Summary: This document contains corrections to the final regulations, which were published in the Federal Register of Wednesday, October 3, 2008 (73 FR 57515). The regulations relate to the obligation to file rate schedules, tariffs and certain service agreements and to the withdrawals and amendments of rate schedules, and tariff or service agreement filings. DATES: Effective on October 29, 2009.

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Office of Generic Drugs. This action is being taken to ensure accuracy and clarity in the agency’s regulations.

DATES: This rule is effective October 29, 2009.


SUPPLEMENTARY INFORMATION: FDA is amending its regulations in part 312 (21 CFR part 312) to clarify where ANDA applicants should submit INDs for in vivo bioavailability and bioequivalence studies in humans. This document adds the address for the Office of Generic Drugs in § 312.140(a)(1).

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 add an address for the submission of INDs related to ANDAs.

List of Subjects in 21 CFR Part 312

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:


2. Section 312.140 is amended by revising 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; except send an IND submission for an in vivo bioavailability or bioequivalence study in humans to support an abbreviated new drug application to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Pl., Rockville, MD 20855.

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