

the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used.

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

(1) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use. This information must include testing to demonstrate accuracy of the temperature control mechanism.

(2) Performance testing must demonstrate the electromagnetic compatibility and electrical safety of the device.

(3) Software verification, validation, and hazard analysis must be performed.

(4) The patient contacting components of the device must be demonstrated to be biocompatible. Material names must be provided.

(5) Labeling must include the following:

(i) A statement describing the potential risk of developing scalp metastasis.

(ii) Information on the patient population and chemotherapeutic agents/regimen for which the device has been demonstrated to be effective.

(iii) A summary of the non-clinical and/or clinical testing pertinent to use of the device.

(iv) A summary of the device technical parameters, including temperature cooling range and duration of cooling.

(v) A summary of the device- and procedure-related adverse events pertinent to use of the device.

(vi) Information on how the device operates and the typical course of treatment.

(6) Patient labeling must be provided and must include:

(i) Relevant contraindications, warnings, precautions, and adverse effects/complications.

(ii) Information on how the device operates and the typical course of treatment.

(iii) Information on the patient population for which there is clinical evidence of effectiveness.

(iv) The potential risks and benefits associated with use of the device.

(v) Postoperative care instructions.

(vi) A statement describing the potential risk of developing scalp metastasis.

Dated: February 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02878 Filed 2–11–16; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice: 9439]

RIN 1400–AD17

Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended

AGENCY: Department of State.

ACTION: Interim final rule; correction.

SUMMARY: The Department of State published a **Federal Register** interim final rule on February 4, 2016, in Volume 81, No. 23, page 5906. The document contains an error in the Regulatory Findings. This document corrects the rule by replacing the text, “included elsewhere in this edition of the **Federal Register**” with “published in the **Federal Register** on February 8, 2016, 81 FR 6430.” There is also a correction in the **ADDRESSES** section, to provide the correct public notice number to find the rule to submit comments on www.regulations.gov.

DATES: This correction is effective on February 19, 2016. Written comments must be received on or before April 4, 2016.

FOR FURTHER INFORMATION CONTACT: Paul-Anthony L. Magadia, U.S. Department of State, Visa Services, Legislation and Regulations Division, Washington, DC 20006, 202–485–7641; email: magadiapl@state.gov.

SUPPLEMENTARY INFORMATION: The Department of State published an interim final rule on February 4, 2016 (81 FR 5906); this document corrects text in the **ADDRESSES** section and in the discussion of Executive Order 12866.

Correction

In the FR Doc 2016–02191, appearing on page 5906 in the **Federal Register** of February 4, 2016 (81 FR 5906):

1. In the second column of page 5906, third item under **ADDRESSES**, the term “XXXX” is corrected to read “9428.”

2. In the third column of page 5907, the first sentence of the discussion regarding “Executive Order 12866: Regulatory Review” is corrected to read: “The costs of this rulemaking are discussed in the companion DHS rule, RIN 1651–AB09, published in the **Federal Register** on February 8, 2016, 81 FR 6430.”

Dated: February 9, 2016.

David S. Newman,

Director of Legal Affairs, Visa Services, Bureau of Consular Affairs, U.S. Department of State.

[FR Doc. 2016–02962 Filed 2–11–16; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation’s regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in March 2016. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective March 1, 2016.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (Klion.Catherine@pbgc.gov), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC’s regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC’s Web site (<http://www.pbgc.gov>).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC’s historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.