

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 2. Section 310.545 is amended by revising paragraph (d)(3) to read as follows:

**§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.**

\* \* \* \* \*

(d) \* \* \*

(3) December 4, 1992, for products subject to paragraph (a)(7) of this section that contain menthol as an antipruritic in combination with the antidandruff ingredient coal tar identified in § 358.710(a)(1) of this chapter. This section does not apply to products allowed by § 358.720(b) of this chapter after April 5, 2007.

**PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

■ 3. The authority citation for 21 CFR part 358 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 4. Section 358.720 is revised to read as follows:

**§ 358.720 Permitted combinations of active ingredients.**

(a) *Combination of active ingredients for the control of dandruff.* Salicylic acid identified in § 358.710(a)(4) may be combined with sulfur identified in § 358.710(a)(7) provided each ingredient is present within the established concentration and the product is labeled according to § 358.750.

(b) *Combination of control of dandruff and external analgesic active ingredients.* Coal tar identified in § 358.710(a)(1) may be used at a concentration of 1.8 percent coal tar solution, on a weight to volume basis, in combination with menthol, 1.5 percent, in a shampoo formulation provided the product is labeled according to § 358.760.

■ 5. New § 358.760 is added to read as follows:

**§ 358.760 Labeling of permitted combinations of active ingredients for the control of dandruff.**

The statement of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an

established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(1) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The label states “dandruff/anti-itch shampoo” or “antidandruff/anti-itch shampoo”.

(2) [Reserved]

(b) *Indications.* The labeling of the product states, under the heading “Uses,” one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The labeling states “[bullet] [select one of the following: ‘for relief of’ or ‘controls’] the symptoms of dandruff [bullet] [select one of the following: ‘additional’ or ‘extra’] relief of itching due to dandruff”.

(2) The following terms or phrases may be used in place of or in addition to the words “for the relief of” or “controls” in the indications in paragraph (b)(1) of this section: “fights,” “reduces,” “helps eliminate,” “helps stop,” “controls recurrence of,” “fights recurrence of,” “helps prevent recurrence of,” “reduces recurrence of,” “helps eliminate recurrence of,” “helps stop recurrence of.”

(3) The following terms may be used in place of the words “the symptoms of” in the indication in paragraph (b)(1) of this section: “scalp” (select one or more of the following: “itching,” “irritation,” “redness,” “flaking,” “scaling”) “associated with”.

(c) *Warnings.* The labeling of the product states, under the heading “Warnings,” the warning(s) listed in § 358.750(c)(1) and (c)(2).

(d) *Directions.* The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs,

unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The labeling states “[bullet] wet hair [bullet] apply shampoo and work into a lather [bullet] rinse thoroughly [bullet] for best results, use at least twice a week or as directed by a doctor”.

(2) [Reserved]

Dated: February 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF STATE**

**22 CFR Part 99**

[Public Notice 5705]

RIN 1400–AC–20

**Intercountry Adoption—Reporting on Non-Convention and Convention Adoptions of Emigrating Children**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State (the Department), with the joint review and approval of the Department of Homeland Security (DHS), is issuing a new rule to implement the requirement in the Intercountry Adoption Act of 2000 (the IAA) to establish a Case Registry for, *inter alia*, emigrating children. This final rule imposes reporting requirements on adoption service providers, including governmental authorities who provide adoption services, in cases involving adoptions of children who will emigrate from the United States. These reporting obligations apply to all intercountry adoptions, regardless of whether they are covered under the 1993 Hague Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption (the Convention). This final rule, although issued with the joint review and approval of DHS pursuant to section 303(d) of the IAA, only adds a new section to the

Department's Convention regulations; no amendments or additions are made to DHS regulations.

**DATES:** This rule is effective April 5, 2007. Information about the date the Convention will enter into force with respect to the United States is provided in 22 CFR 96.17.

**FOR FURTHER INFORMATION CONTACT:** Anna Mary Coburn at 202-736-9081. Hearing- or speech-impaired persons may use the Telecommunications Devices for the Deaf (TDD) by contacting the Federal Information Relay Service at 1-800-877-8339.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Introduction**

The Convention is a multilateral treaty that provides a framework for the adoption of children habitually resident in one country that is a party to the Convention by persons habitually resident in another country that is also a party to the Convention. The Convention establishes procedures to be followed in these intercountry adoption cases and imposes safeguards to protect the best interests of children. When the Convention enters into force with respect to the United States, it will apply to the United States as both a country of origin (outgoing cases, i.e., where children are emigrating from the United States to a foreign country) and a receiving country (incoming cases, i.e., where children are immigrating to the United States from a foreign country).

The implementing legislation for the Convention is the IAA. The IAA requires the Department and DHS to establish a Case Registry to track all intercountry adoption cases: Convention and non-Convention; emigrating and immigrating cases. The Department is, with the joint review and approval of DHS, promulgating this final rule to require adoption service providers that provide adoption services in intercountry adoption cases involving a child emigrating from the United States (including governmental authorities who provide such adoption services) to report certain information to the Department for incorporation into the Case Registry.

### **II. The Final Rule**

The Department issued a proposed rule for public comment (See Proposed Rule on Intercountry Adoption—Reporting on Non-Convention and Convention Adoptions of Emigrating Children, 71 FR 54001-54005, September 13, 2006). No public comments were received. The Department is now issuing the final rule as it was proposed. No changes have

been made to the text of the rule, except that the Department has made certain technical clarifications, including changing the § 99.2 heading and § 99.2(d)(1) to correct any misimpression that the rule applies only to U.S. national children and changing § 99.2(a) to clarify that the reporting requirements do not take effect until the Convention has entered into force for the United States.

### **III. Regulatory Review**

#### *A. Administrative Procedure Act*

In accordance with provisions of the Administrative Procedure Act governing rules promulgated by Federal agencies that affect the public (5 U.S.C. 533), the Department published this rule for public comment.

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

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601-612 and Executive Order 13272, section 3(b), the Department of State has evaluated the effects of this action on small entities, and has determined, and hereby certifies, pursuant to 5 U.S.C. 605(b), that it would not have a significant economic impact on a substantial number of small entities. Overall, the number of outgoing intercountry adoption cases is expected to be very small in comparison with the number of incoming cases. Consequently, very few ASPs that are small entities will also be involved in outgoing cases. Moreover, the rule requires only extremely limited reporting requirements for outgoing cases. Thus, the Department does not believe the economic impact on small entities will be significant. The Department received no public comments on the rule's impact on small entities.

#### *C. 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, Pub. L. 104-121. The rule would not result in an annual effect on the economy of \$100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### *D. The Unfunded Mandates Reform Act of 1995*

Section 202 of the Unfunded Mandates Reform Act of 1995 (UFMA), Pub. L. 104-4; 109 Stat. 48; 2 U.S.C. 1532, generally requires agencies to prepare a statement, including cost-benefit and other analyses, 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 the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year. Moreover, because this rule will not significantly or uniquely affect small governments, section 203 of the UFMA, 2 U.S.C. 1533, does not require preparation of a small government agency plan in connection with it.

#### *E. Executive Order 13132: Federalism*

A rule has federalism implications under Executive Order 13132 if it has substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This regulation will not have such effects, and therefore does not have sufficient federalism implications to require consultations or to warrant the preparation of a federalism summary impact statement under section 6 of Executive Order 13132.

#### *F. Executive Order 12866: Regulatory Review*

The Department of State does not consider this rule to be a "significant regulatory action" within the scope of section 3(f)(1) of Executive Order 12866. Nonetheless, the Department has reviewed the rule to ensure its consistency with the regulatory philosophy and principles set forth in the Executive Order.

#### *G. Executive Order 12988: Civil Justice Reform*

The Department has reviewed this rule in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden. The Department has made every reasonable effort to ensure compliance with the requirements in Executive Order 12988.

#### *H. The Paperwork Reduction Act (PRA) of 1995*

Under the PRA, 42 U.S.C. 3501 *et seq.*, agencies are generally required to submit to the Office of Management and

Budget (OMB) for review and approval information collection requirements imposed on "persons" as defined in the PRA. Section 503(c) of the IAA exempts from the PRA information collection "for purposes of sections 104, 202(b)(4), and 303(d)" of the IAA "or for use as a Convention record as defined" in the IAA. All information collections that relate to outgoing non-Convention cases will be collections made for the purposes of section 303(d) of the IAA, and thereby are exempt. All information collections that relate to outgoing Convention cases will be Convention records as defined in and subject to the preservation requirements of 22 CFR part 98, which implements section 401(a) of the IAA. Additionally, the majority of information collection imposed on persons pursuant to this rule, with respect to both Convention and non-Convention cases, will be for the purposes of obtaining information for congressional reports required under section 104 of the IAA. Accordingly, the Department has concluded that the PRA does not apply to information collected from the public under this rule.

#### List of Subjects in 22 CFR Part 99

Adoption and foster care; International agreements; Reporting and recordkeeping requirements.

■ Accordingly, the Department adds new part 99 to title 22 of the CFR, chapter I, subchapter J, to read as follows:

#### PART 99—REPORTING ON CONVENTION AND NON-CONVENTION ADOPTIONS OF EMIGRATING CHILDREN

Sec.

99.1 Definitions.

99.2 Reporting requirements for adoption cases involving children emigrating from the United States.

99.3 [Reserved].

**Authority:** The Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption (done at The Hague, May 29, 1993), S. Treaty Doc. 105-51 (1998); 1870 U.N.T.S. 167 (Reg. No. 31922 (1993)); The Intercountry Adoption Act of 2000, 42 U.S.C. 14901-14954.

#### § 99.1 Definitions.

As used in this part, the term:

(a) *Convention* means the Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption done at The Hague on May 29, 1993.

(b) Such other terms as are defined in 22 CFR 96.2 shall have the meaning given to them therein.

#### § 99.2 Reporting requirements for adoption cases involving children emigrating from the United States.

(a) Once the Convention has entered into force for the United States, an agency (including an accredited agency and temporarily accredited agency), person (including an approved person), public domestic authority, or other adoption service provider providing adoption services in a case involving the emigration of a child from the United States must report information to the Secretary in accordance with this section if it is identified as the reporting provider in accordance with paragraph (b) of this section.

(b) In a Convention case in which an accredited agency, temporarily accredited agency, or approved person is providing adoption services, the primary provider is the reporting provider. In any other Convention case, or in a non-Convention case, the reporting provider is the agency, person, public domestic authority, or other adoption service provider that is providing adoption services in the case, if it is the only provider of adoption services. If there is more than one provider of adoption services in a non-Convention case, the reporting provider is the one that has child placement responsibility, as evidenced by the following factors:

(1) Entering into placement contracts with prospective adoptive parent(s) to provide child referral and placement;

(2) Accepting custody from a birthparent or other legal guardian for the purpose of placement for adoption;

(3) Assuming responsibility for liaison with a foreign government or its designees with regard to arranging an adoption; or

(4) Receiving information from, or sending information to a foreign country about a child that is under consideration for adoption.

(c) A reporting provider, as identified in paragraph (b) of this section, must report the following identifying information to the Secretary for each outgoing case within 30 days of learning that the case involves emigration of a child from the United States to a foreign country:

(1) Name, date of birth of child, and place of birth of child;

(2) The U.S. State from which the child is emigrating;

(3) The country to which the child is immigrating;

(4) The U.S. State where the final adoption is taking place, or the U.S. State where legal custody for the purpose of adoption is being granted and the country where the final adoption is taking place; and

(5) Its name, address, phone number, and other contact information.

(d) A reporting provider, as identified in paragraph (b) of this section, must report any changes to information previously provided as well as the following milestone information to the Secretary for each outgoing case within 30 days of occurrence:

(1) Date case determined to involve emigration from the United States (generally the time the child is matched with adoptive parents);

(2) Date of U.S. final adoption or date on which custody for the purpose of adoption was granted in United States;

(3) Date of foreign final adoption if custody for purpose of adoption was granted in the United States, to the extent practicable; and

(4) Any additional information when requested by the Secretary in a particular case.

#### § 99.3 [Reserved].

Dated: December 18, 2006.

**Maura Harty,**

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

Dated: February 2, 2007.

**Michael Chertoff,**

*Secretary of Homeland Security, Department of Homeland Security.*

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#### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 117

[CGD11-07-005]

RIN 1625-AA09

#### Drawbridge Operation Regulations; Sacramento River, at Isleton, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Isleton Drawbridge across the Sacramento River, mile 18.7, at Isleton, CA. This deviation allows for a 12-hour notice for openings. The deviation is necessary for the bridge owner, the California Department of Transportation (Caltrans), to coordinate vessel traffic with their scheduled critical maintenance and operating upgrades.