

16. Section 107.240 *Notification requirements* is amended in paragraph (b) by removing the reference to “§ 5.115” and by adding in its place “§ 5.215”, and by removing the old emergency phone number “202-857-8400” and by adding in its place the new emergency phone number “301-443-1240”.

#### **§ 107.250 [Amended]**

17. Section 107.250 *Termination of an infant formula recall* is amended in the introductory paragraph by removing the reference to “§ 5.115” and by adding in its place “§ 5.215”.

### **PART 130—FOOD STANDARDS: GENERAL**

18. The authority citation for 21 CFR part 130 continues to read as follows:

**Authority:** 21 U.S.C. 321, 336, 341, 343, 371.

#### **§ 130.17 [Amended]**

19. Section 130.17 *Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity* is amended in paragraph (c) by removing the words “Chief, Food Standards Branch, Office of Food Labeling, Center for Food Safety and Applied Nutrition (HFS-158)” and by adding in their place “Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-822)”.

### **PART 146—CANNED FRUIT JUICES**

20. The authority citation for 21 CFR part 146 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 348, 371, 379e.

#### **§ 146.132 [Amended]**

21. Section 146.132 *Grapefruit juice* is amended in paragraph (a)(1) by removing the words “Association of Official Analytical Chemists International, 1111 N. 19th St., Suite 210, Arlington, VA 22209” and by adding in their place “AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504”.

### **PART 165—BEVERAGES**

22. The authority citation for 21 CFR part 165 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 343-1, 348, 349, 371, 379e.

#### **§ 165.110 [Amended]**

23. Section 165.110 *Bottled water* is amended as follows:

a. In paragraph (b)(2) by removing the words “American Public Health Association, 1015 15th St. NW., Washington, DC 20005” and by adding in their place “American Public Health Association, 800 I St. NW., Washington, DC 20001”;

b. In paragraph (b)(4)(i)(C) by removing the words “American Public Health Association, 1015 Fifteenth St. NW., Washington, DC 20005” and by adding in their place “American Public Health Association, 800 I St. NW., Washington, DC 20001”;

c. In paragraph (b)(4)(iii)(E) by removing the words “National Technical Information Service (NTIS), U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161” and by adding in their place “National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161”;

d. In paragraph (b)(4)(iii)(E)(1)(ii) by removing the words “National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161” and by adding in their place “National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161”;

e. In paragraph (b)(4)(iii)(E)(1)(i) by removing the words “NTIS, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161” and by adding in their place “National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161”.

### **PART 190—DIETARY SUPPLEMENTS**

24. The authority citation for 21 CFR part 190 continues to read as follows:

**Authority:** Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 342, 350b, 371).

#### **§ 190.6 [Amended]**

25. Section 190.6 *Requirement for premarket notification* is amended in paragraph (a) by removing the words “Office of Special Nutritionals (HFS-450)” and by adding in their place “Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)”.

Dated: March 27, 2001.

**Ann M. Witt,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 01-7980 Filed 3-29-01; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Parts 809 and 864**

**[Docket No. 97N-0135]**

#### **Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing; Delay of Effective Date**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled “Regulatory Review Plan,” published in the **Federal Register** on January 24, 2001 (66 FR 7702), this action temporarily delays for 60 days the effective date of the rule entitled “Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing,” published in the **Federal Register** on April 7, 2000 (65 FR 18230).

**DATES:** The effective date of the “Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing,” amending 21 CFR parts 809 and 864 published in the **Federal Register** on April 7, 2000 (65 FR 18230), is delayed for 60 days, from April 9, 2001, to a new effective date of June 8, 2001.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

**SUPPLEMENTARY INFORMATION:** The rule: (1) Reclassifies over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) and exempts them from premarket notification (510(k)) and current good manufacturing practice requirements; (2) designates OTC test sample collection systems for drugs of abuse testing as restricted devices under the Federal Food, Drug, and Cosmetic Act; and (3) establishes restrictions intended to assure consumers that: The underlying laboratory test(s) are accurate and reliable, the laboratory performing the test(s) has adequate expertise and competency, and the product has adequate labeling and

methods of communicating test results to consumers.

The agency's implementation of this delay of effective date without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The temporary 60-day delay in the effective date is necessary to give the Department of Health and Human Services officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2001, sent to all executive departments and agencies. Given the imminence of the effective date, seeking prior public comment on this temporary delay would have been impractical, as well as contrary to the public interest in the orderly issuance and implementation of regulations. The imminence of the effective date is also good cause for making this action effective immediately upon publication.

Dated: March 23, 2001.

**Ann M. Witt,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 01-7833 Filed 3-29-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF STATE

### 22 CFR Part 22

[Public Notice 3625]

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

**AGENCY:** Bureau of Consular Affairs, State Department.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Schedule of Fees for Consular Services. Specifically, it reduces to \$0 the current \$100 fee for determination or adjudication of citizenship for applicants born abroad who do not have previously issued U.S. Government documentary proof of citizenship. Because the fee does not accurately reflect the cost of the service, the Department is reducing the fee pending the next fee study.

**DATES:** Effective March 30, 2001.

**ADDRESSES:** Office of the Executive Director, Bureau of Consular Affairs, Department of State, SA-1, 10th Floor, 2401 E Street, NW., Washington, DC 20522-0111; fax (202) 663-2499.

#### **FOR FURTHER INFORMATION CONTACT:**

Susan Abeyta, Office of the Executive Director, Bureau of Consular Affairs, Department of State, SA-1, 10th Floor, 2401 E Street, NW., Washington, DC 20522-0111; telephone (202) 663-2500 telefax (202) 663-2499; e-mail address AbeytaSK@state.gov.

#### **SUPPLEMENTARY INFORMATION:**

This amendment to the Schedule of Fees is published as a final rule because it will not have adverse impact on the public and because it is important to have a final rule in place as close in time as possible to the February 27, 2001 effective date of the Child Citizenship Act of 2000 (CCA), Public Law 106-395. The Department is reducing to \$0 the current \$100 fee for adjudication of citizenship cases for persons born abroad who have no prior documentation of their U.S. citizenship. This fee is applicable when a U.S. citizen born abroad applying for a passport cannot present a previous passport, a Consular Report of Birth Abroad, a Certificate of Nationality or a Certificate of Citizenship. The \$100 fee reflected the fact that such persons typically are seeking to establish U.S. citizenship long after their birth; as a result, adjudication of their cases is relatively time consuming. At the time of the cost study underlying the fee, the Department estimated that a fee of \$100 would ensure full cost recovery, allocate the cost to the actual users, and be consistent with the fee established by the Immigration and Naturalization Service for its comparable service, thus removing any cost-based incentive for applicants to file with one agency over the other. See 62 FR 63478, 63479-80 (Dec. 1, 1997).

The Department has decided to reduce the fee to \$0 pending the next fee study for a number of reasons. In practice, the amount of time required by the category of cases varies so greatly that the fee seems excessive in some cases that in fact require little time to adjudicate, while in others it is far below cost recovery. While the \$100 fee was intended to average the costs involved over all users of the particular service, the Department wishes to revisit this approach in light of the wide variation in time required for cases covered by the fee. Also, the number of cases to which the fee applies has been relatively small, so that discontinuing the fee will not have a significant impact on fee revenues. In addition, the Child Citizenship Act of 2000 has created a new class of persons who will be seeking citizenship documentation service and who would be required to pay the \$100 fee if it were maintained.

The Department believes it best to cease collecting the fee until the cost of this service can be reviewed again.

The Department notes that it is in the process of examining its fees in a number of areas, and that subsequent revisions to the fee schedule may result in the restoration of this fee at an appropriate level or the allocation of the cost of this service to other services to ensure appropriate cost recovery. (Prior to the 1998 amendments to the schedule of fees, the cost of this service was allocated to the passport fee.)

#### *Comment Period and Effective Date—Exceptions*

This rule is being promulgated as a final rule without prior notice and comment, and will take effect in less than 30 days after publication. The Department has determined that the rule is exempt from the advance notice and comment procedures of the Administrative Procedures Act under 5 U.S.C. 553(b)(3)(B) (the "good cause" exception to notice and comment and 553(d)(3) (the good cause exception to delayed effective date). The rule reduces a consular fee from \$100 to zero and hence will benefit the public without causing any related adverse impact. Moreover, it is important to have a final rule in place as close in time as possible to the February 27, 2001 effective date of the Child Citizenship Act of 2000 (CCA), Public Law 106-395.

This fee is established under the user charge statutes, 31 U.S.C. 9701 and 22 U.S.C. 4219, which authorizes the President (who delegated his authority to the Secretary of State in Executive Order 10718 of June 27, 1957), to prescribe the fees to be charged for official services performed by U.S. embassies and consulates. Within the Department, these authorities are delegated to the Under Secretary for Management. There is no one in that position at present, but the Under Secretary's authorities have been delegated by the Secretary to the Assistant Secretary for Diplomatic Security until an Under Secretary for Management is appointed.

The Schedule of Fees for Consular Services is set forth in 22 CFR 22.1, as most recently amended on September 7, 2000 (64 FR 54297).

#### **Regulatory Findings**

##### *Administrative Procedure Act*

The Department is publishing this rule as a final rule for the reasons set forth above. The rule makes no substantive regulatory changes.