4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0357]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Medical Device Decision Analysis: A Risk-Tolerance Pilot Study." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Decision Analysis: A Risk-Tolerance Pilot Study--(OMB Control Number 0910-New)

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.

In the Federal Register of April, 19, 2012 (77 FR 23484), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

Survey Instrument	No. of Respondents	No. 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: June 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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