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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. FDA-2019-N-0646]

Change of Address; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending its regulations to reflect a change of address for the Center for Drug Evaluation and Research's (CDER's) Office of Generic Drugs (OGD) Document Room from Rockville, MD, to Beltsville, MD. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective April 1, 2019.

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7997.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 312 and 314 (21 CFR parts 312 and 314) to reflect a change of address for CDER's OGD Document Room from Rockville, MD, to Beltsville, MD. The new address is as follows: Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update a mailing address for those submissions not required to be submitted through FDA's Electronic Submission Gateway. Unless granted a waiver or exemption from the requirements of section 745A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1), submissions under section 505(j) of the FD&C Act (21 U.S.C. 355(j)) are required to be submitted in electronic format.[1]

The amendments are as follows:

- In § 312.140(a)(1), the address for applicants to submit investigational new drug applications (INDs) for in vivo bioavailability and bioequivalence studies to support abbreviated new drug applications (ANDAs) is updated to the Beltsville Central Document Room location.
- In § 314.52(a)(2), for 505(b)(2) applicants submitting a patent certification, the address to send written or electronic communication to obtain the address of a new drug application (NDA) holder or its attorney, agent, or authorized official is updated to the Beltsville Central Document Room location.
- In § 314.53(f)(1), the address for persons other than the NDA holder to send patent listing dispute communication is updated to the Beltsville Central Document Room location.
- In § 314.95(a)(2), for ANDA applicants submitting a patent certification, the address to send written or electronic communication to obtain the address of an NDA holder or its

[1] See FDA guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (January 2019, Revision 6). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

attorney, agent, or authorized official is updated to the Beltsville Central Document Room location.

- In § 314.440(a)(2), the address for applicants to submit ANDAs, amendments, supplements, resubmissions, and correspondence not associated with an ANDA is updated to the Beltsville Central Document Room location.

List of Subjects

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

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 312 and 314 are amended as follows:

PART 312--INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

2. In § 312.140, revise paragraph (a)(1) to read as follows:

§ 312.140 Address for correspondence.

(a) * * *

(1) *For drug products regulated by CDER.* Send the IND submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266.

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

3. The authority citation for part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360cc, 371, 374, 379e, 379k-1.

§ 314.52 [Amended]

4. In § 314.52(a)(2), remove the text "Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855" and add in its place the text "Central Document Room, Attn: Orange Book Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266".

§ 314.53 [Amended]

5. In § 314.53(f)(1), remove the text "Office of Generic Drugs, OGD Document Room, Attention: Orange Book Staff, 7620 Standish Pl., Rockville, MD 20855" and add in its place the text "Central Document Room, Attn: Orange Book Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266".

§ 314.95 [Amended]

6. In § 314.95(a)(2), remove the text "Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855" and add in its place the text "Central Document Room, Attn:

Orange Book Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266".

7. In § 314.440, revise paragraph (a)(2) to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

(a) * * *

(2) Except as provided in paragraph (a)(4) of this section, an abbreviated application under § 314.94, and amendments, supplements, and resubmissions should be directed to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. This includes items sent by parcel post or overnight courier service. Correspondence not associated with an abbreviated application also should be addressed to 5901-B Ammendale Rd., Beltsville, MD 20705-1266.

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Dated: February 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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