Dated: June 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0157]

Draft Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients With Disorders Affecting the Hematopoietic System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System'' dated June 2013. The draft guidance document provides recommendations for manufacturers, generally cord blood banks, to apply for licensure of minimally manipulated, unrelated allogeneic placental/umbilical cord blood, for hematopoietic and immunologic reconstitution. The guidance document is intended to assist manufacturers obtain a biologics license. The guidance contains information about the manufacture of minimally manipulated, unrelated allogeneic placental/umbilical cord blood and how to comply with applicable regulatory requirements. The draft guidance, when finalized, is intended to supersede the guidance entitled ''Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' dated October 2009.

DATES: 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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 16, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System'' dated June 2013. The draft guidance document, when finalized, will provide recommendations for manufacturers to apply for licensure of minimally manipulated, unrelated allogeneic placental/umbilical cord blood, for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment. The guidance document is intended to assist manufacturers obtain a biologics license. The guidance contains information about the manufacture of minimally manipulated, unrelated, allogeneic placental/umbilical cord blood and how to comply with applicable regulatory requirements. The draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' dated October 2009.

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 FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

Elsewhere in this issue of the **Federal Register,** we also are announcing the availability of another, related draft guidance entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System.'' That draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' dated June 2011.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 201 have been approved under OMB control number 0910–0572; 21 CFR part 211 have been approved under OMB control number 0910–0139; 21 CFR part 600 have been approved under OMB control number 0910–0308; 21 CFR parts 601, 610, and FDA Form 356h have been approved under OMB control number 0910–0338; 21 CFR part 1271 have been approved under OMB control number 0910–0543; and FDA Form 3500A has been approved under OMB control number 0910–0291.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[OMB Control Number 0917–0006]

Request for Public Comment: 60-Day Proposed Information Collection: Application for Participation in the IHS Scholarship Program

AGENCY: Indian Health Service.

ACTION: Notice.

SUMMARY: In compliance with Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 60-days advance opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: 0917–0006, ''Application for Participation in the IHS Scholarship Program.'' *Type of Information Collection Request:* Three year extension of the currently approved information collection, 0917–0006, ''Application for Participation in the IHS Scholarship Program.'' *Form Number(s):* IHS–856–3, IHS–856–5 through 856–19, IHS–856–21 through 856–24, IHS–817, and IHS–818 are retained for use by the IHS Scholarship Program (IHSSP) as part of this current Information Collection Request. Reporting forms are found on the IHS Web site at *www.ihs.gov/scholarship*. Form Numbers: IHS–856, IHS–856–2, IHS–856–4, IHS–856–20, IHS–815, and IHS–816 have been deleted from the previous Information Collection Request in an effort to comply with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Need and Use of Information Collection: The IHS Scholarship Branch needs this information for program administration and uses the information to: solicit, process, and award IHS Pre-graduate, Preparatory, and/or Health Professions Scholarship recipients; monitor the academic performance of recipients; and to place recipients at payback sites. The IHS Scholarship Program streamlined the application process by converting the IHS–856 to an electronic tool and reduced the number of required supplemental application and reporting forms to minimize the time needed by applicants and recipients to complete the application process and provide required information after receiving a scholarship from the IHSSP. The IHSSP application is electronically available on the internet at the IHS Web site at: *http://www.ihs.gov/scholarship/apply_now.cfm*.

Affected Public: Individuals, not-for-profit institutions and State, local or Tribal Governments.

Type of Respondents: Students pursuing health care professions.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hours.

Data collection instrument(s)	Number of respondents	Responses per respondent	Total annual response	Burden hour per response*	Annual burden hours
Faculty/Employer Evaluation (IHS–856–3)	1500	2	3000	0.42 (25 min)	1250
Delinquent Federal Debt (IHS–856–5)	1500	1	1500	0.13 (8 min)	200
Course Curriculum Verification (IHS–856–6)	1500	1	1500	0.70 (42 min)	1050
Verification of Acceptance or Decline of Award (IHS–856–7).	500	1	500	0.13 (8 min)	67
Recipient's Initial Program Progress Report (IHS–856–8).	1200	1	1200	0.13 (8 min)	160
Notification of Academic Problem (IHS–856–9).	50	1	50	0.13 (8 min)	7
Change of Status (IHS–856–10)	50	1	50	.045 (25 min)	21
Request for Approval of Deferment (IHS–856–11).	20	1	20	0.13 (8 min)	3
Preferred Placement (IHS–856–12)	150	1	150	0.50 (30 min)	75
Notice of Impending Graduation (IHS–856–13).	170	1	170	0.17 (10 min)	28
Notification of Deferment Program (IHS–856–14).	20	1	20	0.13 (8 min)	3
Placement Update (IHS–856–15)	170	1	170	0.18 (11 min)	31
Annual Status Report (IHS–856–16)	200	1	200	0.25 (15 min)	50
Extern Site Preference Request (IHS–856–17).	300	1	300	0.13 (8 min)	40
Request for Extern Travel Reimbursement (IHS–856–18).	150	1	150	0.10 (6 min)	15
Lost Stipend Payment (IHS–856–19)	50	1	50	0.13 (8 min)	7
Summer School Request (IHS–856–21)	100	1	100	0.10 (6 min)	10
Change of Name or Address (IHS–856–22)	20	1	20	0.13 (8 min)	3
Request for Credit Validation (IHS–856–23)	30	1	30	0.10 (6 min)	3
Faculty/Advisor Evaluation (IHS–856–24)	1500	2	3000	0.42 (25 min)	1250
Scholarship Program Agreement (IHS–817)	175	1	175	0.16 (10 min)	29