to compete effectively in a global environment.

This Statement of Policy has been developed as a means for the Commission to respond flexibly to the challenges posed by the ongoing evolution in electronic access to global markets. The Commission will continue to monitor carefully, and review the Policy Statement as necessary in light of, the ongoing evolution of cross-border electronic direct access and intermediation in order to ensure that it does not adversely affect U.S. cash and futures markets, market participants and customers, as well as the consumers affected by those foreign market transactions.

Issued in Washington, DC, on October 27, 2006 by the Commission.

Eileen A. Donovan,

Acting Secretary of the Commission.

[FR Doc. E6–18513 Filed 11–1–06; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Glycopyrrolate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by IVX Animal Health, Inc. The ANADA provides for veterinary prescription use of glycopyrrolate solution as an injectable preanesthetic agent in dogs and cats.

DATES: This rule is effective November 2, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200–365 that provides for veterinary prescription use of Glycopyrrolate Injectable as a preanesthetic agent in dogs and cats. IVX Animal Health, Inc.'s Glycopyrrolate Injectable is approved as a generic copy of Fort Dodge Animal Health's, Division of Wyeth's ROBINUL-V (glycopyrrolate), approved under NADA 101–777. The ANADA is approved as of October 2, 2006, and the regulations are amended in 21 CFR 522.1066 to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Revise § 522.1066 to read as follows:

§ 522.1066 Glycopyrrolate.

(a) *Specifications.* Each milliliter of solution contains 0.2 milligram glycopyrrolate.

(b) *Sponsors.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 5 micrograms per pound of body weight (0.25 milliliter per 10 pounds of body weight) by intravenous, intramuscular, or subcutaneous injection in dogs or by intramuscular injection in cats.

(2) *Indications for use.* As a preanesthetic agent.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: October 23, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–18444 Filed 11–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 97

[Public Notice 5602]

RIN 1400–AC19

Intercountry Adoption—Department Issuance of Certifications in Hague Convention Adoption Cases

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (the Department) is issuing a final rule to implement the certification and declaration provisions of the 1993 Hague Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption (the Convention) and the Intercountry Adoption Act of 2000 (the IAA) with respect to adoption and custody proceedings taking place in the United States, after review of public comments received in response to the Department's June 16, 2006 issuance of a proposed rule. This final rule governs the application process for Hague Adoption Certificates and Hague Custody Declarations in cases involving emigration of a child from the United States. It also establishes a process for seeking certification, for purposes of Article 23 of the Convention, that an adoption done in the United States following a grant of custody in a Convention country of origin was done in accordance with the Convention.

DATES: This rule is effective December 4, 2006. Information about the date the Convention will enter into force is provided in 22 CFR 96.17.

FOR FURTHER INFORMATION CONTACT: 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. Background

The Convention is a multilateral treaty that provides a framework for the

adoption of children habitually resident in one country party to the Convention by persons habitually resident in another country party to the Convention. It was developed under the auspices of the intergovernmental organization known as the Hague Conference on Private International Law (the Hague Conference).

The United States signed the Convention on March 31, 1994, and the President subsequently transmitted the Convention to the Senate for its advice and consent. On September 20, 2000, the Senate gave its advice and consent to the ratification of the Convention and, at about the same time, Congress enacted the implementing legislation for the Convention—the Intercountry Adoption Act (the IAA), Public Law 106–279, 42 U.S.C. 14901–14952. Consistent with U.S policy on ratification of treaties and the Senate's advice and consent to ratification, the United States will not ratify the Convention until the United States is able to carry out its obligations under the Convention. (See Senate Declaration for Convention Article 22(2) (146 Cong. Rec. S8866 (daily ed. Sept. 20, 2000). Although this final rule is effective in 30 days, parties are not required to comply with the provisions of 22 CFR part 97 until the Convention enters into force for the United States (three months after the United States ratifies it).

This final rule establishes procedures for issuing certifications in Convention adoptions involving the emigration of a child from the United States (outgoing cases) and for seeking certifications regarding adoptions in incoming cases. In response to its issuance of the proposed rule, the Department received insightful public comments that are posted on the Department's Web site at *http://www.travel.state.gov.* The Department is issuing the rule as final with minor changes, taking into account the comments received.

Section 303(c) of the IAA gives the Department responsibility for issuing an official certification that a child resident in the United States has been adopted, or a declaration that custody for the purpose of adoption has been granted, in accordance with the Convention and the IAA. The IAA assigns to State courts with jurisdiction over matters of adoption, or custody for purposes of adoption, the responsibility for receiving and verifying documents required under the Convention, making certain determinations required of the country of origin by the Convention, and determining that the placement is in the best interests of the child. With certain limited exceptions, the Convention requires all Convention parties to recognize adoptions, if the adoption is certified by the country of adoption as having been made in accordance with the Convention. This final rule also establishes a separate, discretionary, procedure pursuant to which the Department may certify that an incoming case finalized in the United States (*i.e.*, a case in which custody was granted abroad but the adoption was done by a U.S. court) was done in accordance with the Convention. The Department may issue this certification if an issue arises concerning recognition of the adoption pursuant to Article 23 of the Convention.

Further background on the Convention and the IAA is provided in the Preamble to the Proposed Rule on Issuance of Hague Convention Certificates and Declarations in Convention Adoption Cases, Section I, 71 FR 34857–34858 (June 16, 2006); the Preamble to the Final Rule on the Accreditation and Approval of Agencies and Persons under the IAA, Section I and II, 71 FR 8064–8066 (February 15, 2006); and the Preamble to the Proposed Rule on the Accreditation of Agencies and Approval of Persons under the Intercountry Adoption Act of 2000, Sections III and IV, 68 FR 54065–54073 (September 15, 2003).

II. Section-by-Section Discussion of Comments

This section provides a detailed discussion of comments received on the proposed rule and describes changes made to the proposed rule. Three general points should be kept in mind in reading this discussion. First, we refer generally to actions of the ''Department'' pursuant to the rule. The rule itself refers to actions of the ''Secretary,'' as the official named in the IAA, but the day-to-day exercise of the Secretary's functions has been delegated (Delegation of Authority 261, 68 FR 56372, September 30, 2003) to the Assistant Secretary for Consular Affairs. Second, this rule directly imposes Federal requirements on State courts to the extent consistent with the IAA. Specifically, the IAA assigns to State courts with jurisdiction over matters of adoption, or custody for purpose of adoption, the responsibility for receiving and verifying documents required under the Convention, making certain determinations required of the country of origin by the Convention, and determining that the placement is in the best interests of the child. In keeping with current U. S. domestic law and philosophy of treaty application in the context of a federalist system, we have imposed the Convention requirements on outgoing cases, which are governed mainly by State law, when the IAA has expressly imposed such Convention requirements. Finally, the Department has changed the title of the proposed rule to clarify that the rule covers both incoming and outgoing case certifications. The title change is not indicative of any substantive changes to the final rule.

Section 97.1 Definitions

No comments on the definitions were received, and no changes to 97.1 have been made. One commenter did recommend that throughout the rule the term ''adoptable'' child be removed because, according to the commenter, the term has historically implied that children are a marketable commodity. Although the Convention itself uses the term ''adoptable'' despite similar objections at the time of drafting, we have changed the word ''adoptable'' to ''eligible for adoption'' whenever possible.

Section 97.2 Application for a Hague Adoption Certificate (HAC) or a Hague Custody Declaration (HCD) (Outgoing Case)

1. *Comment:* Some commenters are concerned about how long the process to obtain a HAC or a HCD will take and that any delays could negatively affect a child waiting for an adoptive placement. One commenter recommends that specific timeframes be added to the rule, such as requiring the Department to issue a HAC or HCD in three business days, to ensure that families who had traveled to adopt a child living the United States did not have to wait too long for a HAC or HCD once the relevant State court issued the final adoption decree or custody decree.

Response: We agree that the HAC or HCD should be swiftly issued. The Department, however, is not including a specific timeframe in the rule. Our goal nonetheless is to issue a HAC or HCD as soon as possible, provided the supporting documentation required under § 96.3 has been submitted.

2. *Comment:* One commenter urges the Department to accept all materials, including applications and supporting documents by fax or e-mail, and to encourage other Central Authorities (CAs) to do the same. The commenter also asks that the Department encourage the CAs of receiving countries to provide any necessary approvals within 24 hours of request, noting that the Netherlands issues approvals within 24 hours.

Response: The Department intends to accept applications and supporting materials via fax and e-mail to the extent practicable. We will encourage

other CAs to accept communications by fax and e-mail as well. We also plan to urge other CAs to act expeditiously to send any necessary approvals to relevant State courts for a Hague outgoing case.

3. *Comment:* One commenter requests that fee payments be permitted by credit card submission via Internet, phone, or fax.

Response: If a fee is charged for issuance of a HAC or HCD, we will make the methods of payment easy and consistent with other federal agency requirements covering payment of fees.

4. *Comment:* One commenter asks which part of the Department will be responsible for issuing HACs and HCDs and where its office will be located.

Response: The Office of Children's Issues in the Bureau of Consular Affairs will issue HACs and HCDs out of its central office in Washington, DC.

5. *Comment:* One commenter asks what type of training will be provided to the staff responsible for adjudicating applications for HACs or HCDs and requests information on how this function will be staffed.

Response: The Department plans to train the Office of Children's Issues case officers thoroughly by using Foreign Affairs Manual (FAM) materials and formal classroom training. With respect to staffing, we do not yet know the number of outgoing cases and thus cannot determine how many officers will be assigned this critical CA function.

6. *Comment:* One commenter requests clarification of the parties that may apply for a HAC or HCD and asks specifically whether birthparent(s) may apply for a HAC or HCD. The commenter also asks whether the citizenship of the adoptive parent(s) or prospective adoptive parent(s) will affect their ability to obtain a HAC or a HCD.

Response: The adoptive parent(s) or prospective adoptive parent(s), who will be habitual residents of the receiving country and typically will not be U.S. citizens, will most likely be the parties to apply for a HAC or a HCD. Despite being non-U.S. citizen adoptive parent(s) or prospective adoptive parent(s), they will be able to apply for and obtain a HAC or HCD. The rule states that ''any party'' to an adoption or custody proceeding may apply for a HAC or HCD; thus, if a birthparent was a party to the adoption or custody proceeding, he or she may apply for a HAC or HCD. Likewise, the adopted child may apply for a HAC or HCD. If various parties to the adoption or custody proceeding apply for HACs or HCDs, more than one copy of the HAC or HCD may be issued. The Department's goal is to provide a HAC or HCD to any party to the adoption or custody proceeding who may need it to obtain recognition and acceptance of the adoption decree or custody for purpose of adoption decree from other Convention countries or from U.S. authorities.

7. *Comment:* Some commenters request clarification of the application process for HACs and HCDs. In particular, commenters want to know if a HAC or HCD is automatically issued even if no party applies. Similarly, other commenters believe that the Department should always issue a HAC or HCD after a State court grants an adoption or custody for purpose of adoption decree. Others are concerned that many parties will be unaware that for outgoing cases involving Convention adoptions, the receiving country is obligated not to permit the child's entry unless the Department (as CA of the country of origin) has issued a HAC or HCD for the child.

Response: Unless there is an application from a party or other interested person, in accordance with § 97.2(a), the Department will not *sua sponte* issue a HAC or HCD. The Department must be notified, via the application process, for the HAC or HCD to be issued. We expect that the adoption service provider working with the family would inform the prospective adoptive parent(s) of any necessary requirements, including the need for a HAC or HCD. In any case, a party or interested person may apply for a HAC or HCD at any time.

Once a party applies for a HAC or HCD, the Department, in its role as CA, must adjudicate the request to determine if the child has been adopted or custody of the child for purposes of adoption has been granted in accordance with the Convention and (except as provided in § 97.4(b)) the IAA. Specifically, section 303(c) of the IAA provides that the Department shall issue a HAC or HCD *on receipt and verification* of the required material and information. The Department may thus not issue a HAC or HCD for all cases.

The rule mirrors the IAA statutory requirements and is not changed in response to the comment. The parties must first apply to a State court to make the needed findings, all derived from the Convention or the IAA, so that the proceeding is Hague-compliant. The Department then reviews the State court findings to adjudicate the application before issuing a HAC or HCD. The Department may not assume that every adoption or custody for purpose of adoption case will automatically conform with the Convention and the IAA, as implemented through § 97.3, and issue a HAC or HCD without adjudicating the application.

We understand that some parties to intercountry adoptions may be unaware of the Convention and the IAA and consequently may not submit to the State court the information the court needs to make the findings required under § 97.3. The Department plans to continue its extensive outreach efforts to inform interested persons about the Convention, the IAA, and the applicable regulations. To date, we have conducted numerous outreach events with State court judges, public domestic authorities, and adoption service providers.

8. *Comment:* One commenter suggests that the Department is withholding recognition of the State court adoption or custody decree if it declines to issue the HAC or HCD.

Response. By verifying compliance with § 97.3 before issuing a HAC or HCD, the Department is acting in accordance with Article 23 of the Convention. The Department's verification that all steps in the adoption and/or custody process complied with the Convention, the IAA, and the regulations implementing the IAA ensures that U.S. children leaving the United States are protected in accordance with the Convention.

9. *Comment:* One commenter requests that the rule include language on the legal effect of a HAC or HCD similar to the language in Section 302(b) of the IAA with respect to incoming cases (*i.e.*, cases in which a child is immigrating to the United States).

Response: Article 23 of the Convention requires other Convention countries to recognize an adoption that has been certified by the competent authority of the State of the adoption. Therefore, Convention countries must recognize any adoption for which the Department has issued a HAC. Including a requirement in U.S. regulations is therefore unnecessary. In addition, the United States has no authority to regulate the receiving countries.

As for the HCD, Article 19 of the Convention provides that the transfer of the child to the receiving country may be carried out only if the requirements of Article 17 have been satisfied. The HCD demonstrates to the receiving country that the United States, as the country of origin, has agreed that the child may be entrusted to the prospective adoptive parent(s) and that the adoption may proceed in the receiving country. The Department expects that the receiving countries will

recognize the HCD as evidence that the Article 17 requirements have been met. In any event, as noted, the United States may not regulate another Convention country.

Section 97.3 Requirements Subject to Verification in an Outgoing Convention Case

1. *Comment:* Several commenters request that the reasonable efforts requirement to locate a placement for the child in the United States in § 97.3(c) not apply when birthparent(s) directly identify prospective parent(s) outside the United States. One commenter suggests that such contacts be permitted as long as an accredited, temporarily accredited, or approved adoption service provider is involved in the case.

Response: This provision cross-references 22 CFR 96.54(a), which specifically excludes from the reasonable efforts requirement cases in which the birthparent(s) have identified specific prospective adoptive parent(s) or in other special circumstances accepted by the State court.

2. *Comment:* One commenter recommends that the rule specify more clearly the steps that must be completed for a reasonable efforts finding to be made by the State court.

Response: As noted above, this provision cross-references 22 CFR 96.54(a), which sets forth the placement standards in outgoing cases, including the reasonable efforts requirement. Specifically, reasonable efforts to find a timely placement for the child in the United States include: (1) Disseminating information on the child and his or her availability for adoption through print, media, and internet resources designed to communicate with potential prospective adoptive parent(s) in the United States; (2) Listing information about the child on a national or State adoption exchange or registry for at least sixty calendar days after the birth of the child; (3) Responding to inquiries about adoption of the child; and (4) Providing a copy of the child background study to potential U.S. prospective adoptive parent(s).

3. *Comment:* One commenter objects to the sixty-day period for listing information about the child on a national or State adoption exchange or registry because research shows that delays in placement negatively impact a child's emotional well-being.

Response: This comment goes to 22 CFR part 96 and was addressed in the context of that rule. Part 96 is now a final rule and no longer open for comment.

4. *Comment:* One commenter asks if the provision in 97.3(f), which limits contacts between the prospective adoptive parent(s) and the child's birthparent(s) or any other person who has care of the child before the adoption, prevents birthparent(s) from identifying prospective adoptive parent(s) via such methods as reviewing parent profiles provided by an attorney for the prospective adoptive parent(s), or provided by an attorney for the birthparent(s), or provided by an agency, or made available online. The commenter also asks if birthparent(s) may identify prospective adoptive parent(s) via referrals from non-relatives or by responding to advertisements placed in newspapers.

Response: Section 97.3(j) implements the requirements in Article 29 of the Convention. Article 29's prohibition on prior contact applies unless the adoption takes place within a family or *the contact is in compliance with the conditions established in the country of origin*, in this case the United States. For this reason, § 97.3(j) permits contacts when a ''relevant State or public domestic authority has established conditions under which such contact may occur and any such contact occurred in accordance with such conditions.'' The answers to the commenter's questions thus depend on local law and regulations.

A State or a public domestic authority may establish conditions on direct contacts between birthparent(s) and prospective adoptive parent(s). If such conditions are set, then contacts that comply with those conditions may occur. If a State has no laws or conditions on direct contacts, then such contacts may not occur because the Convention intends that such contacts be either barred or subject to regulation.

If these principles are applied to the commenter's questions, then the answer to what direct contacts are permitted will necessarily depend on the State where the birthparent(s) are residing. If the State where the birthparent(s) reside permits them to review prospective adoptive parent(s) profiles before the referral or adoption or consider non-relative referrals, then the practice is not *per se* prohibited, but must comply with any specific State requirements, such as those on who may present the information (attorney for prospective adoptive parent(s) or birthparent(s) or adoption service provider). If State requirements are completely silent, then direct contact practices are not allowed. Likewise, if the State permits birthparent(s) to locate prospective adoptive parent(s) through media such as newspapers or Web sites, then such contacts may occur in States which expressly permit such contacts and prescribe the conditions under which such contacts may occur.

5. *Comment:* Another commenter asks if States that allow ''open adoptions'' in which the birthparent(s) and prospective adoptive parents(s) meet and establish a trusting relationship before the adoption must change their laws. The commenter notes that oftentimes the open contacts continue throughout the child's life and that current psychological research supports the conclusion that such bonds are beneficial to the adoptee in the long-run.

Response: These regulations do not require States to change their laws with respect to contacts. As discussed above, pre-birth contacts are permitted in Convention cases if they are allowed by the relevant State law or public domestic authority and the contacts occurred in accordance with required conditions.

6. *Comment:* One commenter asks if the no direct contacts provision of the rule applied to the U.S. government-sponsored *http://www.AdoptUSKids.org* photo listing service. The commenter explains that public domestic authorities put a photo and information about a child eligible for adoption (usually a child or sibling group that has been waiting a long time for a permanent family placement) on the web-based service and families from all over the world may express an interest in the child to the public domestic authority, submit a home study, and then social workers for the public domestic authority determine if a referral and subsequent match are in the best interests of the child. If so, then the public domestic authority undertakes the subsequent steps to complete an adoption, including in some cases, supervising meetings with the birthparent(s), the child, and the prospective adoptive parent(s).

Response: Public domestic authorities must comply with 22 CFR part 97. As discussed above, contacts are generally prohibited, unless the relevant State or public domestic authority has established conditions under which such contact may occur and any such contact occurred in accordance with such conditions. Presumably, because the public domestic authority is coordinating the adoption, it has established procedures on the contacts. If the conditions for the contacts have been enumerated, then the contacts may continue even for Hague cases as long as the contacts comply with the procedures that the public domestic authority established. Thus, if a State or

its public domestic authorities permit birthparent(s) and the child to meet with the prospective adoptive parent(s) then this contact would be permitted. As for the question about the photo-listing service, unless State law prohibits photo-listings of children eligible for adoption, States may continue to post information about such children on the federally-funded national Web site.

Section 97.5 Certification of Hague Convention Compliance in an Incoming Convention Case Where Adoption Occurs in the United States

1. *Comment:* Two commenters are concerned that the certification procedure in § 97.5 means that adoptions of children immigrating to the United States (incoming cases) that are completed in the United States (as receiving country) after the country of origin granted custody for purposes of adoption are not entitled to recognition under Convention Article 23.

Response: Article 23 of the Convention requires other Convention countries to recognize an adoption that has been certified as having been made in accordance with the Convention by the competent authority of the State of the adoption. If custody for purpose of adoption is granted in a Convention country of origin and the prospective adoptive parent(s) subsequently obtain a final adoption decree in a State court, the adoption is entitled to recognition under the Convention, provided that the State court decree is based on a certificate issued by a consular officer pursuant to 22 CFR 42.24(j) certifying that the grant of custody of the child occurred in compliance with the Convention or on the court's determination that the requirements of Article 17 of the Convention have been met. This is true regardless of whether the parent(s) or child apply for the additional certification under § 97.5 because, as pointed out by the commenters, the recognition of the adoption takes place by operation of law with or without subsequent certification by the Department. The U.S. adoption would necessarily be recognized in all U.S. territory, but if the parent(s) or other persons need documentation to show that the Convention adoption finalized in the United States was done in accordance with the Convention, they may seek the certification as outlined in § 97.5. In addition, they may rely on the State court adoption order. We have added a paragraph to § 97.5 to make clear that the final State court order shall constitute the certification under Article 23 of the Convention.

2. *Comment:* One commenter requests that the rule be changed to require prospective adoptive parent(s) who have been granted custody for purpose of adoption by the country of origin (in incoming cases) to complete adoptions in the United States.

Response: The Department is not modifying the rule as requested. Although the prospective adoptive parent(s) failure to finalize the adoption is problematic, the IAA does not require prospective adoptive parent(s) to obtain a final adoption decree in a U.S. State court when only custody for purpose of adoption was granted in the country of origin. Moreover, this rule relates to certifications of adoptions pursuant to the Convention.

We nevertheless share the commenter's concern about adoptions that are not finalized. The Department currently has experience with a few such cases in which the prospective adoptive parent(s) are granted custody for purpose of adoption in the country of origin, bring the child to the United States, and never finalize the adoption. The family is typically intact and the child is benefiting from an ongoing permanent placement so there is no basis for the State to remove the child. Yet, there is no final adoption, the child does not acquire U.S. citizenship under The Child Citizenship Act, and remains a legal permanent resident, subject to deportation under certain limited circumstances. Similarly, the child does not have all the additional benefits of a full legal parent-child relationship. Despite these issues, there is no current authority or new authority in the IAA granting the Department or the Department of Homeland Security (DHS) the authority to compel finalization of the adoption. We plan to continue our outreach and communication efforts to stress to families and adoption service provider(s) the critical importance of finalizing the adoption in both Convention and non-Convention cases.

3. *Comment:* Some commenters request that the rule be changed to mandate that the Department always issue a certification under § 97.5 after the parent(s) complete the final adoption in the United States. One commenter was concerned that a person requesting the certification must show a need for it, including a showing that the child would be traveling overseas.

Response. The Department is not modifying the rule in response to this request. The Department cannot issue a certification under 97.5 absent a request because it has no means to know when a State court issues an adoption decree. However, the intent of § 97.5 was not to limit the issuance of these certifications solely to instances where there is a showing of exceptional need or if the child would be traveling. We have deleted § 97.5(3) that required parties to submit a signed statement explaining the need for such a certification.

4. *Comment:* One commenter is concerned that countries of origin expect copies of the Article 23 certification to be sent in every case where the adoption is completed by a final adoption order in the United States and cite Articles 7, 20, and 23, and of the Convention for support.

Response: The Department believes that its rule on Convention Article 23 certifications is consistent with the Convention provisions cited and implements the Convention. Specifically, as noted above, the IAA does not require that families finalize the adoptions or notify the Department when the adoptions are final. We will use all other available means to obtain information on the final adoption of the child for the child's country of origin, including relying on 22 CFR 96.50(h)(2), which requires accredited agencies, temporarily accredited agencies, and approved persons, to notify the Department of the finalization of the adoption within thirty days of the entry of the final adoption order. We believe that through 22 CFR 96.50(h)(2) combined with the final rule in § 97.5(e), making clear that the State court final adoption decree may serve as the Convention Article 23 certification, the United States will fulfill its Convention obligations.

Regulatory Review

A. Administrative Procedures Act

This rule, through which the Department provides for implementation of the Convention, which focuses on issuance of documents to facilitate cross-border recognition of adoptions done under the Convention, involves a foreign affairs function of the United States and therefore pursuant to 5 U.S.C. 553(a)(1) is not subject to the procedures required by 5 U.S.C. 553 and 554. Nonetheless, the Department published the proposed rule and received public comment on it.

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 rule on small entities and has determined and hereby certifies that this rule would not have a significant

economic impact on a substantial number of 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. Section 4 of UFMA, 2 U.S.C. 1503, excludes regulations necessary for implementation of treaty obligations. This rule falls within this exclusion because it would implement the Convention. In any event, this rule would 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 would 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 rule 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.

The Convention and the IAA do, however, address issues that previously had been regulated primarily at the State level, as discussed in the preamble to the proposed rule on accreditation and approval of agencies and persons, appearing at 68 FR 54064, 54069–54070. In recognition of this fact, section 503(a) of the IAA contains a specific provision limiting preemption of State law to those State law provisions inconsistent with the Convention or the IAA, and only to the extent of the inconsistency. This rule does not create new federalism implications beyond those created by the IAA and the Convention, and the Department has been careful in this rule to defer to State authorities whenever possible consistent with Convention and IAA mandates. We also envision significant outreach and consultation with appropriate State authorities in the implementation of any regulation on this topic.

F. Executive Order 12866: Regulatory Review

This rule, through which the Department provides for implementation of the Convention, which focuses on issuance of documents to facilitate cross-border recognition of adoptions done under the Convention, pertains to a foreign affairs function of the United States; therefore, pursuant to section 3(d)(2) of the Executive Order 12866, this rule is not subject to the review procedures set forth in Executive Order 12866. In addition, the Department is exempt from Executive Order 12866 except to the extent it is promulgating regulations in conjunction with a domestic agency that are significant regulatory actions. The Department of State, however, provided the proposed rule to OMB for comment and incorporated its comments. The Department is not submitting the final rule to OMB, but has reviewed it to ensure consistency with the regulatory philosophy and principles set forth in Executive Order 12866.

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 Paperwork Reduction Act (PRA), 42 U.S.C. 3501 *et seq.*, agencies are generally required to submit to OMB for review and approval information collection requirements imposed on ''persons'' as defined in the PRA. Section 503(c) of the IAA, however, exempts from the PRA any 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. Convention record is defined in section 3(11) of the IAA to mean ''any item, collection, or grouping of information contained in an electronic or physical document, an electronic collection of data, a photograph, an audio or video tape, or any other information storage medium of any type whatever that contains information about a specific past, current, or prospective Convention adoption (regardless of whether the adoption was made final) that has been preserved in accordance with section 401(a) by the Secretary of State or the Attorney General.'' Information collections imposed on persons pursuant to this rule would relate directly to specific Convention adoptions (whether final or not), insofar as collections would be used by the Department in its determination of whether a Convention adoption, or a grant of custody for purposes of a Convention adoption, has been conducted in accordance with the Convention and the IAA. Upon receipt, these information collections would be subject to the preservation requirements set forth in 22 CFR part 98 to implement section 401(a) of the IAA. Accordingly, the Department has concluded that the PRA would not apply to information collected from the public under this rule, for the purpose of determining entitlement to a Hague Adoption Certificate or Hague Custody Declaration, or a certification of Convention compliance pursuant to § 97.5, because such documents would be collected for use as Convention records.

The Department intends, nonetheless, to consider carefully how to minimize the burden on the public of information collections contained in this rule as such collections, in particular the required application form, continue to be developed.

List of Subjects in 22 CFR Part 97

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

■ Accordingly, the Department adds new part 97 to title 22 of the CFR, chapter I, subchapter J, to read as follows:

PART 97—ISSUANCE OF ADOPTION CERTIFICATES AND CUSTODY DECLARATIONS IN HAGUE CONVENTION ADOPTION CASES

Sec.

97.1 Definitions.
97.2 Application for a Hague Adoption Certificate or a Hague Custody Declaration (Outgoing Convention Case).
97.3 Requirements Subject to Verification in an Outgoing Convention Case.
97.4 Issuance of a Hague Adoption Certificate or a Hague Custody Declaration (Outgoing Convention Case).
97.5 Certification of Hague Convention Compliance in an Incoming Convention Case Where Final Adoption Occurs in the United States.
97.6–97.7 [Reserved].

Authority: 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)); Intercountry Adoption Act of 2000, 42 U.S.C. 14901–14954.

§ 97.1 Definitions.

As used in this part:

(a) *Adoption Court* means the State court with jurisdiction over the adoption or the grant of custody for purpose of adoption.

(b) *U.S. Authorized Entity* means a public domestic authority or an agency or person that is accredited or temporarily accredited or approved by an accrediting entity pursuant to 22 CFR part 96, or a supervised provider acting under the supervision and responsibility of an accredited agency or temporarily accredited agency or approved person.

(c) *Foreign Authorized Entity* means a foreign Central Authority or an accredited body or entity other than the Central Authority authorized by the relevant foreign country to perform Central Authority functions in a Convention adoption case.

(d) *Hague Adoption Certificate* means a certificate issued by the Secretary in an outgoing case (where the child is emigrating from the United States to another Convention country) certifying that a child has been adopted in the United States in accordance with the Convention and, except as provided in § 97.4(b), the IAA.

(e) *Hague Custody Declaration* means a declaration issued by the Secretary in an outgoing case (where the child is emigrating from the United States to another Convention country) declaring that custody of a child for purposes of adoption has been granted in the United States in accordance with the Convention and, except as provided in § 97.4(b), the IAA.

(f) Terms defined in 22 CFR 96.2 have the meaning given to them therein.

§ 97.2 Application for a Hague Adoption Certificate or a Hague Custody Declaration (Outgoing Convention Case).

(a) Once the Convention has entered into force for the United States, any party to an outgoing Convention adoption or custody proceeding may apply to the Secretary for a Hague Adoption Certificate or a Hague Custody Declaration. Any other interested person may also make such application, but such application will not be processed unless such applicant demonstrates that a Hague Adoption Certificate or Hague Custody Declaration is needed to obtain a legal benefit or for purposes of a legal proceeding, as determined by the Secretary in the Secretary's discretion.

(b) Applicants for a Hague Adoption Certificate or Hague Custody Declaration shall submit to the Secretary:

(1) A completed application form in such form as the Secretary may prescribe, with any required fee;

(2) An official copy of the order of the adoption court finding that the child is eligible for adoption and that the adoption or proposed adoption is in the child's best interests and granting the adoption or custody for purposes of adoption;

(3) An official copy of the adoption court's findings (either in the order granting the adoption or custody for purposes of adoption or separately) verifying, in substance, that each of the requirements of § 97.3 has been complied with or, if the adoption court has not verified compliance with a particular requirement in § 97.3, authenticated documentation showing that such requirement nevertheless has been met and a written explanation of why the adoption court's verification of compliance with the requirement cannot be submitted; and

(4) Such additional documentation and information as the Secretary may request at the Secretary's discretion.

(c) If the applicant fails to submit all of the documentation and information required pursuant to paragraph (b)(4) of this section within 120 days of the Secretary's request, the Secretary may consider the application abandoned.

§ 97.3 Requirements Subject to Verification in an Outgoing Convention Case.

(a) *Preparation of Child Background Study.* An accredited agency, temporarily accredited agency, or public domestic authority must complete or approve a child background study that includes information about the child's identity, adoptability, background, social environment, family history, medical history (including that of the child's family), and any special needs of the child.

(b) *Transmission of Child Data.* A U.S. authorized entity must conclude that the child is eligible for adoption and, without revealing the identity of the birth mother or the birth father if these identities may not be disclosed under applicable State law, transmit to a foreign authorized entity the background study, proof that the necessary consents have been obtained, and the reason for its determination that the proposed placement is in the child's best interests, based on the home study and child background study and giving due consideration to the child's upbringing and his or her ethnic, religious, and cultural background.

(c) *Reasonable Efforts to find Domestic Placement.* Reasonable efforts pursuant to 22 CFR 96.54 must be made to actively recruit and make a diligent search for prospective adoptive parent(s) to adopt the child in the United States and a timely adoptive placement in the United States not found.

(d) *Preparation and Transmission of Home Study.* A U.S. authorized entity must receive from a foreign authorized entity a home study on the prospective adoptive parent(s) prepared in accordance with the laws of the receiving country, under the responsibility of a foreign Central Authority, foreign accredited body, or public foreign authority, that includes:

(1) Information on the prospective adoptive parent(s)' identity, eligibility, and suitability to adopt, background, family and medical history, social environment, reasons for adoption, ability to undertake an intercountry adoption, and the characteristics of the children for whom they would be qualified to care;

(2) Confirmation that a competent authority has determined that the prospective adoptive parent(s) are eligible and suited to adopt and has ensured that the prospective adoptive parent(s) have been counseled as necessary; and

(3) The results of a criminal background check.

(e) *Authorization to Enter.* The Central Authority or other competent authority of the receiving country must declare that the child will be authorized to enter and reside in the receiving country permanently or on the same basis as the adopting parent(s).

(f) *Consent by Foreign Authorized Entity.* A foreign authorized entity or competent authority must declare that it

consents to the adoption, if its consent is necessary under the law of the relevant foreign country for the adoption to become final.

(g) *Guardian Counseling and Consent.* Each person, institution, and authority (other than the child) whose consent is necessary for the adoption must be counseled as necessary and duly informed of the effects of the consent (including whether or not an adoption will terminate the legal relationship between the child and his or her family of origin); must freely give consent expressed or evidenced in writing in the required legal form without any inducement by compensation of any kind; and consent must not have been subsequently withdrawn. If the consent of the mother is required, it may be given only after the birth of the child.

(h) *Child Counseling and Consent.* As appropriate in light of the child's age and maturity, the child must be counseled and informed of the effects of the adoption and the child's views must be considered. If the child's consent is required, the child must also be counseled and informed of the effects of granting consent, and must freely give consent expressed or evidenced in writing in the required legal form without any inducement by compensation of any kind.

(i) *Authorized Entity Duties.* A U.S. authorized entity must:

(1) Ensure that the prospective adoptive parent(s) agree to the adoption;

(2) Agree, together with a foreign authorized entity, that the adoption may proceed;

(3) Take all appropriate measures to ensure that the transfer of the child takes place in secure and appropriate circumstances and, if possible, in the company of the adoptive parent(s) or the prospective adoptive parent(s), and arrange to obtain permission for the child to leave the United States; and

(4) Arrange to keep a foreign authorized entity informed about the adoption process and the measures taken to complete it, as well as about the progress of the placement if a probationary period is required; to return the home study and the child background study to the authorities that forwarded them if the transfer of the child does not take place; and to be consulted in the event a new placement or alternative long-term care for the child is required.

(j) *Contacts.* Unless the child is being adopted by a relative, there may be no contact between the prospective adoptive parent(s) and the child's birthparent(s) or any other person who has care of the child prior to the competent authority's determination that the prospective adoptive parent(s) are eligible and suited to adopt and the adoption court's determinations that the child is eligible for adoption, that the requirements in paragraphs (c) and (g) of this section have been met, and that an intercountry adoption is in the child's best interests, *provided that* this prohibition on contacts shall not apply if the relevant State or public domestic authority has established conditions under which such contact may occur and any such contact occurred in accordance with such conditions.

(k) *Improper financial gain.* No one may derive improper financial or other gain from an activity related to the adoption, and only costs and expenses (including reasonable professional fees of persons involved in the adoption) may be charged or paid.

§ 97.4 Issuance of a Hague Adoption Certificate or a Hague Custody Declaration (Outgoing Convention Case).

(a) Once the Convention has entered into force for the United States, the Secretary shall issue a Hague Adoption Certificate or a Hague Custody Declaration if the Secretary, in the Secretary's discretion, is satisfied that the adoption or grant of custody was made in compliance with the Convention and the IAA.

(b) If compliance with the Convention can be certified but it is not possible to certify compliance with the IAA, the Secretary personally may authorize issuance of an appropriately modified Hague Adoption Certificate or Hague Custody Declaration, in the interests of justice or to prevent grave physical harm to the child.

§ 97.5 Certification of Hague Convention Compliance in an Incoming Convention Case Where Final Adoption Occurs in the United States.

(a) Once the Convention has entered into force for the United States, any person may request the Secretary to certify that a Convention adoption in an incoming case finalized in the United States was done in accordance with the Convention.

(b) Persons seeking such a certification must submit the following documentation:

(1) A copy of the certificate issued by a consular officer pursuant to 22 CFR 42.24(j) certifying that the granting of custody of the child has occurred in compliance with the Convention;

(2) An official copy of the adoption court's order granting the final adoption; and

(3) Such additional documentation and information as the Secretary may request at the Secretary's discretion.

(c) If a person seeking the certification described in paragraph (a) of this section fails to submit all the documentation and information required pursuant to paragraph (b) of this section within 120 days of the Secretary's request, the Department may consider the request abandoned.

(d) The Secretary may issue the certification if the Secretary, in the Secretary's discretion, is satisfied that the adoption was made in compliance with the Convention. The Secretary may decline to issue a certification, including to a party to the adoption, in the Secretary's discretion. A certification will not be issued to a non-party requestor unless the requestor demonstrates that the certification is needed to obtain a legal benefit or for purposes of a legal proceeding, as determined by the Secretary in the Secretary's discretion.

(e) A State court's final adoption decree, when based upon the certificate issued by a consular officer pursuant to 22 CFR 42.24(j), certifying that the grant of custody of the child has occurred in compliance with the Convention, or upon its determination that the requirements of Article 17 of the Convention have been met constitutes the certification of the adoption under Article 23 of the Convention.

§ 97.6–97.7 [Reserved]

Dated: October 12, 2006.

Maura Harty,

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

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9295]

RIN 1545–BF98

AJCA Modifications to the Section 6011, 6111, and 6112 Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary and final regulations under sections 6011, 6111, and 6112 of the Internal Revenue Code that modify the rules relating to the disclosure of reportable transactions and the list maintenance requirements. These regulations affect taxpayers