Dated: April 30, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0271]

Agency Information Collection Activities; Proposed Collection; Comment Request; Consumer Survey on the Impact of Perceptions of the 2006 Spinach Recall on Current Spinach Consumption

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 proposed survey of how consumer perceptions of the 2006 spinach recall affect their current spinach consumption behaviors.

DATES: Submit written or electronic comments on the collection of information by July 11, 2008.

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 the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Consumer Survey on the Impact of Perceptions of the 2006 Spinach Recall on Current Spinach Consumption

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (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. Under this authority, FDA is planning to conduct a consumer survey to assess how current perceptions of the 2006 spinach recall affect attitudes toward, and decisionmaking regarding, current spinach consumption. FDA will use the study to evaluate how its communications about the 2006 spinach recall affected consumers. In particular, FDA plans to evaluate the effects of emotions and cognition associated with consumer recollection of the 2006 spinach outbreak on current spinach consumption behavior.

In September 2006, the United States experienced an outbreak of E. coli 0157:H7 infections in several States. Outbreak investigation by the Centers for Disease Control and Prevention, FDA, and Federal, State, and local partners linked the E. coli 0157:H7 to bagged fresh spinach that was sold nationwide (*http://www.fda.gov/bbs/topics/NEWS/2007/NEW01593.html*). On September 14, 2006, FDA held a press teleconference and issued a press release alerting consumers about the outbreak (*http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html*). In addition to warning of the seriousness of the outbreak, the press release advised that consumers ''not eat bagged fresh spinach at this time.'' On September 16, 2006, FDA expanded its advice to consumers, advising them ''to not eat fresh spinach or fresh spinach-containing products until further notice'' (*http://www.fda.gov/bbs/topics/NEWS/2006/NEW01452.html*). Finally, FDA reported in its September 22, 2006, press statement that spinach grown outside the limited geographical area to which the outbreak had been traced was not implicated in the outbreak and could be consumed (*http://www.fda.gov/bbs/topics/NEWS/2006/NEW01462.html*). This report stated, ''The public can be confident that spinach grown in the non-implicated areas can be consumed. Other produce grown in these counties is not implicated in this outbreak. Processed spinach (e.g., frozen and canned spinach) is also not implicated in this outbreak.''

Market research has shown that the 2006 fresh spinach recall had a tremendous economic impact on the spinach industry, as retail sales values continued to lag for months after the recall was over (*http://www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm*). Consumer confidence in the product has been blamed for the slow recovery.

The survey will be used to gauge whether and how FDA and media communication about the recall affected consumers' enduring emotional and cognitive perceptions about the product, and whether or not these perceptions have an impact on their current spinach consumption. Findings from this study will be used to help FDA more effectively communicate with consumers.

The data will be collected using a Web-based questionnaire. A pool of 35,000 people will be screened (through self-report) on current and past fresh spinach consumption. A random sample of 1,000 consumers will be selected.

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	35,000	1	35,000	0.0055	192.5
Survey	1,000	1	1,000	0.167	167
Total					359.5

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

FDA's burden estimate is based on prior experience with consumer surveys that are similar to this proposed survey.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–10467 Filed 5–9–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0398] (formerly Docket No. 2007E–0131)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OMNARIS 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 approved for marketing the human drug product OMNARIS (ciclesonide). OMNARIS is indicated for the treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OMNARIS (U.S. Patent No. 5,482,934) from Altana Pharma AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 16, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of OMNARIS 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 OMNARIS is 3,196 days. Of this time, 2,893 days occurred during the testing phase of the regulatory review period, while 303 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*: January 21, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 21, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 22, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for OMNARIS (NDA 22–004) was initially submitted on December 22, 2005.

3. *The date the application was approved*: October 20, 2006. FDA has verified the applicant's claim that NDA 22–004 was approved on October 20, 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 1,748 days of patent term extension.