TABLE 5.—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

PHS Guideline Section	Description of Collection of Information Activity	21 CFR Section (unless otherwise stated)
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council's (NRC) Guide	AAALAC International Rules of Accreditation[2] and NRC Guide[3]
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care	211.100 and 211.122
3.2.6	Animal facility SOPs	PHS Policy[1]
3.3.3	Validate assay methods	211.160(a)
3.6.1	Procurement and processing of xenografts using documented aseptic conditions	211.100 and 211.122
3.6.2	Develop, implement, and enforce SOP's for procurement and screening processes	211.84(d) and 211.122(c)
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient	312.32(c)
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected	312.23(a)(6)
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify >2 yrs.); investigator case histories (2 yrs. After investigation is discontinued)	312.23(a)(6)(iii)(*f*) and (a)(6)(iii)(*g*), and 312.62(b) and (c)
4.1.2	Sponsor to justify amount and type of reserve samples	211.122
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal)	312.57(a)
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection	312.32
4.2.2.1	Document collaborations (transfer of obligation)	312.52
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly)	312.50
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories	312.57 and 312.62(b)

[1] The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" (*http://www.grants.nih.gov/grants/olaw/references/phspol.htm*). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[2] AAALAC International Rules of Accreditation (*http://www.aaalac.org/accreditation/rules.cfm*). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[3] The NRC's "Guide for the Care and Use of Laboratory Animals" (1996).

Dated: November 12, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27658 Filed 11–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Recovery Services for Adolescents and Families—New

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment will conduct a data collection on the helpfulness of recovery support services for young people and their families after leaving substance abuse treatment. Specifically, the Recovery Services for Adolescents and Families (RSAF) project is evaluating a pilot test of the following recovery support services for young people and their families find the following recovery support services helpful: (1) Telephone/text message support; (2) a recovery-oriented social networking site; and (3) a family program. Approximately 200 adolescent respondents will be asked to complete 4 data collection forms (some repeated) during 5 interviews (baseline and 4 follow-ups) over a 12 month period after enrollment or discharge from treatment. Approximately 200 collateral respondents (*i.e.,* a parent/guardian/concerned other) will be asked to complete 7 data collection forms (some repeated) during 5 interviews (baseline and 4 follow-ups) over a 12 month period after their adolescent's enrollment or discharge from treatment. Approximately 15 to 20 project staff respondents, including Project Coordinators, Telephone Support Volunteers, a Social Network Site Moderator, Family Program Clinicians,

and a Support Services Supervisor, will be asked to complete between 2 and 5 data collection forms at varying intervals during the delivery of recovery support services. Across all respondents, a total of 28 data collection forms will be used. Depending on the time interval and task, information collections will take anywhere from about 5 minutes to 2 hours to complete. A description of each data collection form follows:

Adolescent Participant

• *Global Appraisal of Individual Needs—Initial (GAIN–I 5.6.0 Full).* The GAIN is an evidence-based assessment used with both adolescents and adults and in outpatient, intensive outpatient, partial hospitalization, methadone, short-term residential, long-term residential, therapeutic community, and correctional programs. There are over 1,000 questions in this initial version that are in multiple formats, including multiple choice, yes/no, and open-ended. Eight content areas are covered: Background, Substance Use, Physical Health, Risk Behaviors and Disease Prevention, Mental and Emotional Health, Environment and Living Situation, Legal, and Vocational. Each section contains questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. GPRA data are gathered as part of this instrument in support of performance measurement for SAMHSA programs. It is administered at intake into treatment by clinical staff and used as baseline data for the project.

• *Global Appraisal of Individual Needs—Monitoring 90 Days (GAIN–M90 5.6.0 Full).* The GAIN is an evidence-based assessment used with both adolescents and adults and in outpatient, intensive outpatient, partial hospitalization, methadone, short-term residential, long-term residential, therapeutic community, and correctional programs. There are over 500 questions in this follow-up version that are in multiple formats, including multiple choice, yes/no, and open-ended. Eight content areas are covered: Background, Substance Use, Physical Health, Risk Behaviors and Disease Prevention, Mental and Emotional Health, Environment and Living Situation, Legal, and Vocational. Each section contains questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. GPRA data are gathered as part of this instrument in support of performance measurement for SAMHSA programs. It is administered by project staff at each of the follow-up timepoints.

• *Supplemental Assessment Form (SAF 0309).* The SAF contains 72 questions that are a combination of multiple choice, yes/no, and open-ended formats. Content areas include: race, happiness with parent or caregiver in several life areas, participation in prosocial activities, receipt of and satisfaction with telephone support services, and usage of and satisfaction with the project's social networking site. It is administered by project staff at each of the follow-up timepoints.

Collateral Participant (Parent/Guardian)

• *Global Appraisal of Individual Needs—Collateral Monitoring—Initial (GCI).* The GCI contains over 200 items in this initial version that are in multiple formats, including multiple choice, yes/no, and open-ended. The following content areas are covered: relationship to the adolescent respondent, background, and the adolescent's background and substance use, environment and living situation, and vocational information. There are questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. It is administered at baseline by project staff.

• *Global Appraisal of Individual Needs—Collateral Monitoring—Monitoring (GCM 5.3.3).* The GCM contains over 200 items in this follow-up version that are in multiple formats, including multiple choice, yes/no, and open-ended. The following content areas are covered: relationship to the adolescent respondent, background, and the adolescent's background and substance use, environment and living situation, and vocational information. There are questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. It is administered at each of the follow-up timepoints by project staff.

• *Supplemental Assessment Form—Collateral (SAF—Collateral).* The SAF contains 72 questions that are a combination of multiple choice, yes/no, and open-ended formats. Content areas include: knowledge about the adolescent's participation in prosocial activities, receipt of and satisfaction with telephone support services, and usage of and satisfaction with the project's social networking site. It is administered at each of the follow-up timepoints by project staff.

• *Self-Evaluation Questionnaire (SEQ).* The SEQ contains 40 multiple choice items that ask the collateral about feelings and symptoms of anxiety. It is administered at each of the follow-up timepoints by project staff.

• *Family Environment Scale (FES).* The FES contains 18 yes/no items that measure family cohesion and conflict. It is administered at each of the follow-up timepoints by project staff.

• *Relationship Happiness Scale (Caregiver Version).* The Relationship Happiness Scale contains 8 items that ask the collateral about happiness with his/her relationship with the adolescent respondent in various life areas. It is administered at each of the follow-up timepoints by project staff.

Project Coordinator

• *Eligibility Checklist.* The Eligibility Checklist contains 12 yes/no items that are used to determine whether or not an adolescent meets inclusion/exclusion criteria for the project and is eligible to be approached for informed consent. It is completed prior to informed consent by project staff.

• *Telephone Support Volunteer Notification Form.* This form contains a participant's name and contact information. It is completed by project staff and given to volunteers to notify them when someone is assigned to receive telephone support.

• *Family Program Notification Form.* This form contains a participant's name. It is completed by project staff and given to clinicians to notify them when someone is assigned to the family support group.

• *Follow-Up Locator Form—Participant (FLF–P).* The FLF–P contains over 50 items that are a combination of yes/no, multiple choice, and open-ended formats. At the time of informed consent, data are gathered by project staff about an adolescent's contact information, personal contacts, criminal justice contacts, school/job contacts, hang-out information, Internet contacts, and identifying information in order to locate and interview that adolescent over multiple follow-up intervals.

• *Follow-Up Locator Form—Collateral (FLF–C).* The FLF–C contains over 50 items that are a combination of yes/no, multiple choice, and open-ended formats. Data are gathered about a collateral's contact information, personal contacts, and job contacts in order to locate and interview that collateral over multiple follow-up

intervals. It is administered at the time of informed consent by project staff.

• *Follow-Up Contact Log.* The Follow-Up Contact Log is open-ended and provides space for all data collected during attempted and completed follow-up contacts, over the phone and in-person, to be recorded. It is completed throughout the follow-up time period.

• *Volunteer/Staff Survey.* The Volunteer/Staff Survey contains 10 items in fill-in-the-blank, yes/no, and multiple choice formats. Items ask about background, demographic information, and role in the project. It is completed once by all volunteers and staff at the start of the project.

Telephone Support Volunteer

• *Telephone Support Case Review Form.* The Telephone Support Case Review Form contains multiple rows that allow a volunteer to record 5 pieces of data about adolescents that they make phone calls to: initials, treatment discharge status/date, weeks since treatment discharge, date of last telephone session, and number of completed telephone sessions since discharge. This allows the volunteer and supervisor to monitor the progress of active cases. The form is completed by the volunteers every week.

• *Telephone Support Call Log.* The Telephone Support Call Log is open-ended and provides space for all data collected during attempted and completed support contacts to be recorded. The form is completed by the volunteer throughout the period of telephone support.

• *Adolescent Telephone Support Documentation Form.* The Adolescent Telephone Support Documentation Form contains 22 items that are asked of an adolescent during a telephone support contact by a volunteer. The form is used to record yes/no and open-ended responses to questions asking about substance use and recovery-related activities. The volunteers complete the form every time there is a telephone support session with an adolescent.

• *Telephone Support Discharge Form.* The Telephone Support Discharge Form contains 10 fields to record the following information at the end of an adolescent's participation in telephone support: adolescent name, today's date, volunteer name, notification date, telephone support intake date, telephone support discharge date, reason for discharge, number of completed sessions, referral for more intervention, and successful contact for more intervention. This form is completed by volunteers when telephone support ends for each adolescent.

• *Volunteer/Staff Survey (Telephone Support Volunteer)*—See *Volunteer/Staff Survey (Project Coordinator)* above.

Social Network Site Moderator

• *Social Networking Moderator Log.* The Social Networking Moderator Log contains 11 fields for the moderator to record usage data for the project's social networking site. The moderator tracks number of visits to the site, number of unique visitors, messages posted, chat room attendance, and problems with users. This form is completed weekly by project staff.

• *Volunteer/Staff Survey*—See *Volunteer/Staff Survey (Project Coordinator)* above.

Family Program Clinician

• *Family Program Progress Notes.* The Family Program Progress Notes form is open-ended and provides space for all data collected during attempted and completed family program contacts to be recorded. This form is completed by the clinician throughout the time family members are active in the family support program.

• *Family Program Attendance Log.* The Family Program Attendance Log is used to record 6 pieces of information about each attempted session: Session number, scheduled date, was the session rescheduled (yes/no), was the family member a no-show (yes/no), did the family member attend the session (yes/no), and comments. This form is completed by the clinician throughout the time family members are active in the family support program.

• *Family Program Case Review Report.* The Family Program Case Review Report contains multiple rows that allow a clinician to record information that allows the clinician and supervisor to monitor the progress of active cases. Areas asked about include: family program procedures delivered, date of last session, and weeks in family program. This form is completed by the clinician weekly throughout the time family members are active in the family support program.

• *Family Program Discharge Form.* The Family Program Discharge Form contains 9 fields to record the following information at the end of participation in the family program: caregiver name, today's date, adolescent name, notification date, clinician name, family program intake date, family program discharge date, reason for discharge, and number of completed sessions. This form is completed by the clinician each time family members of a given participant end involvement in the family support program.

• *Volunteer/Staff Survey*—See *Volunteer/Staff Survey (Project Coordinator)* above.

Support Services Supervisor

• *Adolescent Telephone Support Quality Assurance Checklist.* This checklist contains 43 items that ask the supervisor to rate how well a telephone support volunteer delivered required service components to adolescents. Volunteers are rated on a scale of 1 through 5 in the following areas: substance use since last call (no use), substance use since last call (use), substance use since last call (still using), substance use since last call (stopped using), attendance at 12-step meetings, recovery-related activities, activities related to global health, follow-up since last call, closing the call, overall, general clinical skills, and overall difficulty of session. This form is completed for each reviewed recording of a telephone session by a supervisor.

• *Social Networking Quality Assurance Checklist.* This checklist contains 17 items that ask the supervisor to rate how well a social networking site moderator delivered required service components to adolescents. The moderator is rated on a scale of 1 through 5 in the following areas: group discussions, administrative tasks, overall, and general skills. This form is completed for each review of the social networking site by a supervisor.

• *Family Program QA Checklist.* This checklist contains 72 items that ask the supervisor to rate how well a family program clinician delivered required service components to family members. The clinician is rated on a scale of 1 through 5 in the following areas: initial meeting motivational strategies, domestic violence precautions, functional analysis of substance use, positive communication skills, use of positive reinforcement, time out from positive reinforcement, allowing the identified patient to experience the natural consequences of substance use, helping concerned significant others' enrich their own lives, maintaining the identified patient in recovery-oriented systems of care, and general. This form is completed for each reviewed recording of a family session by a supervisor.

• *Volunteer/Staff Survey*—See *Volunteer/Staff Survey (Project Coordinator)* above.

The following table is a list of the hour burden of the information collection by form and by respondent:

DETAILED INFORMATION ON FORMS GROUPED BY RESPONDENT

Instrument/form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annualized hour burden *
Adolescent Participant					
GAIN–I 5.6.0 Full	200	1	200	2	400
GAIN–M90 5.6.0 Full	200	4	800	1	800
SAF	200	5	1,000	.25	250
Subtotal	200		2,000		1,450
Collateral (Parent/Guardian/Concerned Other) Participant					
Collateral-I	200	1	200	.25	50
Collateral-M	200	4	800	.25	200
Collateral SAF	200	5	1,000	.25	250
Self-Evaluation Questionnaire	200	5	1,000	.16	250
Family Environment Scale (Cohesion and Conflict Scales)	200	5	1,000	.08	80
Relationship Happiness Scale (Caregiver)	200	5	1,000	.08	80
Subtotal	200		5,000		910
Project Coordinator					
Eligibility Checklist	4	50	200	.25	50
Locator—Participant	4	50	200	.32	64
Locator—Collateral	4	50	200	.25	50
Follow-Up Contact Log	4	50	200	.16	32
Telephone Support Volunteer Notification Form	4	50	200	.16	32
Family Program Notification Form	4	50	200	.16	32
Volunteer/Staff Survey	4	1	4	.25	1
Subtotal	4		1,204		261
Telephone Support Volunteer					
Telephone Support Case Review Form	8	450	3,600	.25	900
Telephone Support Call Log	8	25	200	.16	32
Telephone Support Documentation Form	8	450	3,600	.5	1,800
Telephone Support Discharge Form	8	25	200	.16	32
Volunteer/Staff Survey	8	1	8	.25	2
Subtotal	8		7,608		2,766
Social Network Site Moderator					
Social Networking Moderator Log	1	52	52	.5	26
Volunteer/Staff Survey	1	1	1	.25	.25
Subtotal	1		53		26.25
Family Program Clinician					
Family Program Progress Notes	4	650	2,600	.16	416
Family Program Attendance Log	4	50	200	.08	16
Family Program Case Review Form	4	650	2,600	.25	650
Family Program Discharge Form	4	50	200	.16	32
Volunteer/Staff Survey	4	1	4	.25	1
Subtotal	4		5,604		1,115
Support Services Supervisor					
Telephone Support QA Checklist	1	12	12	1	12
Social Networking QA Checklist	1	12	12	.5	6
Family Program QA Checklist	1	12	12	1	12
Volunteer/Staff Survey	1	1	1	.25	.25
Subtotal	1		37		30.25
Total	418		21,506		6,558.50

ANNUALIZED SUMMARY TABLE

Respondents	Number of respondents	Total responses	Total annualized hour burden *
Adolescent	200	2,000	1,450
Collateral	200	5,000	910
Project Coordinator	4	1,204	261
Telephone Support Volunteer	8	7,608	2,766
Social Network Site Moderator	1	53	26.25
Family Program Clinician	4	5,604	1,115
Support Services Supervisor	1	37	30.25
Total	418	21,506	6,558.50

Written comments and recommendations concerning the proposed information collection should be sent by December 18, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: November 12, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–27641 Filed 11–17–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0532]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Nutrition Facts Label Formats

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 an experimental study of Nutrition Facts label formats.

* Total Annualized Hour Burden = Total Responses × Hours per Response.

DATES: Submit written or electronic comments on the collection of information by January 19, 2010.

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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Experimental Study of Nutrition Facts Label Formats—(Section 903(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C))) (OMB Control Number 0910–NEW)

I. Description

Nutrition information is required on most packaged foods and this information must be provided in a specific format as defined in 21 CFR 101. 9. When FDA was determining which Nutrition Facts label format to require, the agency undertook consumer research to evaluate alternatives (Refs. 1, 2, and 3). More recently, FDA conducted qualitative consumer research on the format of the Nutrition Facts label on behalf of the agency's Obesity Working Group (OWG) (Ref. 4), which was formed in 2003 and tasked with outlining a plan to help confront the problem of obesity in the United States (Ref. 5). In addition to conducting consumer research, in response to the OWG plan FDA issued two Advance Notices of Proposed Rulemaking (ANPRM) requesting comments on format changes to the Nutrition Facts label. One ANPRM requested comments on whether and, if so, how to give greater emphasis to calories on the Nutrition Facts label (Ref. 6) and the other requested comments on whether and, if so, how to amend the agency's serving size regulations (Ref. 7). In 2007, FDA issued an ANPRM requesting comments on whether the agency should require that certain nutrients be added or removed from the Nutrition Facts label (Ref. 8).