§ 163.1 Definitions.

* * * * *

(a) * * *

(2) * * *

(ix) The maintenance of any documentation that the importer may have in support of a claim for preferential tariff treatment under the United States-Australia Free Trade Agreement (AFTA), including an AFTA importer's supporting statement.

* * * * *

■ 10. Appendix to Part 163 is amended by adding a listing under section IV in numerical order to read as follows:

Appendix to Part 163—Interim (a)(1)(A) List

* * * * *

IV. * * *

§ 10.723–10.727 AFTA records that the importer may have in support of an AFTA claim for preferential tariff treatment, including an importer's supporting statement.

* * * * *

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

■ 11. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

■ 12. Section 178.2 is amended by adding new listings for ''§§ 10.723 and 10.724'' to the table in numerical order to read as follows:

§ 178.2 Listing of OMB control numbers.

19 CFR Section	Description	OMB control No.
*	*	*
§§ 10.723 and 10.724	Claim for preferential tariff treatment under the US-Australia Free Trade Agreement	1651–0117
*	*	*

* * * * *

R. Gil Kerlikowske,

Commissioner.

Approved: February 5, 2015.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2015–02720 Filed 2–9–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA–2015–D–0268]

Individual Patient Expanded Access Applications: Form FDA 3926; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of draft guidance.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Individual Patient Expanded Access Applications: Form FDA 3926.'' The draft guidance provides for public comment and describes draft Form FDA 3926 (Individual Patient Expanded Access—Investigational New Drug Application (IND)), which, when finalized, FDA intends to make available for licensed physicians to use for expanded access requests for individual patient INDs. Individual patient expanded access allows for the use of an investigational drug outside of a clinical trial for an individual patient who has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. When finalized, draft Form FDA 3926 is intended to provide a streamlined alternative for submitting an Investigational New Drug Application (IND) for use in cases of individual patient expanded access.

DATES: February 10, 2015. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 13, 2015. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by April 13, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Bickel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6353, Silver Spring, MD 20993–0002, 301–796–0210; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Individual Patient Expanded Access Applications: Form FDA 3926.'' The draft guidance provides draft Form FDA 3926 for public comment. When finalized, draft Form FDA 3926 will be available for licensed physicians to use for expanded access requests for individual patient INDs as an alternative to Form FDA 1571 (Investigation New Drug Application (IND)).

On August 13, 2009, FDA published a final rule (74 FR 40900, August 13, 2009) to amend its IND regulations by removing the certain sections of part 312 (21 CFR part 312) on treatment use of investigational drugs and adding subpart I of part 312 on expanded access (part 312, subpart I).

Subpart I describes the following categories of expanded access:

• Expanded access for individual patients, including for emergency use;
• Expanded access for intermediate-size patient populations (smaller than those typical of a treatment IND or treatment protocol); and
• Expanded access through a treatment IND or treatment protocol (designed for use in larger patient populations).

The final rule was, among other things, intended to increase awareness and knowledge of expanded access programs and the procedures for obtaining investigational drugs for treatment use for patients who have serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives. The final rule was also intended to facilitate the availability, when appropriate, of investigational new drugs for treatment use, while protecting patient safety and avoiding interference with the development of investigational drugs for marketing under approved applications.

The draft guidance is intended to address the submission of draft Form FDA 3926, when finalized, for a new individual patient expanded access IND by a licensed physician. For information on expanded access in general, including how to submit an expanded access protocol to an existing IND, see FDA's draft guidance for industry ''Expanded Access to Investigational Drugs for Treatment Use—Qs and As'' (available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*).

FDA may permit expanded access to an investigational new drug for an individual patient when the applicable criteria in § 312.305(a), which pertains to all types of expanded access, and the criteria in § 312.310(a), which pertains to individual patient expanded access, including in an emergency, are met. The physician may satisfy some of the submission requirements by referring to information in an existing IND, ordinarily the one held by the manufacturer, if the physician obtains permission from that IND holder. If permission is obtained, the physician should then provide FDA a letter of authorization (LOA) from the existing IND holder that permits FDA to reference that IND.

Section 312.305(b) sets forth the submission requirements for all expanded access uses. One of the requirements under § 312.305(b)(2) is that a ''cover sheet'' must be included ''meeting the requirements of § 312.23(a).'' This provision applies to several types of submissions under part 312, ranging from commercial INDs under § 312.23 involving large groups of patients enrolled in clinical trials to requests from licensed physicians to use an investigational drug for an individual patient. FDA is concerned that its goal of facilitating access to drugs for individual patient treatment use may have been complicated by difficulties experienced by physicians in submitting Form FDA 1571 (currently used by sponsors for all types of IND submissions) including associated documents, which is not tailored to requests for individual patient expanded access.

In an effort to streamline the submission process for individual patient expanded access INDs, FDA intends to make draft Form FDA 3926 available, when finalized, for licensed physicians to request expanded access to an investigational drug outside of a clinical trial for an individual patient who has a serious or immediately life-threatening disease or condition and for whom there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition (*i.e.,* for individual patient expanded access, including in emergencies). Draft Form FDA 3926 is shorter than Form FDA 1571 and requests the following information: (1) Patient's initials and date of submission; (2) clinical information; (3) treatment information; (4) LOA from the investigational drug's manufacturer, if applicable; (5) physician's qualifications; (6) physician's contact information and the physician's IND number, which is not the same as the manufacturer's IND number, (if the number is known); (7) request for authorization to use draft Form FDA 3926, when finalized, for individual patient expanded access applications instead of Form FDA 1571; and (8) certification statement and physician's signature. Draft Form FDA 3926 is provided in the draft guidance for public comment as Appendix 1.

As discussed in the draft guidance, FDA intends to accept submission of draft Form FDA 3926, when finalized, to comply with the IND submission requirements in §§ 312.23, 312.305(b), and 312.310(b). To the extent that information required under part 312 is not contained in draft Form FDA 3926, FDA intends to consider the submission of that form, when finalized, with the box in item 7 checked and the form signed by the physician, to constitute a request under § 312.10 to waive any other applicable application requirements, including additional information included in Form FDA 1571 and Form FDA 1572 (Statement of Investigator, providing the identity and qualifications of the investigator conducting the clinical investigation).

In an emergency situation that requires the patient to be treated before a written submission can be made, the request to use the investigational drug for individual patient expanded access may be made by telephone (or other rapid means of communication) to the appropriate FDA review division, and authorization of the emergency use may be given by the FDA official over the telephone, provided the physician explains how the expanded access use will meet the requirements of §§ 312.305 and 312.310 and agrees to submit an expanded access submission within 15 working days of FDA's initial authorization of the expanded access use (§ 312.310(d)).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the use of draft Form FDA 3926, when finalized, by licensed physicians for individual patient expanded access applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Title: Draft Guidance on Individual Patient Expanded Access Applications: Form FDA 3926.

Description: The draft guidance provides for public comment and describes draft Form FDA 3926. When finalized, draft Form FDA 3926 will be available for licensed physicians to request the use of an investigational drug outside of a clinical trial for an individual patient who has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition (*i.e.,* for individual patient expanded access). FDA regulations (§ 312.305(b)(2)) require that a cover sheet meeting the requirements of § 312.23(a) (currently Form FDA 1571) be submitted for all expanded access requests.

As explained in the draft guidance, the following information would be submitted to FDA by those using draft Form FDA 3926 when it is finalized:

- Patient's initials and date of submission.
- Clinical information, including indication, brief clinical history of the patient (age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy), and the rationale for requesting the proposed treatment, including an explanation of why the patient lacks other therapeutic options.
- Treatment information, including the investigational drug's name and manufacturer and the treatment plan. The plan should include the planned dose, route of administration, planned duration of treatment, monitoring procedures, and planned modifications to the treatment plan in the event of toxicity.
- LOA obtained from the investigational drug's manufacturer and attached to draft Form FDA 3926, if applicable.
- Physician's qualification statement that specifies the medical school attended, year of graduation, medical specialty, state medical license number, current employment, and job title. Alternatively, the first few pages of the physician's curriculum vitae may be attached, provided they include the information described previously.
- Physician's contact information, including the physical address, email address, telephone number, facsimile number, and physician's IND number, if known.
- Request for authorization to use Form FDA 3926, when finalized, for the initial submission of individual patient expanded access applications instead of Form FDA 1571.
- Signature of the physician certifying that treatment will not begin until 30 days after FDA receives the application, unless the submitting physician receives earlier notification from FDA that the treatment may proceed; that the physician will obtain informed consent, consistent with Federal requirements; that an institutional review board (IRB) that complies with the Federal IRB requirements will be responsible for initial and continuing review and approval of the treatment use; and that in the case of an emergency request, treatment may begin without prior IRB approval, provided that the IRB is notified of the emergency treatment within 5 working days of treatment.

Section 312.305(b)(2) of FDA's expanded access regulations sets forth the submission requirements for all types of expanded access requests for investigational drugs. Section 312.310(b) contains additional submission requirements for individual patient expanded access requests, and § 312.310(d) contains the requirements for requesting individual patient expanded access for emergency use. FDA currently has OMB approval under control number 0910–0014 for individual patient expanded access information collection under §§ 312.305(b), 312.310(b), and 312.310(d). As shown in Table 1, based on data for the number of these responses to FDA during 2011, 2012, and 2013, we estimate that we will receive approximately 593 requests annually for individual patient expanded access use from approximately 393 licensed physicians and will receive approximately 560 requests annually for individual patient expanded access emergency use from approximately 397 licensed physicians.

The current OMB approval also estimates that it takes each licensed physician approximately 8 hours to request each individual patient expanded access use and approximately 16 hours to request each individual patient expanded access for emergency use. These estimates are based on the use of Form FDA 1571. When a finalized Form FDA 3926 is submitted instead of current Form FDA 1571, we estimate that the burden time will be 45 minutes, resulting in a burden reduction of 7 hours and 15 minutes for each individual patient expanded access request and a burden reduction of 15 hours and 15 minutes for each individual patient expanded access for emergency use request. That estimate is based on information provided by Department of Health and Human Services (DHHS) personnel who are familiar with preparing and reviewing expanded access submissions by practicing physicians. As shown in Table 1, we estimate a total of approximately 864.75 hours annually for requesting individual patient expanded access use and individual patient expanded access emergency use using draft Form FDA 3926, when finalized. This is a reduction of 16,727.25 hours from what was approved under OMB control number 0910–0014 for these submissions.

The total estimated reporting burden for the draft guidance is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

[Reduces currently approved burden of 17,592 hours under 0910–0014 by 16,727.25 hours] [1]

Draft guidance on individual patient expanded access applications; Form FDA 3926	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (minutes)	Total hours
Expanded access submission for treatment of an individual patient, including submission of draft Form FDA 3926, when finalized, instead of Form FDA 1571	790	1.46	1,153	45	864.75

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm;* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm;* or *http://www.regulations.gov.*

Dated: February 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02561 Filed 2–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 96

[Public Notice: 9023]

RIN 1400–AD45

Adoptions: Regulatory Change To Clarify the Application of the Accreditation Requirement and Standards in Cases Covered by the Intercountry Adoption Universal Accreditation Act

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the Department of State (Department) interim rule on the accreditation and approval of adoption service providers in intercountry adoptions, and adopts the interim rule as final. The revisions reflect the requirement of the Intercountry Adoption Universal Accreditation Act of 2012 (UAA) that the accreditation standards developed in accordance with the 1993 Hague Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption (Convention) and the Intercountry Adoption Act of 2000 (IAA), which previously only applied in Convention adoption cases, apply also in non-Convention adoption cases. Non-convention adoption cases are known as ''orphan'' cases, defined in the Immigration and Nationality Act (INA). This rule also revises the accreditation rule by referring to the Department of Homeland Security (DHS) Convention home study regulation and deleting obsolete references, such as any reference to temporary accreditation.

DATES: This document finalizes the interim final rule published on July 14, 2014 (79 FR 40629), and is effective February 10, 2015.

FOR FURTHER INFORMATION CONTACT: Office of Legal Affairs, Overseas Citizen Services, U.S. Department of State, CA/OCS/L, SA–17, Floor 10, Washington, DC 20522–1710; (202) 485–6079.

SUPPLEMENTARY INFORMATION:

Why is the Department promulgating this rule?

This rule clarifies that under the Intercountry Adoption Universal Accreditation Act of 2012 (UAA), signed into law January 14, 2013, and effective July 14, 2014, the accreditation requirement and standards found in 22 CFR part 96 apply to any person (including non-profit agencies, for-profit agencies and individuals but excluding government agencies and tribal authorities), providing adoption services on behalf of prospective adoptive parents in an ''orphan'' intercountry adoption case described under section 101(b)(1)(F) of the Immigration and Nationality Act. Specifically, under Section 2 of the UAA ''[t]he provisions of title II and section 404 of the Intercountry Adoption Act of 2000 (42 U.S.C. 14901 *et seq.*), and related implementing regulations, shall apply to any person offering or providing adoption services in connection with a child described in section 101(b)(1)(F) of the Immigration and Nationality Act (8 U.S.C. 1101(b)(1)(F)), to the same extent as they apply to the offering or provision of adoption services in connection with a Convention adoption.''

Title II of the Intercountry Adoption Act of 2000 (IAA) (Pub. L. 106–279) requires that any person providing adoption services in a Convention case be an accredited, approved, or an exempted adoption service provider, and section 404 imposes civil and criminal penalties for violations of the Act. On February 15, 2006 the Department of State published implementing regulations at 71 FR 8064, on the accreditation and approval of agencies and persons in accordance with the Convention and the IAA.

The UAA extends that rule from Convention cases to ''orphan'' cases. This regulatory change includes a number of technical edits to facilitate interpretation of the regulatory requirements and clarify designated accrediting entities' authority under the UAA and the IAA.

The Department is amending the regulation to make 22 CFR part 96, as affected by the UAA, easier to read. This rule will aid the accrediting entity applying the standards and adoption service providers required to comply with the standards. In particular, this rule adds references to the UAA where the IAA is referenced; adds a sentence concerning the UAA effective date; redefines ''Central Authority'' to include competent authorities, thereby clarifying how the term applies in countries that are not party to the Convention; redefines adoption records to include non-Convention case records and changes Section 96.25(b) concerning accrediting entity access to non-Convention records in cases subject to the UAA; defines the terms INA, IAA, and intercountry adoption; refers to ''accreditation and approval'' instead of to ''Convention accreditation and approval;'' revises § 96.46(a)(4) to clarify that foreign supervised providers in non-Convention countries may not have a pattern of licensing suspensions relating to key Convention principles; and revises references to ''Convention adoption,'' ''cases subject to the Convention,'' ''Convention case,'' ''Convention country,'' and ''Convention-related activity'' to ensure that such references include non-Convention adoptions, activities, countries, and cases under the UAA.

Additionally, this rule corrects the references in 22 CFR 96.37(f)(2), and 96.47(a)(4) and (b), to refer to the correct Department of Homeland Security (DHS) definition of home study preparer and home study requirements. When the original rule was issued in 2006, DHS had not yet published its final rule concerning home studies in Convention cases. Thus, the 2006 State Department rule referred to the ''orphan'' home study requirements under 8 CFR 204.3(b) and (e), instead of the Convention home study requirements found in 8 CFR 204.301 and 311. This rule references the correct DHS regulation. The change clarifies that the home study must be prepared by an accredited agency, approved person, exempted provider, or a supervised provider. In addition, when the home study is not performed in the first instance by an accredited agency, then an accredited agency must review and approve it. The orphan and Convention home study requirements also differ concerning the required elements,