estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Health and Diet Survey (OMB Control Number 0910–0545)—Extension

FDA is seeking extension of OMB approval for the Health and Diet Survey, which is a voluntary consumer survey intended to gauge and track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition and physical activity. The authority for FDA to collect the information derives from the FDA Commissioner's authority provided in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The survey consists of two independent data collection activities. One collection, entitled ''Health and Diet Survey—General Topics,'' tracks a broad range of consumer attitudes, awareness, knowledge and self-reported behaviors related to key diet and health issues. The other collection, entitled ''Health and Diet Survey—*Dietary Guidelines* Supplement,'' will provide FDA with updated information about consumer attitudes, awareness, knowledge, and behavior regarding various elements of nutrition and physical activity based on the key recommendations of the *Dietary Guidelines for Americans*, which are jointly issued by the Department of Health and Human Services (HHS) and Department of Agriculture every 5 years.

The information to be collected with the Health and Diet Survey—General Topics will include: (1) Awareness of diet-disease relationships; (2) food and dietary supplement label use; (3) dietary practices including strategies to lose or maintain weight; and, (4) awareness and knowledge of dietary fats. The information to be collected with the Health and Diet Survey—*Dietary Guidelines* Supplement will include: (1) Awareness and sources of information; (2) attitudes toward diet and physical activity; and, (3) practice and knowledge related to recommended behaviors. The survey will also ask about perceptions and use of Federal nutrition information, special diet, weight status, health status, and demographics.

FDA and other Federal agencies will use the information from the Health and Diet Survey to evaluate and develop strategies and programs to encourage and help consumers adopt healthy lifestyles. The information will also help the FDA and other Federal agencies evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health.

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 states and the District of Columbia. Participation will be voluntary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
General Topics: Pretest	27≤	1	27	0.25	6.75
General Topics: Screener	10,000	1	10,000	0.02	200
General Topics: Survey	3,000	1	3,000	0.25	750
Dietary Guidelines Supplement: Screener	4,000	1	4,000	0.02	80
Dietary Guidelines Supplement: Survey	1,200	1	1,200	0.22	264
Total					1,300.75

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

FDA has based its estimate of the number of respondents and the burden hours per response on its experience with the Health and Diet Survey over the past 3 years. The agency will use a screener to select an eligible adult respondent in each household to participate in the survey. For the Health and Diet Survey—General Topics data collection activity a total of 3,000 adults in the 50 states and the District of Columbia will be interviewed by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions and 15 minutes (0.25 hours) to complete the entire survey. Prior to the administration of the survey, the agency plans to conduct a pretest to identify and resolve potential problems. The pretest will be conducted with 27 participants; we estimate that it will take a respondent 15 minutes (0.25 hours) to complete the pretest. For the Health and Diet Survey—*Dietary Guidelines*Supplement data collection activity a total sof 1,200 adults in the 50 states and the District of Columbia will be interviewed by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions and 13.2 minutes (0.22 hours) to complete the entire survey. Target sample size of the combined data collection is 4,200 respondents who complete the survey.

Dated: May 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10086 Filed 5–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007E–0009]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MYOZYME 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 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: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 MYOZYME (recombinant human acid alpha glucosidase). MYOZYME is indicated for use in patients with Pompe disease (GAA deficiency). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MYOZYME (U.S. Patent No. 6,118,045) from Genzyme Corp., Erasmus MC, Erasmus Universiteit, and The Universiteit Leiden, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 6, 2007, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of MYOZYME 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 MYOZYME is 1,225 days. Of this time, 950 days occurred during the testing phase of the regulatory review period, while 275 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*: December 22, 2002. The applicant claims November 25, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 22, 2002, which was 30 days after FDA receipt of the IND.

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)*: July 28, 2005. The applicant claims July 29, 2005, as the date the biologics license application (BLA) for MYOZYME (BLA 125141/0) was initially submitted. However, FDA records indicate that BLA 125141/0 was submitted on July 28, 2005.

3. *The date the application was approved*: April 28, 2006. FDA has verified the applicant's claim that BLA 125141/0 was approved on April 28, 2006.

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 1,251 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 or electronic comments and ask for a redetermination by July 24, 2007. 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 November 21, 2007. 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: May 7, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–10087 Filed 5–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0516]

Determination of Regulatory Review Periods for Purposes of Patent Extension; SPRYCEL—New Drug Applications 21–986 and 22–072

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SPRYCEL—new drug applications (NDAs) 21–986 and 22–072 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