Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Dated: April 12, 2012.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2012–9303 Filed 4–18–12; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0357]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Decision Analysis: A Risk-Tolerance Pilot 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 the survey entitled ''Medical Device Decision Analysis: A Risk-Tolerance Pilot Study.''

DATES: Submit either electronic or written comments on the collection of information by June 18, 2012.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

I. Background

A recent study of obesity indicates that 35.5 percent of men and 35.8 percent of women in America reported being obese in 2010. This represents an increase from 27.5 percent and 33.4 percent in 2000 for men and women, respectively (Ref. 1). People who are obese are more likely to suffer from diabetes, cardiovascular disease, respiratory and metabolic disease, and sleep apnea, as well as other physical and psychological disabilities. By some estimates, as much as $140 billion were spent in 2008 to treat obesity-related diseases (Ref. 2). Studies have shown that weight loss can significantly reduce the burden of obesity-related comorbidities (Refs. 3 and 4), and that weight lost as a result of laparoscopic banding or other weight-loss surgeries positively impacts quality of life and burden of disease (Refs. 5 through 7). However, like any surgical procedure, these surgeries are associated with substantial risks, including risks of potentially life-threatening events (Ref. 6), that patients and physicians must weigh against any potential benefits when making an informed treatment decision.

With the assistance of advisory panels, FDA determines the acceptable risk threshold of a medical intervention against its effectiveness as demonstrated in clinical evidence. In addition, individual patients and patient-advocacy groups anecdotally express their opinions about their needs and tolerance for risks to FDA through letters and public testimonies during advisory panel meetings. To evaluate the scientific validity of systematically eliciting patient perspectives on outcomes associated with weight-loss devices, the Agency requests approval of a pilot survey to quantify obesity patients' benefit-risk preferences.

The choice-format preference-elicitation survey will ask obese individuals (with a body mass index of 30 kg/m^2 or above) to evaluate a series of choices between pairs of hypothetical medical devices. Each hypothetical device will be defined by the amount and duration of weight loss, side effects, risks associated with hypothetical weight-loss devices, and the effect of the device on weight-related comorbidities. The survey was developed using findings from a literature review of the outcomes associated with weight-loss devices, interviews with obesity patients, and expert opinion.

An invitation to the online survey will be sent to a sample of 1,000 obese adults in the United States. Among the adults who receive the invitation, about

600 are expected to complete the consent form and about 450 are expected to qualify for the study and complete the survey in full. In addition to the choice-format questions, the survey also will collect information on respondent demographics, disease history, and weight-management history. There is no cost to respondents other than about 25 minutes of their time.

Final results will provide an estimate of the maximum levels of various treatment-related risks that obesity patients would be willing to accept to achieve specific levels of weight loss or improvements in weight-related diseases. These results will be used to investigate the viability of choice-format surveys as a way to quantify patients' risk tolerance for the therapeutic benefits of weight-loss devices.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Survey instrument	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Survey invitation	1,000	1	1,000	0.03	30
Consent form	700	1	700	0.03	21
Full survey	450	1	450	0.42	189
Total					240

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

II. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ogden, C.L., M.D. Carroll, B.K. Kit, and K.M. Flegal, ''Prevalence of Obesity and Trends in Body Mass Index Among U.S. Children and Adolescents, 1999–2010,'' *Journal of the American Medical Association,* vol. 307, no. 5, pp. 483–490, 2012.
2. Finkelstein, E.A., J.G. Trogdon, J.W. Cohen, and W. Dietz, ''Annual Medical Spending Attributable to Obesity: Payer- and Service-Specific Estimates,'' *Health Affairs,* vol. 28, no. 5, pp. w822-w831, 2009.
3. Dhabuwala, A., R.J. Cannan, and R.S. Stubbs, ''Improvement in Comorbidities Following Weight Loss From Gastric Bypass Surgery,'' *Obesity Surgery,* vol. 10, pp. 428–435, 2000.
4. Sjöström, L., A. Lindroos, M. Peltonen, *et al.,* ''Lifestyle, Diabetes, and Cardiovascular Risk Factors 10 Years After Bariatric Surgery,'' *The New England Journal of Medicine,* vol. 351, no. 26, pp. 2683–2693, 2004.
5. Dixon, J.B., M.E. Dixon, and P.E. O'Brien, ''Quality of Life After Lap-Band Placement: Influence of Time, Weight Loss, and Comorbidities,'' *Obesity Research,* vol. 9, no. 11, pp. 713–721, 2001.
6. Buchwald, H., Y. Avidor, E. Braunwald et al., ''Bariatric Surgery: A Systematic Review and Meta-Analysis,'' *Journal of the American Medical Association,* vol. 292, no. 14, pp. 1724–1728, 2004.
7. Dixon, J.B., M.J. Hayden, G.W. Lambert, et al., ''Raised CRP Levels in Obese Patients: Symptoms of Depression Have an Independent Positive Association,'' *Obesity,* vol. 16, no. 9, pp. 2010–2015, 2008.

Dated: April 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–9435 Filed 4–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012–N–0001]

Food and Drug Administration Patient Network Annual Meeting; Input Into Food and Drug Administration Benefit-Risk Decisionmaking: Opportunities and Challenges; Hosted by the Food and Drug Administration Office of Special Health Issues; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a meeting for patients, caregivers, independent patient advocates and patient advocate groups, and health professional groups to explore ways to more effectively include patient input in regulatory decisionmaking on drug, device, and biological products. The meeting will serve as a forum for FDA's patient stakeholders and the general public, including health professionals, academia, and industry to learn about the regulatory process related to the medical product life cycle, analyze where in the process patient input may be most practical and most valuable, and explore practicable approaches to collecting and incorporating meaningful input that well represents broad patient perspectives into regulatory decisions.

DATES: *Date and Time:* The meeting will be held on May 18, 2012, from 9 a.m. to 4:30 p.m. Register at *http://fda.contractmeetings.com/home* on or before May 4, 2012. Please include the name and title of the person attending, the name of the organization, the role within the organization, email address, and telephone number. There is no registration fee for this conference. Early registration is suggested because space is limited. We request that organizations limit the number of representatives to two. For further registration information or problems with the Web site, call Cindy de Sales, 1–240–316–3200, ext. 207.

If you need special accommodations due to a disability, please contact Steve Morin at least 7 days in advance.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503) Silver Spring, MD 20993.

Contact Person: Steve Morin, Office of Special Health Issues, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0161, FAX: 301–847–8623, *Steve.Morin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. FDA Patient Network

This is the inaugural FDA Patient Network Annual Meeting hosted by the FDA Office of Special Health Issues, the Agency's liaison to the patient and health professional communities. This annual meeting is being hosted in conjunction with the launch of the overarching FDA Patient Network program. The FDA Patient Network is a new resource for patients, caregivers, independent patient advocates, and patient advocate groups that seek to:

- Educate and inform patient stakeholders about FDA, its regulatory