

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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Certifier D. Hawkins

[Docket No. 2002N-0277]

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final regulation that appeared in the **Federal Register** of December 9, 2004 (69 FR 71562). The document issued a final regulation that requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records allow for the identification of the immediate previous sources and immediate subsequent recipients of food. The document was published with some errors. This document corrects those errors.

DATES: This rule is effective February 7, 2005.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1400.

SUPPLEMENTARY INFORMATION: In FR Doc. 04-26929, appearing on page 71562 in the **Federal Register** of Thursday, December 9, 2004, the following corrections are made to the **SUPPLEMENTARY INFORMATION:**

1. On page 71562, in the first column, under **DATES** after “Compliance Dates” the phrase “except that for small businesses employing fewer than 500, but more than 10 full-time equivalent employees, the compliance date is June 9, 2005;” is corrected to read “except that for small businesses employing fewer than 500, but more than 10 full-time equivalent employees, the compliance date is June 9, 2006;”.

2. On page 71564, in the second column, the sixth bullet, beginning in the 4th line, the phrase “except that the compliance date for small businesses employing fewer than 500, but more than 10 full-time equivalent employees is June 9, 2005,” is corrected to read “except that the compliance date for small businesses employing fewer than 500, but more than 10 full-time equivalent employees is June 9, 2006;”.

3. On page 71565, in the second column, the last bullet, second sentence, the sentence “Small businesses have June 9, 2005, of this final rule to come into compliance with these regulations, and very small businesses have December 11, 2006, of this final rule to come into compliance with these regulations.” is corrected to read “Small businesses have until June 9, 2006, to come into compliance with these regulations, and very small businesses have until December 11, 2006, to come into compliance with these regulations.”

4. On page 71609, in the third column, in the 1st complete paragraph, the sentences “Section 1.368 of the final rule requires large businesses (500 or more full-time equivalent employees) to be in compliance within December 9, 2005. Small businesses (those with fewer than 500, but more than 10 full-time equivalent employees) must be in compliance within June 9, 2005, and very small businesses that employ 10 or fewer full-time equivalent employees

must be in compliance within December 11, 2006.” are corrected to read “Section 1.368 of the final rule requires large businesses (500 or more full-time equivalent employees) to be in compliance by December 9, 2005. Small businesses (those with fewer than 500, but more than 10 full-time equivalent employees) must be in compliance by June 9, 2006, and very small businesses that employ 10 or fewer full-time equivalent employees must be in compliance by December 11, 2006.”

5. On page 71627, in the third column, beginning in the 12th line from the bottom, the sentence “For example, from CA, LA, and TX alone, DOT reports over 12 percent of intrastate truck tonnage is from FDA-regulated products (ref. 18).” is corrected to read “For example, for California in 1997, DOT reports 12.8 percent of revenue from specialized freight transportation is for intrastate traffic in agricultural products (ref. 18).”

6. On page 71651, in the first column, in Reference 18, the phrase “U.S. Department of Transportation, available at <http://www.transtats.bts.gov>, accessed on April 6, 2004.” is corrected to read “1997 Economic Census, Transportation and Warehousing, Geographic Area Series, California 1997, issued January 2000, U.S. Department of Commerce.”

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

■ Therefore, 21 CFR part 1 is corrected by making the following correcting amendments:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 8. In § 1.363, revise paragraph (b) to read as follows:

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

* * * * *

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(e) to establish, maintain, or establish and maintain, records required under § 1.352(a), (b), (c), or (d), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the act.

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■ 9. In § 1.368, revise paragraph (a) to read as follows:

§ 1.368 What are the compliance dates for this subpart?

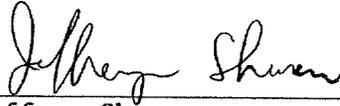
* * * * *

(a) The compliance date for the requirements in this subpart is June 9,

2006, for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

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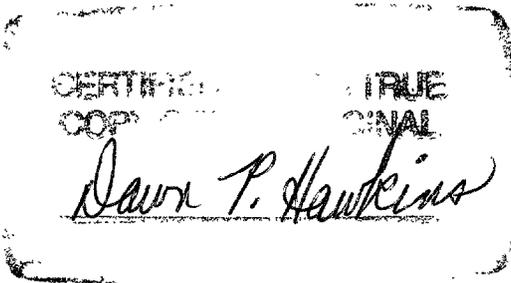
Dated: 2/16/05
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Jeffrey Shuren,
Assistant Commissioner for Policy.

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