

signed August 27, 2009, and effective September 15, 2009 is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

\* \* \* \* \*

**ANM WA, ES Kelso, WA [Modified]**

Southwest Washington Regional Airport, WA  
(Lat. 46°07'05" N., long. 122°53'54" W.)

\* \* \* \* \*

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Southwest Washington Regional Airport, and 2.4 miles each side of the 290° bearing of the airport extending 9.1 miles west, and 4.3 miles each side of the 337° bearing of the airport extending 22.2 miles northwest, and 5.8 miles west and 3 miles east of the 012° bearing of the airport extending 18.2 miles north of the airport.

Issued in Seattle, Washington, on June 14, 2010.

**Kevin Nolan,**

*Acting Manager, Operations Support Group,  
Western Service Center.*

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**BILLING CODE 4910-13-M**

**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 investigational new drug applications (INDs) for in vivo bioavailability and bioequivalence studies in humans that are intended to support ANDAs. This action is being taken to ensure accuracy and clarity in the agency's regulations.

**DATES:** This rule is effective August 1, 2010.

**FOR FURTHER INFORMATION CONTACT:** Martin Shimer, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl.,

MPN II, Rockville, MD 20855, 240-276-8675.

**SUPPLEMENTARY INFORMATION:** FDA is amending 21 CFR 314.440(a)(2) to update the address for applicants to submit ANDAs and ANDA amendments, supplements, and resubmissions. FDA is also amending 21 CFR 312.140(a)(1) to update the address for ANDA applicants to submit INDs for in vivo bioavailability and bioequivalence studies that are intended to support ANDAs. The new address for all these submissions is Office of Generic Drugs (HFD-600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North VII, 7620 Standish Pl., Rockville, MD 20855. 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.

**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 21 CFR 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.

**§ 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:

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

**§ 314.440 [Amended]**

■ 4. Section 314.440 is amended in the first sentence of paragraph (a)(2) by removing "II, 7500 Standish Place., rm. 150" and adding in its place "VII, 7620 Standish Pl."

Dated: June 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**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