Request for Approval under the "Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery" (OMB Control Number: 0910-0697)

A. TITLE OF INFORMATION COLLECTION: Request for Medical Product Safety Network (MedSun) Qualitative Feedback Generic Clearance about Newsletter Services

1. PURPOSE:

   The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Office of Surveillance and Biometrics (OSB) Division of Patient Safety Partnerships (DPSP), is seeking approval for a Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery. This will be used with participants in the Medical Product Safety Network (MedSun) to survey their feedback on the MedSun Newsletter – PDF file format sent to MedSun sites only as well as Newsletter updates on the MedSun website (public domain). We request approval to evaluate the usefulness of the MedSun Newsletter (PDF sent to MedSun sites and website updates) so we may improve it, as needed. A copy of the Questionnaire is submitted as Attachment A.

   This memo serves to request approval to evaluate how effective the information and materials provided in the MedSun Newsletter (PDF sent to MedSun sites and website updates) has been to the sites in helping them become aware of timely medical device safety information, the role devices play in patient care, to report device problems, and how to train their staff to report to FDA. We will use the results of the qualitative feedback to improve, where needed, the materials we provide in the MedSun Newsletter (PDF sent to MedSun sites and website updates).

2. DESCRIPTION OF RESPONDENTS:

   MedSun is a program that is conducted by FDA to obtain information about problems with medical devices from user facility (hospitals, outpatient diagnostic centers, outpatient treatment centers, emergency services and home health agencies) representatives, primarily Risk Managers. We have been collecting medical device event data via our internet-based reporting system for ten years (data collection for MedSun started in February 2002). We have developed training materials, posters, educational offerings and medical device safety information - all of which have been distributed via the MedSun Newsletter (PDF sent to MedSun sites and website updates) to aid in training and motivating the sites to report to the program, and to aid them in promoting patient safety within their institutions.

3. TYPE OF COLLECTION: (Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.)

[ ] Customer Comment Card/Complaint Form [] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software [ ] Small Discussion Group

[ ] Focus Group [X] Other: Qualitative Feedback

4. CERTIFICATION:

I certify the following to be true:

a) The collection is voluntary.
b) The collection is low-burden for respondents and low-cost for the Federal Government.
c) The collection is non-controversial and does not raise issues of concern to other Federal Agencies.
d) The results are not intended to be disseminated to the public.
e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.
f) The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Diana Rivi, Marilyn Flack

5. PERSONALLY IDENTIFIABLE INFORMATION (PII):

a) Is personally identifiable information (PII) collected? [ ] Yes [X] No
b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
c) If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ] Yes [ ] No

6. GIFTS OR PAYMENT:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] No

BURDEN HOURS:

Respondents are from the Private Sector

No. of Respondents: 1200
Participation Time: 15 minutes

7. BURDEN**:** Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
Private Sector – MedSun Representatives	1200	15	300 hours
Totals	**1200**	15	**300 hours**

8. FEDERAL COST:

The estimated annual cost to the Federal government is: $300 to purchase SurveyMonkey Survey Platform

B. STATISTICAL METHODS

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents:

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[X] Yes [ ] No

Potential Universe of Respondents: Each hospital site dedicates staff who enter reports into the MedSun software and who receive the MedSun Newsletter (PDF sent to MedSun sites and website updates) – these persons are called the 'MedSun representatives' and it is these representatives that will be contacted to complete the survey. There are approximately 1200 representatives who meet these criteria. DPSP Staff that implements the MedSun program, notably Staff that manages the MedSun Newsletter, have the professional emails belonging to these representatives. Representatives will be alerted to the survey via email.
Sampling Plan: All 1200 will be included.

Administration of the Instrument:

1. How will you collect the information? (Check all that apply)

   [X] Web-based or other forms of Social Media
   [ ] Telephone
   [ ] In-person
   [ ] Mail
   [ ] Other, Explain

2. Will interviewers or facilitators be used? [ ] Yes [X] No