These devices also do not include any device intended for use to select patient therapy, predict patient response to therapy, or to screen for disease as well as any device with a claim for a particular diagnosis, prognosis, monitoring, or risk assessment.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Premarket notification submissions must also include the following information:

(i) A detailed description of all probes included in the kit;

(ii) Purpose of each probe;

(iii) Probe molecular specificity;

(iv) Probe specificity;

(v) Probe limits;

(vi) Probe sensitivity;

(vii) Specification of required ancillary reagents, instrumentation, and equipment;

(viii) Specification of the specimen collection, processing, storage and slide preparation methods;

(ix) Specification of the assay procedure;

(x) Specification of control elements that are incorporated into the recommended testing procedures;

(xi) Specification of risk mitigation elements: Description of all additional procedures, methods, and practices incorporated into the directions for use that mitigate risks associated with testing;

(xii) Specification of the criteria for test result interpretation and reporting;

(xiii) Device analytical sensitivity data;

(xiv) Device analytical specificity data;

(xv) Device reference limit data;

(xvi) Device precision/reproducibility data;

(xvii) Device stability data to include:

(A) Real-time stability,

(B) Freeze-thaw stability,

(C) Transport and temperature stability,

(D) Post-hybridization signal stability,

(E) Photostability of probe, and

(xviii) Documentation that demonstrates the clinical validity of the device. The documentation must include data from clinical studies, a minimum of two peer-reviewed published literature references using the specific device seeking marketing clearance, or both. Documentation for the clinical studies and peer-reviewed published literature references cited must include the following elements:

(A) Documentation that the sponsor's probe was used in the literature reference,

(B) Number and type of specimens,

(C) Target population studied,

(D) Upper reference limit, and

(E) Range of positive probe results.

(2) Your § 809.10(b)(12) of this chapter compliant labeling must include a statement summarizing the data identified in paragraphs (b)(1)(xiii) through (xviii) of this section and a description of the studies supporting the information, including the pre-specified acceptance criteria for these performance studies, justification for the pre-specified acceptance criteria, and whether the pre-specified acceptance criteria were met.

(3) Your § 809.10 of this chapter compliant labeling must include:

(i) A warning that reads ''The assay results are intended to be interpreted only by a qualified pathologist or cytogeneticist.''

(ii) A warning that reads ''This device is not for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening.''

(iii) A warning that reads ''The use of this device for diagnosis, monitoring or risk assessment has not been established.''

Dated: August 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–20882 Filed 9–2–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 22

[Public Notice: 8858]

RIN 1400–AD47

Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates—Visa and Citizenship Services Fee Changes; Correction

AGENCY: Department of State.

ACTION: Interim final rule; correction.

SUMMARY: The Department of State published a **Federal Register** document on August 28, 2014, in Volume 79, No. 167, page 51247, amending the Schedule of Fees for Consular Services (Schedule) for certain nonimmigrant visa application processing fees, certain immigrant visa application processing and special visa services fees, and certain citizenship services fees. The document contained an incorrect effective date. This document corrects the document by changing the effective date that the new fees will go into effect from September 6, 2014 to September 12, 2014 and the date that comments must be received by from October 21, 2014 to October 26, 2014.

DATES: The interim rule published on August 28, 2014 (79 FR 51247), becomes effective September 12, 2104. Written comments must be received on or before October 26, 2014.

ADDRESSES: Interested parties may submit comments to the Department by any of the following methods:

- *Visit the Regulations.gov Web site at: http://www.regulations.gov* and search the RIN 1400–AD47 or docket number DOS–2014–0016.
- *Mail (paper, disk, or CD–ROM):* U.S. Department of State, Office of the Comptroller, Bureau of Consular Affairs (CA/C), SA–17 8th Floor, Washington, DC 20522–1707.
- *E-Mail: fees@state.gov.* You must include the RIN (1400–AD47) in the subject line of your message.
- All comments should include the commenter's name, the organization the commenter represents, if applicable, and the commenter's address. If the Department is unable to read your comment for any reason, and cannot contact you for clarification, the Department may not be able to consider your comment. After the conclusion of the comment period, the Department will publish a Final Rule (in which it will address relevant comments) as expeditiously as possible.

FOR FURTHER INFORMATION CONTACT: Celeste Scott, Special Assistant, Office of the Comptroller, Bureau of Consular Affairs, Department of State; phone: 202–485–6681, telefax: 202–485–6826; Email: *fees@state.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 2014, in Volume 79, No. 167, page 51247, in the **DATES** section of the document it states the dates the new fees become effective is September 6, 2014, and written comments must be received on or before October 21, 2014. The correct date new fees become effective is September 12, 2014, and written comments must be received on or before October 26, 2014.

Correction

In FR Doc 2014–20516, appearing on page 51247 in the **Federal Register** of August 28, 2014 (79 FR 51247), in the third column, the effective date and comment period end date are corrected in the **DATES** section of this document.

Dated: August 28, 2014.

Patrick Kennedy,

Under Secretary of State for Management, Department of State.

[FR Doc. 2014–21045 Filed 9–2–14; 8:45 am]

BILLING CODE 4710–06–P