

TABLE 4.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN FOR HUMAN DRUGS AND BIOLOGICS¹

Total human drugs burden hours	64,475,247
Total biologics burden hours	6,901,454
Total burden hours	71,376,701

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

Dated: February 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E-0254]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ERBITUX 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 written or electronic comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 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 biological product ERBITUX (cetuximab). ERBITUX, used in combination with irinotecan, is indicated for the treatment of epidermal growth factor receptor (EGFR)-expressing metastatic colorectal carcinoma in patients who are refractory to irinotecan-based chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ERBITUX (U.S. Patent No. 6,217,866) from Aventis Pharmaceuticals, 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 8, 2005, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ERBITUX represented the first permitted commercial marketing or use of the product. Shortly 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 ERBITUX is 3,375 days. Of this time,

3,192 days occurred during the testing phase of the regulatory review period, while 183 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:* November 18, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 18, 1994.

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):* August 14, 2003. The applicant claims August 12, 2003, as the date the product license application (BLA) for ERBITUX (BLA 125084) was initially submitted. However, FDA records indicate that BLA 125084 was submitted on August 14, 2003.

3. *The date the application was approved:* February 12, 2004. FDA has verified the applicant's claim that BLA 125084 was approved on February 12, 2004.

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 391 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination by April 18, 2006. 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 16, 2006. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one

copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6-2354 Filed 2-16-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0283]

Guidance for Industry on Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#171) entitled "Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." This guidance describes the procedures that the agency recommends for the review of requests for waiver of *in vivo* demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance via the Internet at <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl.,

Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Marilyn Martinez, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7577, e-mail: marilyn.martinez@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 3, 2004 (69 FR 46553), FDA published a notice of availability for a draft guidance document entitled "Draft Guidance for Industry: Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles" giving interested persons until October 18, 2004, to submit comments on the draft guidance and until October 4, 2004, to comment on the information collection. FDA considered all comments received and, where appropriate, made changes in the guidance. The final guidance differs from the draft guidance in the following ways: (1) The relationship between granting or denying a waiver based on a demonstration of bioequivalence and granting or denying a generic approval based on the safety of a biomass Type A article has been clarified; (2) the nature of the information needed to support, and the applicability of, the "Comparison of Formulations" approach described in the guidance has been clarified; (3) the title of table 1 of the guidance has been clarified; (4) one value in table 2 of the guidance has been updated; and (5) other relatively minor editing has been done to clarify the substance of the document. There were no comments directed specifically at the collection of information.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on the 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA is announcing that a collection of information entitled "Guidance for Industry: Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles" has been approved

by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. In the **Federal Register** of October 24, 2005 (70 FR 61451), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. The valid OMB control number for this collection of information is 0910-0575. It expires on January 31, 2009. A copy of the supporting statement is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

IV. Comments

As with all FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket, and where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments at any time. Submit a single copy of electronic comments or two paper copies of any comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Copies of the guidance document entitled "Waivers of *In Vivo* Demonstration of Bioequivalence of Certain Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles" may be obtained from the Center for Veterinary Medicine's Home Page at <http://www.fda.gov/cvm> and from the Division of Dockets Management Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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