- Clinical outcomes for the different treatment options.
- Complications.
- Harms and adverse events.
- Persistence of benefits and harms over time.
- Generalizability to the Medicare population in routine practice.

In addition to evaluating the available data, the Committee will identify areas in which the current data are deficient and in which additional research is warranted. Background information about this topic, including panel materials, is available at *http://www.cms.hhs.gov/coverage*.

II. Meeting Procedures

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary for MCAC (see **FOR FURTHER INFORMATION CONTACT**) and submit the following to the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice: (1) A brief statement of the general nature of the evidence or arguments you wish to present; (2) the names and addresses of proposed participants; and (3) a written copy of your presentation. Your presentation should consider the questions we have posed to the Committee and focus on the issues specific to the topic.

The questions will be available on the following Web site: *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage* We require that you declare at the meeting whether you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15 minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

III. Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. Register by contacting Maria Ellis by phone or e-mail as specified in the **ADDRESSES** section. Please provide your full name (as it appears on your State-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex.

IV. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by the dates specified in the **DATES** section. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

The on-site check-in for visitors will begin at 7 a.m. Please allow sufficient time to go through the security checkpoints at both the entrance to the grounds and the entrance to the building.

Security measures also include a full inspection of vehicles, inside and exterior areas (rear, trunk, and engine) at the entrance to the grounds. In addition, all individuals entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of or support of a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for a demonstration or to support a demonstration.

Parking permits and instructions will be issued upon arrival.

Authority: 5 U.S.C. App. 2, section 10(a).

Dated: May 8, 2007.

Barry M. Straube,

Chief Medical Officer and Director, Office of Clinical Standards and Quality.

[FR Doc. E7–9780 Filed 5–24–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0200]

Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey

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 FDA's Health and Diet Survey.

DATES: Submit written or electronic comments on the collection of information by July 24, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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.

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.