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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

Docket No. CDC-2012-0003

RIN 0920-AA47

**Establishment of User Fees for Filovirus Testing of Nonhuman
Primate Liver Samples**

AGENCY: Centers for Disease Control and Prevention (HHS/CDC),
Department of Health and Human Services (HHS).

ACTION: Correcting amendment.

SUMMARY: On February 10, 2012, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS) published a Direct Final Rule (DFR) that solicited public comment on the establishment of user fees for filovirus testing of all nonhuman primates that die during the HHS/CDC-required 31-day quarantine period for any reason other than trauma. That document incorrectly listed the effective date as March 12, 2012. On February 10, 2012, HHS/CDC also published in the Federal Register a companion Notice of Proposed Rulemaking (NPRM) (77 FR

7109) that proposed identical filovirus testing and user fee requirements. In both the DFR and NPRM, HHS/CDC indicated that if it did not receive any significant adverse comments by April 10, 2012, it would publish a document in the **Federal Register** withdrawing the NPRM and confirming the effective date of the DFR within 30 days after the end of the comment period.

Because of the error in effective date the DFR took effect prior to the expiration of the comment period. Because of this error and due to receiving significant adverse public comments, HHS/CDC is amending 42 CFR 71.53 by removing paragraph (j) which will have the same effect as the withdrawal of the DFR. HHS/CDC will carefully review the comments received on the notice of proposed rulemaking published on February 10, 2012.

DATES: This action is effective [Insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: For questions concerning this document: Ashley A. Marrone, JD, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop E-03, Atlanta, Georgia 30333; telephone 404-498-1600. For information concerning program operations: Dr. Robert Mullan, Centers for Disease Control

and Prevention, 1600 Clifton Road, N.E., Mailstop E-03, Atlanta, Georgia 30333; telephone 404-498-1600.

SUPPLEMENTARY INFORMATION:

On February 10, 2012 HHS/CDC published a Direct Final Rule (DFR) (77 FR 6971) amending 42 CFR 71.53 by adding a new paragraph (j) to establish a user fee for filovirus testing of nonhuman primates. HHS/CDC took this action because (1) testing is no longer being offered by the only private, commercial laboratory that previously performed these tests and (2) we believed that these requirements were non-controversial and unlikely to generate significant adverse comment. The DFR incorrectly listed the effective date as March 12, 2012. On February 10, 2012, HHS/CDC also published a companion Notice of Proposed Rulemaking (NPRM) (77 FR 7109) that proposed identical filovirus testing and user fee requirements in the Federal Register. In both the DFR and NPRM, HHS/CDC indicated that if it did not receive any significant adverse comments by April 10, 2012, it would publish a document in the **Federal Register** withdrawing the notice of proposed rulemaking and confirming the effective date of the direct final rule within 30 days after the end of the comment period. Because of the error in effective date the DFR took effect prior to the expiration of the comment period.

HHS/CDC is now amending 42 CFR 71.53 by removing paragraph (j) which will have the same effect as if HHS/CDC had withdrawn the DFR. HHS/CDC is taking this action because of the error in effective date and due to having received significant adverse public comments. HHS/CDC will carefully review the comments received on the notice of proposed rulemaking published on February 10, 2012.

List of Subjects in 42 CFR Part 71

Communicable diseases, Public health, Quarantine, Reporting and recordkeeping requirements, Testing, User fees.

Accordingly, 42 CFR part 71 is corrected by making the following correcting amendment:

PART 71 -FOREIGN QUARANTINE

1. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); section 361-369, PHS Act, as amended (42 U.S.C. 264-272); 31 U.S.C. 9701.

2. Effective [Insert date of publication in the Federal Register],
amend § 71.53 by removing paragraph (j).

Dated: June 6, 2012

Kathleen Sebelius

Secretary

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