FDA received no submissions under § 660.36, however FDA is using the estimate of one protocol submission in the event one is submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2008, which totaled 6,314, for the various submission requirements of samples and protocols for the licensed biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the other protocols than under § 610.2.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	65	95.5	6,208	3	18,624
660.6(b)	2	44	88	5	440
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	1	17	17	5	85
Total	69		6,314		19,155

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

Dated: February 24, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4750 Filed 3–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0083]

Agency Information Collection Activities; Proposed Collection; Comment Request; Gluten-Free Labeling of Food Products Experimental Study

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary consumer study entitled ''Gluten-Free Labeling of Food Products Experimental Study.''

DATES: Submit written or electronic comments on the collection of information by May 5, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's 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.

Gluten-Free Labeling of Food Products Experimental Study

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. FDA is planning to conduct an experimental study about gluten-free labeling of food products. The Gluten-Free Labeling of Food Products Experimental Study will collect information from both consumers who have celiac disease or gluten intolerance and those who do not have either condition. The purpose of the study is to gauge perceptions of characteristics related to claims of ''gluten-free'' and allowed variants (e.g., ''free of gluten,'' ''without gluten,'' ''no gluten''), in addition to other types of statements (e.g., ''made in a gluten-free facility'' or ''not made in a facility that processes gluten-containing foods'') on the food label. The study will also

assess consumer understanding of ''gluten-free'' claims on foods that are naturally free of gluten, and gauge consumer reaction to a product carrying a gluten claim concurrently with a statement about the amount of gluten the product contains.

The data will be collected over the Internet from samples derived from two sources: (1) A membership list from a celiac disease special interest organization and (2) an online consumer panel. Participation in the study is voluntary.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	6,000	1	6,000	0.0055	33
Pretest	140	1	140	.167	23.38
Experiment	5,000	1	5,000	.167	835
Total					891.38

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

Approximately 6,000 respondents will be screened. We estimate that it will take a respondent 20 seconds (0.0055 hours) to complete the screening questions, for a total of 33 hours. A pretest will be conducted with 140 participants; we estimate that it will take a respondent 10 minutes (0.167 hours) to complete the pretest, for a total of 23.38 hours. Five thousand adults will complete the experiment. We estimate that it will take a respondent 10 minutes (0.167 hours) to complete the entire experiment, for a total of 835 hours. Thus, the total estimated burden is 891.38 hours. FDA's burden estimate is based on prior experience with consumer experiments that are similar to this proposed experiment.

Dated: February 23, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4766 Filed 3–5–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0105]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ARRANON 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 human drug 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 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 ARRANON (nelarabine). ARRANON is indicated for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ARRANON (U.S. Patent No. 5,424,295) from,SmithKline Beecham Corp. (DBA GlaxoSmithKline), and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 28, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ARRANON 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 ARRANON is 4,163 days. Of this time, 3,980 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the