DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. FDA–2010–N–0010]

Change of Address; 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 regulations to update the address for applicants to submit abbreviated new drug applications (ANDAs) and ANDA amendments, supplements, and resubmissions. FDA is also updating the address for ANDA applicants to submit INDs for in vivo bioavailability and bioequivalence studies that are intended to support ANDAs. 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 an address for the submission of ANDAs; ANDA amendments, supplements, and resubmissions; and INDs related to ANDAs.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

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


§312.140 [Amended]

2. Section 312.140 is amended in paragraph (a)(1) by removing “II, 7500” and adding in its place “VII, 7620”.

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

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


§314.440 [Amended]

4. Section 314.440 is amended in the first sentence of paragraph (a)(2) by removing “II, 7500” and adding in its place “VII, 7620”.


Leslie Kux, Acting Assistant Commissioner for Policy.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–305F]

RIN 1117–AB16

Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final Rule.

SUMMARY: The Drug Enforcement Administration (DEA) is designating the precursor chemical, 4-anilino-N-phenethyl-4-piperidine (ANPP) as an immediate precursor for the schedule II controlled substance fentanyl under the definition set forth in 21 U.S.C. 802(23). Furthermore, DEA is finalizing the control of ANPP as a schedule II substance under the Controlled Substances Act (CSA), pursuant to the authority in 21 U.S.C. 811(e), which states that an immediate precursor may be placed in the same schedule as the controlled substance it produces, without regard to the procedures required by 21 U.S.C. 811(a) and (b) and without regard to the findings required by 21 U.S.C. 811(a) and 812(b).

ANPP is the immediate chemical intermediary in the synthesis process currently used by clandestine laboratory operators for the illicit manufacture of the schedule II controlled substance fentanyl. In 2005 and 2006, the distribution of illicitly manufactured fentanyl caused an unprecedented outbreak of hundreds of fentanyl-related