

donors. Section 1270.33(f) requires records to be retained regarding the determination of the suitability of the donors and such records required under § 1270.21. Section 1270.33(h) requires all records to be retained at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration of the tissue, whichever is the latest. Section 1270.35(a) through (d) requires specific records to be maintained to document the following: (1) The results and interpretation of all required infectious disease tests, (2) information on the identity and relevant medical records of the donor, (3) the receipt and/or distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. Based on information from the Center for Biologics Evaluation and Research's (CBER's) database system, FDA estimates that there are approximately 257 tissue establishments of which 145 are conventional tissue banks and 112 are eye tissue banks. Based on information provided by industry, there are an estimated total of 1,959,270

conventional tissue products and 82,741 eye tissue products recovered per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 57,275 donors of conventional tissue and 54,115 donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirements in part 1270. Based on information provided by CBER's database system, 90 percent of the conventional tissue banks are members of AATB ( $145 \times 90\% = 130$ ), and 77 percent of eye tissue banks are members of EBAA ( $112 \times 77\% = 86$ ). Therefore, recordkeeping by these 216 establishments ( $130 + 86 = 216$ ) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 41 establishments, which is 16 percent of all establishments ( $257 - 216 = 41$ , or  $41/257 = 16\%$ ).

FDA assumes that all current tissue establishments have developed written

procedures in compliance with part 1270. Therefore, their information collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures for § 1270.31(a) and (b), estimated to take an annual average of 1 hour. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h), include documenting the results and interpretation of all required infectious disease tests and results and the identity and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section                                  | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Response | Total Hours |
|---|----------------------|------------------------------------|----------------------|--------------------|-------------|
| 1270.31(a), (b), (c), and (d) <sup>2</sup>      | 41                   | 1                                  | 41                   | 24                 | 984         |
| 1270.31(a) and (b) <sup>3</sup>                 | 41                   | 2                                  | 82                   | 1                  | 82          |
| 1270.33(a), (f), and (h) and 1270.35(a) and (b) | 41                   | 8,404                              | 344,564              | 1                  | 344,564     |
| 1270.35(c)                                      | 41                   | 15,938                             | 653,458              | 1                  | 653,458     |
| 1270.35(d)                                      | 41                   | 1,992                              | 81,672               | 1                  | 81,672      |
| Total   |                      |                                    |                      |                    | 1,080,760   |

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

<sup>2</sup> Review and update of SOPs.

<sup>3</sup> Documentation of deviations from SOPs.

Dated: February 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-E-0206]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; FIRMAGON

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for

FIRMAGON 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 written 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.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**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 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 FIRMAGON (degarelix acetate). FIRMAGON is indicated for treatment of patients with advanced prostate cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FIRMAGON (U.S. Patent No. 5,925,730) from Ferring BV, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FIRMAGON 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 FIRMAGON is 2,695 days. Of this time, 2,394 days occurred during the testing phase of the regulatory review period, while 301 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 act) (21 U.S.C. 355(i)) became effective:* August 10, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 10, 2001.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* February 28, 2008. FDA has verified the applicant's claim that the new drug application (NDA) 22-201 was submitted on February 28, 2008.

3. *The date the application was approved:* December 24, 2008. FDA has verified the applicant's claim that NDA 22-201 was approved on December 24, 2008.

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 1,498 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**) written or electronic comments and ask for a redetermination by April 30, 2010. 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 30, 2010. 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: February 9, 2010.

**Jane A. Axelrad,**

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

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2010-D-0075]**

#### **Draft Guidance for Industry on Non-Inferiority Clinical Trials; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Non-Inferiority Clinical Trials." This draft guidance provides sponsors and review staff in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) with the agency's interpretation of the underlying principles involved in the use of non-inferiority (NI) study designs to provide evidence of the effectiveness of a drug or therapeutic biologic product. The draft guidance offers advice on when NI studies can be interpretable, how to choose the NI margin, and how to analyze the results.

**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 written or electronic comments on the draft guidance by June 1, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or to the Office of Communication, Outreach and Development, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.