

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2016-C-2767]

Listing of Color Additives Exempt From Certification; Calcium Carbonate; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of December 8, 2017, for the final rule that appeared in the **Federal Register** of November 7, 2017, and that amended the color additive regulations to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and inks used on the surface of chewing gum.

DATES: Effective date of final rule published in the **Federal Register** of November 7, 2017 (82 FR 51554) confirmed: December 8, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1071.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 7, 2017 (82 FR 51554), we amended the color additive regulations to add § 73.70, "Calcium carbonate," (21 CFR 73.70) to provide for the safe use of calcium carbonate to color soft and hard candies and mints, and in inks used on the surface of chewing gum, except that it may not be used to color chocolate for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), unless added color is authorized by such standards.

We gave interested persons until December 7, 2017, to file objections or requests for a hearing. We explained that to file an objection, among other things, persons must specify with particularity the provision(s) to which

they object. We also explained that if a person who properly submits an objection wants a hearing, he or she must specifically request a hearing and that failure to do so will constitute a waiver of the right to a hearing (82 FR 51554 at 51557).

We received two comments regarding our decision to amend the color additive regulations to provide for the safe use of calcium carbonate to color soft and hard candies and mints, and in inks used on the surface of chewing gum. Neither comment, however, specified with particularity the provision(s) of the regulation to which they objected nor specifically requested a hearing. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of November 7, 2017, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the November 7, 2017, final rule. Accordingly, the amendments issued thereby became effective December 8, 2017.

Dated: January 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Part 22

[Public Notice 9450]

RIN 1400-AD71

Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule finalizes the interim final rule published in the **Federal Register** on September 8, 2015. Specifically, the rule implemented changes to the Schedule of Fees for Consular Services ("Schedule") for certain passport and citizenship services fees. This rulemaking addresses public comments and adopts as final the changes to these fees.

DATES: In accordance with the Congressional Review Act, this rule is effective on April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Rob Schlicht, Office of the Comptroller, Bureau of Consular Affairs, Department of State; phone: 202-485-6685, telefax: 202-485-6826; email: fees@state.gov.

SUPPLEMENTARY INFORMATION: For the complete explanation of the background of this rule, including the rationale for the change, the authority of the Department of State ("Department") to make the fee changes in question, and an explanation of the study that produced the fee amounts, consult the prior public notices cited in the "Background" section below.

Background

The Department published an interim final rule in the **Federal Register**, 80 FR 53704, on September 8, 2015, amending sections of 22 CFR part 22. Specifically, the rule amended the Schedule of Fees for Consular Services and provided 60 days for comments from the public. During this 60-day comment period, 15 comments were received by mail, email, and through the submission process at [regulations.gov](http://www.regulations.gov).

This rule establishes the following fees for the categories below:

- Administrative Processing of Request for Certificate of Loss of Nationality (CLN) \$2,350
- Passport Book Application Fee (age 16 and older) from \$70 to \$50
- Passport Book Application Fee (under age 16) from \$40 to \$20
- Passport Security Surcharge from \$40 to \$60

The original publication of the interim final rule included an incorrect effective date of September 23, 2015, for the above changes in the Passport Book Application fees and Passport Security Surcharge. That date subsequently was corrected. See 80 FR 55242. The correct effective date is reflected herein; it is September 26, 2015.

Analysis of Comments

In the 60-day period since the publication of the interim final rule, 15 comments were received. Twelve of the comments were about the Administrative Processing of Request for CLN fee. The other three comments were about Executive Branch fees or U.S. citizenship.

Many of the comments suggested that the fee for Administrative Processing of Request for CLN creates a barrier to expatriation. Most asserted that the fee is excessive and that many individuals will be unable to pay it. However, one comment expressed support for

collecting the fee from those attempting to evade taxes. Several asked for clarification about the amount of the fee, including one comment seeking confirmation that the Department had not doubled the CLN fee. Two challenged the analysis of processing costs used to justify the fee. Several cited the Expatriation Act of 1868 or the Universal Declaration of Human Rights when asserting that expatriation is a constitutional or human right.

In collecting the CLN fee, the Department has not restricted or burdened the right of expatriation. Further, the fee is not punitive and is unrelated to the Foreign Account Tax Compliance Act (FATCA) mentioned in some comments, except to the extent that the Act caused an increase in consular workload that must be paid for by user fees. Rather, the fee is a cost-based user fee for consular services. Conforming to guidance from the Office of Management and Budget (OMB), federal agencies make every effort to ensure that each service provided to specific recipients is self-sustaining, charging fees that are sufficient to recover the full cost to the government. (See OMB Circular A-25, ¶ 6(a)(1), (a)(2)(a).) Because costs change from year to year, the Department conducts an annual update of the costs for providing consular services in the form of a Cost of Service Model (CoSM). In addition to enabling the government to recover costs, the study also helps the Department to avoid charging consumers more than the cost of the services they consume. The CoSM is an activity-based costing (ABC) model that the Department developed following guidance provided in Statement 4 of OMB's Statement of Federal Financial Accounting Standards, available at <http://www.fasab.gov/pdffiles/sffas-4.pdf>. Setting the fee at \$2,350 reflects the cost for the service as determined by the model. In sum, the Administrative Processing of Request for CLN fee is a "user charge," which reflects the full cost to the U.S. government of providing the service, as determined through analysis based on federal financial accounting standards.

The Department has not doubled the CLN fee. In the past, the Department collected a fee only from U.S. nationals (*i.e.*, U.S. citizens and non-citizen nationals) taking the oath of renunciation. The Department did not charge a fee for the service of documenting a non-renunciatory relinquishment, which it performed much less frequently. However, requests for documentation of relinquishment of nationality on the basis of a non-renunciatory relinquishment have

increased significantly in recent years, and the Department expects the number to remain at an elevated level in the future. The services performed for both individuals who renounce nationality and individuals who apply for documentation on the basis of a non-renunciation relinquishment are similar, requiring close and detailed case-by-case review of the factors involved. The fiscal year 2013 CoSM update demonstrated that both services are extremely costly. For these reasons, the \$2,350 fee now applies to relinquishments under 8 U.S.C. 1481(a)(1) to 8 U.S.C. 1481(a)(4) (and predecessor statutes) and to relinquishments by renunciation under 8 U.S.C. 1481(a)(5). With this change, the Department renamed the service "Administrative Processing of Request for Certificate of Loss of Nationality."

The right of expatriation is addressed in the Immigration and Nationality Act and the Universal Declaration of Human Rights. The CLN fee does not impinge on the right of expatriation. Rather, the fee reflects the resources necessary for the U.S. government to verify that all constitutional and other requirements for expatriation are satisfied in every case. As described in the interim final rule and in an earlier rule that raised the fee for taking the oath of renunciation to \$2,350 (80 FR 51464), expatriation for a U.S. national requires a thorough, serious, time-consuming process, in view of U.S. Supreme Court jurisprudence that declared unconstitutional an involuntary or forcible expatriation. In *Afroyim v. Rusk*, 387 U.S. 253 (1967) and *Vance v. Terrazas*, 444 U.S. 252 (1980), the Supreme Court ruled that expatriation requires the voluntary commission of an expatriating act with the intention or assent of the citizen to relinquish citizenship. It is therefore incumbent upon the Department to maintain and implement procedures that allow consular officers and other Department employees to ensure these requirements are satisfied in every expatriation case.

Several commenters requested information on the relinquishment process, *e.g.* payment options and documentation. Individuals desiring to relinquish their U.S. citizenship should consult travel.state.gov and may contact the appropriate U.S. embassy with any questions on the process. Embassy contact information can be found at usembassy.gov.

Conclusion

The Department adjusted the fees in light of the CoSM's findings that the U.S. government was not covering fully its costs for providing these consular

services. Pursuant to OMB guidance, the Department endeavors to recover the cost of providing services that benefit specific individuals, as opposed to the general public. See OMB Circular A-25, ¶ 6(a)(1), (a)(2)(a). For this reason, the Department has adjusted the Schedule of Fees.

Regulatory Findings

A. Administrative Procedure Act (APA)

The Department of State published this rule as an interim final rule on September 8, 2015, and provided 60 days for comment. 80 FR 53704. The rule will be effective 60 days after publication, in accordance with the APA.

B. Regulatory Flexibility Act/Executive Order 13272: Small Business

The Department of State has reviewed this rulemaking and certifies that this rule will not have a significant economic impact on a substantial number of small entities.

C. The Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4, 109 Stat. 48, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

D. The Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of the United States-based companies to compete with foreign-based companies in domestic and import markets.

E. Executive Orders 12866 and 13771

The Office of Management and Budget reviewed this rule, and determined it is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866. As this rule is not a significant regularly action, it is except from the requirements of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs." See OMB

Memorandum M–17–21, “Guidance Implementing Executive Order 13771” of April 5, 2017.

F. Executive Order 13563

The Department of State has considered this rule in light of Executive Order 13563 and affirms that this regulation is consistent with the guidance therein. G. Executive Orders 12372 and 13132: Federalism

*H. Executive Order 13175—
Consultation and Coordination With
Indian Tribal Governments*

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of section 5 of Executive Order 13175 do not apply to this rulemaking.

I. Paperwork Reduction Act

This rule does not impose or revise information collections subject to the provisions of the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

For a summary of the regulatory findings and analyses regarding this rulemaking, please refer to the findings and analyses published with the interim final rule, which can be found at 80 FR 53704, which are adopted herein. Section 22.1, Items 2.(a), 2.(b), and 2.(g) of this rule became effective September 26, 2015. Section 22.1, Item 8 became effective November 9, 2015. As noted above, the Department considered the comments submitted in response to the interim final rule and does not adopt them. Thus, the rule remains in effect.

List of Subjects in 22 CFR Part 22

Consular services, Fees, Passports and visas.

**PART 22—SCHEDULE OF FEES FOR
CONSULAR SERVICES—
DEPARTMENT OF STATE AND
FOREIGN SERVICE**

■ Accordingly, the interim final rule amending 22 CFR part 22, which was published in the **Federal Register**, 80 FR 53704, on September 8, 2015 is adopted as final without change.

Carl C. Risch,

*Assistant Secretary for Consular Affairs,
Department of State.*

[FR Doc. 2018–01850 Filed 1–30–18; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 22

[Public Notice 10027]

RIN 1400–AD81

**Schedule of Fees for Consular
Services, Department of State and
Overseas Embassies and
Consulates—Passport Services Fee
Changes**

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State implements an adjustment to the Schedule of Fees for Consular Services of the Department of State’s Bureau of Consular Affairs (“Schedule of Fees” or “Schedule”) to raise the execution fee for passport books and cards from \$25 to \$35. The Department is adjusting this fee in light of the findings of the most recently approved update to the Cost of Service Model to better align the fees for consular services with the costs of providing those services.

DATES: In accordance with the Congressional Review Act, this rule is effective on April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Rob Schlicht, Management Analyst, Office of the Comptroller, Bureau of Consular Affairs, Department of State; phone: 202–485–6685, telefax: 202–485–6826; email: fees@state.gov.

SUPPLEMENTARY INFORMATION:

Background

This rule makes a change to the Schedule of Fees for passport services (passport books and cards). The Department published a notice of proposed rulemaking (NPRM) on September 19, 2016 (81 FR 64088), with 60 days provided for public comment. This final rule addresses the relevant comments. Justification for this rulemaking can be found in the NPRM.

Analysis of Comments

The Department received 34 comments, of which 26 are addressed herein. The other eight were duplicates submitted to regulations.gov and fees@state.gov.

The majority of the comments were in favor of raising the fee from \$25 to \$35. Four were opposed to raising the fee and one comment referred to visa fees which are not addressed in this rulemaking.

A majority of the comments that were in favor of the fee increase cited increased overhead, with most mentioning staffing and postage as major costs. Other comments expressed

the view that the small increase in fee would not affect business or personal travel.

Two commenters who opposed the fee increase expressed concern that the fee would be a burden to some travelers. Although the Department is sympathetic to the impact the fee increase may have on the public, the fee increase reflects the result of an evaluation to determine the cost of the service provided so that the U.S. Government may recover the full cost of the service in accordance with 31 U.S.C. 9701 and guidance from the Office of Management and Budget (OMB). Federal agencies make every effort to ensure that fees for services are sufficient to recover the full cost to the government. (See OMB Circular A–25, ¶ 6(a)(1), (a)(2)(a).)

Two commenters stated that the government should work more efficiently rather than raise fees. The Department of State’s Bureau of Consular Affairs along with its partner acceptance facilities strive to optimize business functions to increase efficiency and effectively manage financial and capital resources funded by consular fees. There are approximately 7,400 acceptance facilities throughout the United States, including those at post offices and clerks of court. This fee is necessary to ensure that acceptance agents are compensated for the time and materials required to accept applications on behalf of the Department of State. The fee has remained the same for over nine years even though the cost of labor and material has increased during the same time period. In 2008, the Department lowered the execution fee for passport books from \$30 to \$25 based on costs at the time. The proposed \$10 increase to \$35, from the current fee of \$25, is in line with cost increases for both the Department and United States Postal Service during the past nine years.

In an effort to improve business practices, the Department publishes a guide that standardizes processes for acceptance facilities and provides annual training to ensure the processes are followed. Additionally, the Department conducts regular audits and inspections of the acceptance facilities to protect the integrity of the application process, prevent mis/malfeasance, and promote standardization and efficiency.

The revenue from retained consular fees fund CA’s domestic and overseas operations and consular-related programs. These operations protect the lives and serve the interests of United States citizens and strengthen U.S. border security.

One commenter stated that the amount of time and effort it takes to