participants in the study Management Information System (MIS).

Annual Burden Estimates

The following table provides the combined burden estimates for the previously-approved field data collection instrument, and the current request. Burden for all instruments is annualized over three years.

Activity/respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
Collection of Field Data (Approved April 20, 2012)				
Selecting Study Grantees Discussions/grantee and partner organization staff	50	1	60	50
Introductory Script and Baseline Survey (Currently Requested)				
Introductory Script:				
(1) Grantee staff	30	70.2	10	351
(2) Program applicants	2,105	1	10	351
Baseline Survey:				
(1) Study participants	2,000	1	30	1.000
Study MIS (Currently Requested)				
Study MIS:				
(1) Grantee staff	30	2,517	2	2,517

Estimated Total Annual Burden Hours: 4,269.

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.E0P.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2012–15440 Filed 6–26–12; 8:45 am]

BILLING CODE 4184–37–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0747]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form and Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form and Type A Medicated Articles'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.Vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 19, 2012, the Agency submitted a proposed collection of information entitled ''Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form and Type A Medicated Articles'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0575. The approval expires on June 30, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–15721 Filed 6–26–12; 8:45 am]

BILLING CODE 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 July 27, 2012.

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: 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: 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	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: June 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–15720 Filed 6–26–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0369]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Under the Federal Import Milk Act

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 July 27, 2012.

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 0910–0212. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov.*

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.

Regulations Under the Federal Import Milk Act—21 CFR Part 1210 (OMB Control Number 0910–0212)—Extension

Under Federal Import Milk Act (FIMA) (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F (21 U.S.C. 142).

FDA's regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

In the **Federal Register** of April 20, 2012 (77 FR 23732), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter in response to the notice. The letter contained one relevant comment, while additional comments were outside the scope of the four collection of information topics on which the notice solicits comments and will not be discussed in this document.

(Comment 1) One comment suggested that ''huge bureaucratic expenses created by the usa [sic] for 2 forms'' for taxpayers.

(Response) While FDA appreciates the comment, the commenter did not specify which two forms might create an undue expense for taxpayers. Each form relating to this information collection request is necessary for the proper performance of FDA's functions. FDA has examined each form related to this information collection request to assure its efficiency.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.11	FDA 1996/Sanitary inspection of dairy farms	2	200	400	1.5	600
1210.12	FDA 1995/Physical examination of cows	1	1	1	0.5	0.5
1210.13	FDA 1994/Tuberculin test	1	1	1	0.5	0.5
1210.14	FDA 1997/Sanitary inspections of plants	2	1	2	2	4
1210.20	FDA 1993/Application for permit	2	1	2	0.5	1
1210.23	FDA 1815/Permits granted on certificates	2	1	2	0.5	1