TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Written procedures for conducting verification activities; 1.506(b), 1.511(c)(3).	11,701	1	11,701	2	23,402
Determination and documentation of appropriate supplier verification activities; 1.506(d)(1)–(2), 1.511(c)(5)(i).	11,701	4	46,804	3.25	152,113
Review of appropriate supplier verification activities determined by another entity; 1.506(d)(3), 1.511(c)(5)(iii).	11,701	2	23,402	0.33 (20 minutes)	7,723
Conduct/review audits; 1.506(e)(1)(i), 1.511(c)(4)(ii)(A).	11,701	2	23,402	3	70,206
Conduct periodic sampling/testing; 1.506(e)(1)(ii), 1.511(c)(4)(ii)(B).	11,701	2	23,402	1	23,402
Review records; 1.506(e)(1)(iii), 1.511(c)(4)(ii)(C)	11,701	2	23,402	1.6	37,443
Document your review of supplier verification activity records; 1.506(e)(3), 1.511(c)(4)(iii).	11,701	6	70,206	0.25 (15 minutes)	17,552
1.507(a)(1)	11,701	3.17	37,092	1.25	46,365
Written assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4).	11,701	8.72	102,038	0.50 (30 minutes)	51,019
Disclosures that accompany assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4).	102,038	1	102,038	0.50 (30 minutes)	51,019
Document assurances from customers; 1.507(c)	36,522	2.8	102,262	0.25 (15 minutes)	25,566
Document corrective actions; 1.508(a) and 1.512(b)(4).	2,340	1	2,340	2	4,680
Investigate and determine FSVP adequacy; 1.508(b), 1.511(c)(1).	2,340	1	2,340	5	11,700
Subtotal for FSVP Recordkeeping Itemized Above.			4,984,046		1,917,186
Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511(b).	11,701	2.88	33,699	2.25	75,823
Document very small importer/certain small foreign supplier status; 1.512(b)(1).	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier 1.512(b)(3).	50,450	2.8	141,260	2.25	317,835
Total					2,361,294

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

We are retaining the currently approved burden estimates. The FSVP requirements became effective May 30, 2017, and we continue to evaluate associated burden.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22953 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–E–0675, FDA–2018–E–0678, and FDA–2018–E–0689]

Determination of Regulatory Review Period for Purposes of Patent Extension; BESPONSA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for BESPONSA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 21, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 22, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 21, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 21, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2018–E–0675, FDA–2018–E–0678, and FDA–2018–E–0689 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BESPONSA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product BESPONSA (inotuzumab ozogamicin). BESPONSA is indicated for treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Subsequent to this approval, the USPTO received patent term restoration applications for BESPONSA (U.S. Patent Nos. 8,153,768; 8,835,611; and 8,747,857) from Wyeth Holdings LLC, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 4, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of BESPONSA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for BESPONSA is 5,298 days. Of this time, 5,057 days occurred during the testing phase of the regulatory review period, while 241 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* February 16, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 16, 2003.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): December 20, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for BESPONSA (BLA 761040) was

initially submitted on December 20, 2016.

3. *The date the application was approved:* August 17, 2017. FDA has verified the applicant's claim that BLA 761040 was approved on August 17, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 654 days, 703 days, or 1,099 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22958 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4308]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Labeling of Red Blood Cell Units With Historical Antigen Typing Results

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 21, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Draft Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Labeling of Red Blood Cell Units With Historical Antigen Typing Results, OMB Control Number 0910–NEW

The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The draft guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under 21 CFR 601.12.

Description of Respondents: Establishments that collect blood and blood components intended for transfusion.

Burden Estimate: We believe that the information collection provisions in the draft guidance do not create a new burden for respondents and are part of usual and customary business practices. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

The guidance also recommends establishments that collect blood and blood components for transfusion should convey to transfusion services the practices for repeating historical RBC typing results on current donations and for labeling RBC units with historical RBC antigen typing results.

We believe that collection establishments have already developed standard operating procedures for including the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label, and for conveying any change in their antigen typing or labeling practices to their consignees, including practices for repeating historical RBC typing results on current donations and for labeling RBC units with historical RBC antigen typing results.

In the **Federal Register** of January 3, 2017 (82 FR 130), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six comments on the guidance; however, no comments were related to the collection of information.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR