TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURES [1]

Activity/21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]	Total operating and maintenance costs
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2)	0.1	1	0.1	200	20	$50
Clinical images; facility [2]—900.4(c), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	1.44	4,154	
Clinical images; AB [3]—900.4(c)	5	1	5	416	2,080	230,773
Phantom images; facility [2]—900.4(d), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	0.72	2,077	
Phantom images; AB [3]—900.4(d)	5	1	5	208	1,040	
Annual equipment evaluation and survey; facility [2]—900.4(e), 900.11(b)(1), and 900.11(b)(2)	8,654	1	8,654	1	8,654	8,654
Annual equipment evaluation and survey; AB [3]—900.4(e)	5	1	5	1,730	8,650	
Provisional mammography facility certificate extension application—900.11(b)(3)	0	1	0	0.5	1	
Mammography facility certificate reinstatement application—900.11(c)	312	1	312	5	1,560	24,000,000
Lay summary of examination—900.12(c)(2)	8,654	5,085	44,005,590	0.083	3,652,464	
Lay summary of examination; patient refusal [4]—900.12(c)(2)	87	1	87	0.5	44	
Report of unresolved serious complaints—900.12(h)(4)	20	1	20	1	20	
Information regarding compromised quality; facility [2]—900.12(j)(1)	20	1	20	200	4,000	300
Information regarding compromised quality; AB [3]—900.12(j)(1)	20	1	20	320	6,400	600
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500	19,375
Reconsideration of accreditation—900.15(c)	5	1	5	2	10	
Notification of requirement to correct major deficiencies—900.24(a)	0.4	1	0.4	200	80	68
Notification of loss of approval; major deficiencies—900.24(a)(2)	0.15	1	0.15	100	15	25.50
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60	51
Notification of loss of approval; minor deficiencies—900.24(b)(3)	0.15	1	0.15	100	15	25.50
Total					3,691,842	24,259,921

[1] There are no capital costs associated with this collection of information.
[2] Total hours have been rounded.

Dated: February 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04677 Filed 2–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0156]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZYTIGA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the

actual amount of extension that the Director of Patents and Trademarks 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 drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZYTIGA (abiraterone acetate). ZYTIGA is indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZYTIGA (U.S. Patent No. 5,604,213) from BTG International LTD, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 9, 2012, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZYTIGA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZYTIGA is 1,927 days. Of this time, 1,797 days occurred during the testing phase of the regulatory review period, while 130 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* January 19, 2006. The applicant claims January 28, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 19, 2006, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 20, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for ZYTIGA (NDA 202–379) was submitted on December 20, 2010.

3. *The date the application was approved:* April 28, 2011. FDA has verified the applicant's claim that NDA 202–379 was approved on April 28, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,024 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by April 29, 2013. 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 August 27, 2013. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document. Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04645 Filed 2–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0162]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LAVIV and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: 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 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 Patents and Trademarks 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 recently approved for marketing the human biologic product LAVIV (azficel-T). LAVIV is an autologous cellular product indicated for improvement of moderate to severe