

Dated: July 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-19300 Filed 7-30-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 211, 226, 510, and 514

[Docket No. 88N-0038]

RIN 0910-AA02

#### Records and Reports Concerning Experience With Approved New Animal Drugs; Delay of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Interim final rule; delay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is delaying the effective date of an interim final rule entitled "Records and Reports Concerning Experience With Approved New Animal Drugs," published in the *Federal Register* of February 4, 2002 (67 FR 5046). The interim final rule amended FDA's regulations for records and reports concerning experience with approved new animal drugs, with an effective date of August 5, 2002. FDA is delaying the effective date so it can submit and seek approval on the information collection provisions of the rule under the Paperwork Reduction Act of 1995 and address comments received on the interim final rule.

**DATES:** The effective date published at 67 FR 5046, February 4, 2002, is delayed indefinitely. FDA will announce in the *Federal Register* an effective date.

**FOR FURTHER INFORMATION CONTACT:** Glenn Peterson, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0224, or gpeterso@cvm.fda.gov.

Dated: July 25, 2002.

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[FR Doc. 02-19299 Filed 7-30-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Parts 1310, 1313

[DEA-229F]

RIN 1117-AA65

#### Change of Address for Filing Chemical Import/Export Declarations (DEA Form 486), Reports for the Importation or Exportation of Tableting and Encapsulating Machines, and Other Related Reports

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Final rule.

**SUMMARY:** DEA is amending the Code of Federal Regulations (CFR) to change the address for filing certain required reports. These reports include: Import/Export Declarations, including international transactions, for listed chemicals (DEA Form 486); Reports for the importation or exportation of tableting and encapsulating machines (not a DEA Form-486); Quarterly reports on the importation or exportation of listed chemicals when the DEA Form 486 is waived; Reports for the return of exported listed chemicals or exported tableting and encapsulating machines; and Advance notices of importation for transshipment or transfer of listed chemicals. DEA is changing the address in the CFR because the U.S. Postal Service assigned DEA a new post office box when the post office was relocated. **EFFECTIVE DATE:** July 31, 2002.

**FOR FURTHER INFORMATION CONTACT:** Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

#### SUPPLEMENTARY INFORMATION:

#### Why Is DEA Changing the Address for Filing Certain Reports?

The U.S. Postal Service has assigned DEA a new post office box number that replaces the one listed in the Code of Federal Regulations for filing certain required reports. This occurred when the U.S. Postal Service relocated the post office. DEA does not have any discretion concerning this change.

#### What Is the New Address?

DEA is revising Title 21, Code of Federal Regulations, wherever it mentions: P.O. Box 28346, Washington, DC 20038.

The new address for filing the affected reports is: P.O. Box 27284, Washington, DC 20038.

With publication of this rule, all reports must be sent to the new address.

#### What Reports Are Affected?

Title 21 of the Code of Federal Regulations requires that certain reports for listed chemicals and tableting and encapsulating machines must currently be filed with the Drug Enforcement Administration at the old address (P.O. Box 28346). The reporting requirements are described in 21 CFR parts 1310 and 1313.

In 21 CFR part 1310, reports affected by the address change include those for the importation and exportation of tableting and encapsulating machines (21 CFR 1310.05(c)) and reports concerning the return of exported tableting or encapsulating machines (21 CFR 1310.06(g)).

In 21 CFR part 1313, the following reports are affected by the address change:

(1) DEA Form 486 for authorization to import listed chemicals (21 CFR 1313.12(b));

(2) Quarterly reports on importations of listed chemicals when the advance notification is waived and no DEA Form 486 is required (21 CFR 1313.12(e));

(3) DEA Form 486 for authorization to export listed chemicals (DEA 1313.21(b));

(4) Quarterly reports on exportation of listed chemicals when the advance notification is waived and no DEA Form 486 is required (21 CFR 1313.21(e));

(5) Reports concerning the return of exported listed chemicals (21 CFR 1313.22(e));

(6) Advance notices of importation for transshipment or transfer of listed chemicals (21 CFR 1313.31(b)); and

(7) DEA Form 486s from brokers or traders for authorization of international transactions of listed chemicals (21 CFR 1313.32(b)(1)).

#### Regulatory Certifications

*Administrative Procedure Act (5 U.S.C. 553)*

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. This rule pertains to agency management, organization and procedure. DEA has no discretion in the change of the post office box number and thus finds it unnecessary and impracticable to permit public notice and comment. Therefore, DEA is publishing this document as a final rule.