(a) through (f) and (k) has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001. We are not reestimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as explained in the following paragraphs, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, an amendment, or a supplement contain patent information described under § 314.53.

Section 314.53 requires that an applicant submitting an NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on Forms FDA 3542 and 3542a, the required patent information described in this section.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, an amendment, or a supplement (collectively referred to as ''application'') the required patent declaration(s) on Form FDA 3542a for each ''patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product'' (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method of use. If a patent is issued after the application is filed with FDA, but before the application is approved, the applicant must submit the required patent information on Form FDA 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use for listing in the Orange Book. In addition, for patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 314.50 (citing § 314.53)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form FDA 3542	183	2.8	512	5	2,560
Form FDA 3542a	201	2.8	563	20	11,260
Total	13,820				

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

The numbers of patents submitted to FDA for listing in the Orange Book in 2010, 2011, and 2012 were 351, 329, and 458, respectively, for an annual average of 379 (351 patents + 329 patents + 458 patents)/3 years = 379 patents/year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our previous review of submissions, we believe that approximately 14 percent of the patents submitted are included in multiple NDA submissions, and thus require multiple patent declarations. Therefore, we estimate that 53 (379 patents × 14 percent) patents will be multiple listings, and there will be a total of 432 patents (379 patents + 53 patents = 432 patents) declared on Form FDA 3542. We approved 84, 93, and 86 NDAs in 2010, 2011, and 2012, respectively, of which approximately 71 percent submitted patent information for listing in the Orange Book. The remaining NDAs submitted Form FDA 3542 as required and declared that there were no relevant patents. We also approved approximately 101, 83, and 101 NDA supplements in 2010, 2011, and 2012, respectively, for which submission of a patent declaration would be required. We estimate there will be 183 instances (based on an average of 88 NDA approvals and 95 supplement approvals per year) where an NDA holder would be affected by the patent declaration requirements, and that each of these NDA holders would, on average, submit 2.8 declarations (432 patent declarations + 76 no relevant patent declarations)/183 instances = 2.8 declarations per instance) on Form FDA 3542. We filed 96, 91, and 112 NDAs in 2010, 2011, and 2012, respectively, and 100, 91, and 112 NDA supplements in 2010, 2011, and 2012, respectively, for which submission of a patent declaration would be required. We estimate there will be 201 instances (based on an average of 100 NDAs filed and 101 NDA supplements filed per year) where an NDA holder would be affected by the patent declaration requirements. We estimate, based on a proportional increase from the number of declarations for approved NDAs, that there will be an annual total of 563 declarations (201 instances × 2.8 declarations per instance = 563 declarations) on Form FDA 3542a submitted with these applications. Based upon information provided by regulated entities and other information, we previously estimated that the information collection burden associated with § 314.50(h) (citing § 314.53) and Forms FDA 3542 and 3542a will be approximately 5 hours and 20 hours per response, respectively.

Dated: June 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14299 Filed 6–14–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0490]

Draft 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; 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 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'' dated June 2013. The draft guidance document provides advice to potential sponsors, such as cord blood banks, registries, transplant centers, or individual physicians serving as sponsor-investigators, to assist in the submission of an Investigational New Drug Application (IND) for certain hematopoietic progenitor cells from placental/umbilical cord blood (HPC, Cord Blood), when such HPC, Cord Blood units are not licensed, and when a suitable human leukocyte antigen matched cord blood transplant is needed for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment and there is no satisfactory alternative treatment available. If unlicensed HPC, Cord Blood units are made available for clinical use, they must be distributed under an IND. The 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.

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 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'' dated June 2013. The draft guidance, when finalized, will provide advice to potential sponsors to assist in the submission of an IND for certain HPC, Cord Blood, when such HPC, Cord Blood units are not licensed in accordance with Title 21 Code of Federal Regulations Part 601 (21 CFR part 601), and when a suitable human leukocyte antigen matched cord blood transplant is needed for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment and there is no satisfactory alternative treatment available. If unlicensed HPC, Cord Blood units are made available for clinical use, they must be distributed under an IND meeting the applicable requirements in 21 CFR part 312. The 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.

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: 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.'' That 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.

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 312 have been approved under OMB control number 0910–0014; 21 CFR part 56 have been approved under OMB control number 0910–0130; 21 CFR part 1271 have been approved under OMB control number 0910–0543; and Form FDA 1571 has been approved under OMB control number 0910–0014.

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.

[FR Doc. 2013–14096 Filed 6–14–13; 8:45 am]

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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.

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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