1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: July 7, 2000. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on June 8, 2000. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on July 7, 2000, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: December 26, 2001. The applicant claims December 21, 2001, as the date the premarket approval application (PMA) for ACRYSOF (PMA P930014/S009) was initially submitted. However, FDA records indicate that PMA P930014/S009 was submitted on December 26, 2001.

3. *The date the application was approved*: June 24, 2003. FDA has verified the applicant's claim that PMA P930014/S009 was approved on June 24, 2003.

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 832 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 June 2, 2008. 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 September 29, 2008. 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: November 16, 2007.

Jane A. Axelrad,

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

[FR Doc. E8–6851 Filed 4–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0184]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Submit written or electronic comments on the collection of information by June 2, 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, including each proposed extension of an existing 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.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i) (OMB Control Number 0910–0133)—Extension

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''[w]henever * * * such action will promote honesty and fair dealing in the interest of consumers * * * .'' Under section 403(g) of the act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable

definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

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
130.17(c)	13	2	26	25	650
130.17(i)	1	2	2	2	4
Total					654

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

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received October 1, 2004, through September 30, 2007, and information from firms that have submitted recent requests for temporary marketing permits.

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 through FDMS only.

Dated: March 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–6887 Filed 4–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0188]

Food Protection Plan; Outreach Activities; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a public docket to receive information and comments related to its comprehensive Food Protection Plan (the Plan) released in November 2007. The new Plan presents a robust strategy to protect the nation's food supply from both unintentional contamination and deliberate attack. FDA is establishing this docket for the purpose of soliciting comments from its stakeholders on the Plan and the questions set forth in this notice.

DATES: Submit written or electronic comments by July 31, 2008.

ADDRESSES: Submit written comments 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*. To ensure timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. All comments to FDA on the Plan should be submitted through the docket.

FOR FURTHER INFORMATION CONTACT: Kari Barrett, Office of the Commissioner (HF–60), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–9831, FAX: 301–827–2866.

SUPPLEMENTARY INFORMATION:

I. Background

For more than 100 years, FDA has protected the health of Americans by ensuring the safety of the food supply (other than meat, poultry, and processed egg products that are regulated by the U.S. Department of Agriculture). Every day across the country people eat out, buy groceries, cook meals for their families, and feed their pets. Americans expect that all their food will be safe, and FDA plays a critical role in making sure this is true. Specifically, FDA is responsible for the safety of 80 percent of all food sold in the United States.

The U.S. food supply is one of the safest in the world. Current trends in the food industry promise better nutrition and wider choices for consumers. At the same time, new trends in demographics, consumption, food production technology, and business practices all pose challenges for maintaining this safe food supply. For example, consumers today want the convenience of opening a bag of salad that is already prepared. In the past a single head of lettuce that was contaminated may have resulted in one family being ill. Now, a contaminated head of lettuce may be processed with many others and be placed into bags of convenience salad that many consumers can buy. These bags of salad, if contaminated, could result in hundreds of illnesses.

The supply of food consumed in the United States is increasingly imported, introducing a greater challenge for improving the information FDA has regarding conditions under which food is produced in foreign countries. The United States trades with over 150 countries and territories with products coming into over 300 U.S. ports. Fifteen percent of the food supply by volume in the United States is imported. Sixty percent of fresh fruits and vegetables are imported. More than 75 percent of seafood is imported. Although many foreign countries have well developed regulatory systems to ensure food safety, others have systems that may not be able to ensure food safety to the same degree.

FDA also faces the challenge of foodborne illnesses caused by known hazards as well as new threats. In 1999, the Centers for Disease Control and Prevention estimated that there were approximately 76 million cases per year of illness from foodborne agents in the United States, with 325,000 hospitalizations and 5,000 deaths. Foodborne illnesses are caused by more than 200 different foodborne pathogens (agents that can cause illness) of which we are aware. The variety of agents associated with foodborne illness has steadily grown over the last few decades, and there is every probability that this list will continue to increase. In addition, the recent incident in which vegetable protein products were contaminated with melamine was a deliberate act for economic gain. Although this was not considered an act of terrorism, it resulted in the sickness and death of cats and dogs.

Another important challenge is effective communication. FDA, States, and industry receive food safety