

alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal

Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 22, 2005.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.436 is amended by removing the commodity potato from the table in paragraph (a); by alphabetically adding new commodities to the table in paragraph (a); and by adding paragraph (c) to read as follows:

#### § 180.436 Cyfluthrin; tolerances for residues.

(a) \* \* \*

| Commodity  | Parts per million |
|--|-------------------|
| Almond, hulls .....  | 0.5               |
| Brassica, leafy greens, subgroup 5B .....                      | 7.0               |
| Fruit, pome, group 11 .....                                    | 0.5               |
| Fruit, stone, group 12 .....                                   | 0.3               |
| Grape .....  | 1.0               |
| Grape, raisin .....  | 3.5               |
| Nut, tree, group 14 .....                                      | 0.01              |
| Pea and bean, dried shelled, except soybean, subgroup 6C ..... | 0.15              |
| Peanut .....   | 0.01              |
| Peanut, hay .....  | 6.0               |
| Pistachio .....  | 0.01              |
| Turnips, greens .....  | 7.0               |
| Vegetable, cucurbit, group 9 .....                             | 0.1               |
| Vegetable, fruiting, group 8 .....                             | 0.5               |
| Vegetable, leafy greens, except Brassica, group 4 .....        | 6.0               |
| Vegetable, tuberous and corm, subgroup 1C .....                | 0.01              |
| Wheat, forage .....  | 5.0               |
| Wheat, hay .....   | 6.0               |
| Wheat, straw .....   | 6.0               |

\* \* \* \* \*

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of cyfluthrin in or on the following raw agricultural commodities:

| Commodity           | Parts per million |
|---------------------|-------------------|
| Grass, forage ..... | 6.0               |
| Grass, hay .....    | 8.0               |

\* \* \* \* \*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Office of the Secretary

##### Office of Inspector General

#### 45 CFR Part 61

RIN 0906-AA46

#### Health Care Fraud and Abuse Data Collection Program: Reporting of Final Adverse Actions; Correction

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Correction amendment.

**SUMMARY:** This document corrects the final regulations establishing the Healthcare Integrity and Protection Data Bank (HIPDB), the national health care fraud and abuse data collection program for the reporting and disclosing of certain adverse actions taken against health care providers, suppliers and practitioners and for maintaining a data base of final adverse actions taken against health care providers, suppliers and practitioners. In the implementing HIPDB regulations published in the **Federal Register** on October 26, 1999 (64 FR 57740), an inadvertent error appeared in the regulations text concerning the definition of the term

“any other negative action or finding.” As a result, we are correcting the definition of the term to assure the technical correctness of these regulations.

**EFFECTIVE DATE:** September 13, 2005.

**FOR FURTHER INFORMATION CONTACT:** Joel Schaer, OIG Regulations Officer, Office of External Affairs, (202) 619-0089.

**SUPPLEMENTARY INFORMATION:** On October 26, 1999, the HHS Office of Inspector General (OIG) issued final regulations (64 FR 57740) that established a national health care fraud and abuse data collection program—the Healthcare Integrity and Protection Data Bank (HIPDB)—for the reporting and disclosing of certain final adverse actions taken against health care providers, suppliers and practitioners, and for maintaining a data base of final adverse actions taken against health care providers, suppliers and practitioners. The final rule established a new 45 CFR part 61 to implement the requirements for reporting of specific data elements to, and procedures for obtaining information from, the HIPDB. In that final rule, an inadvertent error appeared in § 61.3—the definitions section of the regulations—and is now being corrected.

Specifically, § 61.3 expanded on previous regulatory definitions and provided additional examples of the scope of various terms set forth in the statute. On page 57755 of the preamble, summarizing the various revisions being made to the final rule, we indicated that with respect to the definition for the term “any other negative action or finding” there are certain kinds of actions or findings that would not meet the intent of the statute and *not* be reportable. We cited, as an example, administrative actions, such as limited training permits, limited licenses for telemedicine, fines or citations that do not restrict a practitioner’s practice, or personnel actions for tardiness, that were *not* within the range of actions intended by the statute. As a result, we agreed to add a clarifying phrase to this term. The revised definition would exclude administrative fines or citations, corrective action plans and other personnel actions, unless they are (1) connected to the billing, provision or delivery of health care services, and (2) taken in conjunction with other licensure or certification actions such as revocation, suspension, censure, reprimand, probation, or surrender. However, we inadvertently omitted this clarifying language to the regulations text of the rule itself. Therefore, to be consistent with the intended clarification and the overall intent of the

final rulemaking, we proposed correcting this inadvertent error in the definition of the term “any other negative action or finding” that appeared on page 57759 in the October 26, 1999 final regulations to include this additional clarifying language.

#### **Proposed Correction Notice and Response to Comments**

On June 24, 2005, OIG published a proposed notice (70 FR 36554) setting forth the intended correction to the definition of the term “any other negative action or finding” in 45 CFR 61.3, and soliciting public comments regarding our intent to clarify the existing definition of the term in accordance with the earlier final rulemaking.

As a result of that proposed correction amendment, OIG received two comments. While one commenter fully supported our decision to include the clarifying language to ensure technical correctness of the regulations, a second commenter mistakenly interpreted the clarifying language as narrowing the regulatory exceptions and was concerned that the amendatory language would result in States having to report a large number of relatively minor corrective action plan actions that could unfairly prejudice the party about whom or which the report was made. In response to the second commenter’s concern, we reiterate that a corrective action plan independent of an adverse licensing action is *not* reportable. Only corrective action plans submitted in conjunction with a specific adverse licensing action would be required to be reported on a single form report. (The HIPDB report form includes a narrative description section that is to be used by the reporting entity to describe the details of the action. This section of the report requires the reporter to provide details about why the action was taken, as well as other pertinent details, which may include a corrective action plan or other remedial steps such as citations or personnel actions.) This clarifying language does not result in any additional reporting requirements on behalf of the reporting entity.

#### **List of Subjects in 45 CFR Part 61**

Billing and transportation services, Durable medical equipment suppliers and manufacturers, Health care insurers, Health maintenance organizations, Health professions, Home health care agencies, Hospitals, Penalties, Pharmaceutical suppliers and manufacturers, Privacy, Reporting and recordkeeping requirements, Skilled nursing facilities.

■ Accordingly, 45 CFR part 61 is amended by making the following correcting amendment:

#### **PART 61—HEALTHCARE INTEGRITY AND PROTECTION DATA BANK FOR FINAL ADVERSE INFORMATION ON HEALTH CARE PROVIDERS, SUPPLIERS AND PRACTITIONERS**

■ 1. The authority citation for part 61 continues to read as follows:

**Authority:** 42 U.S.C. 1320a-7e.

■ 2. Section 61.3 is amended by republishing the introductory text, and by revising the definition for the term “Any other negative action or finding” to read as follows:

#### **§ 61.3 Definitions.**

The following definitions apply to this part:

\* \* \* \* \*

*Any other negative action or finding* by a Federal or State licensing agency means any action or finding that under the State’s law is publicly available information, and rendered by a licensing or certification authority, including but not limited to, limitations on the scope of practice, liquidations, injunctions and forfeitures. This definition also includes final adverse actions rendered by a Federal or State licensing or certification authority, such as exclusions, revocations or suspension of license or certification that occur in conjunction with settlements in which no finding of liability has been made (although such a settlement itself is not reportable under the statute). This definition excludes administrative fines or citations and corrective action plans and other personnel actions, unless they are:

(1) Connected to the delivery of health care services, and

(2) Taken in conjunction with other licensure or certification actions such as revocation, suspension, censure, reprimand, probation or surrender.

\* \* \* \* \*

Dated: September 2, 2005.

**Ann C. Agnew,**

*Executive Secretary to the Department.*

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