or 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV)). The Division of Drug Information Resources no longer exists. The agency contact for this information is now the Orange Book Staff, Office of Generic Drugs.

In § 314.53(f), FDA is updating the agency unit to which notifications of requests for correction of patent information should be directed. The Drug Information Services Branch no longer exists. These notifications should now be sent to the Office of Generic Drugs Document Room, attention the Orange Book Staff.

In § 314.107(e), FDA is updating the listing of agency units to which a 505(b)(2) applicant must send notification of entry of an order or judgment in a court action. Instead of the appropriate division in the Office of Drug Evaluation I and Office of Drug Evaluation II, these notifications should now be sent to the appropriate division in the Office of New Drugs.

In § 314.107(f)(2)(iv), FDA is updating the agency recipient of a 505(b)(2) applicant's required notification that a legal action has been filed within 45 days of receipt of a notice of paragraph IV certification (submitted under section 505(b)(2)(A)(iv) of the act) from the appropriate division in the Center for Drug Evaluation and Research to the appropriate division in the Office of New Drugs.

In § 314.125(b)(16), FDA is correcting a cross-reference to the agency's regulations on institutional review boards (21 CFR part 56) by replacing "part 58" with "part 56."

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice

and public comment are unnecessary because the amendments to the regulations provide only technical changes to correct an inaccurate citation and to update agency contacts, and are nonsubstantive.

List of Subjects in 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 part 314 is amended as follows:

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

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

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

§ 314.52 [Amended]

■ 2. Section 314.52 is amended in paragraph (a)(2) by removing “Division of Drug Information Resources (HFD–80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857” and by adding in its place “Orange Book Staff, Office of Generic Drugs, at the address identified on FDA’s Web site (<http://www.fda.gov/cder/ogd>)”.

§ 314.53 [Amended]

■ 3. Section 314.53 is amended in paragraph (f) by removing “Drug Information Services Branch (HFD–84), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857” and by adding in its place “Office of Generic Drugs, OGD Document Room, Attention: Orange

Book Staff, at the address identified on FDA's Web site (<http://www.fda.gov/cder/ogd>)”.

§ 314.95 [Amended]

■ 4. Section 314.95 is amended in paragraph (a)(2) by removing “Division of Drug Information Resources (HFD–80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857” and by adding in its place “Orange Book Staff, Office of Generic Drugs, at the address identified on FDA's Web site (<http://www.fda.gov/cder/ogd>)”.

§ 314.107 [Amended]

■ 5. Section 314.107 is amended in paragraph (e) by removing “Office of Drug Evaluation I (HFD–100) or Office of Drug Evaluation II (HFD–500), whichever is applicable,” and by adding in its place “Office of New Drugs” and in paragraph (f)(2)(iv) by removing “Center for Drug Evaluation and Research” and by adding in its place “Office of New Drugs”.

§ 314.125 [Amended]

■ 6. Section 314.125 is amended in paragraph (b)(16) by removing “part 58” and by adding in its place “part 56”.

Dated: 2/27/09
February 27, 2009.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 09-????? Filed ??-??-09; 8:45 am]

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