

(estradiol valerate and estradiol valerate/dienogest), PERTZYE (pancrelipase), PREZISTA (darunavir), REYATAZ (atazanavir), SKLICE (ivermectin), TISSEEL (Fibrin Sealant), TORISEL (temsirolimus), ULTRESA (pancrelipase), Vertical Expandable Prosthetic Titanium Rib (VEPTR), VIREAD (tenofovir disoproxil fumarate).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 24, 2014. Oral presentations to the public will be scheduled on March 3, 2014, between approximately 11:30 a.m. and 12:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 14, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 18, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee

meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 8, 2014.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2014-00475 Filed 1-13-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2004-N-0451]

#### **Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 033**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews ("FDA Recognized Consensus Standards"). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 033" ("Recognition List Number: 033"), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

**DATES:** Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

**ADDRESSES:** Submit written requests for single copies of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 033" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that office in processing your

requests, or fax your request to 301-847-8149.

Submit electronic comments concerning this document, or recommendations for additional standards for recognition, by email to [standards@cdrh.fda.gov](mailto:standards@cdrh.fda.gov). Submit written comments to the contact person (see **FOR FURTHER INFORMATION CONTACT**). This document may also be accessed on FDA's Internet site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 033 modifications and other standards related information.

#### **FOR FURTHER INFORMATION CONTACT:**

Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring, MD 20993-0002, 301-796-6287.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the

supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

**II. Modifications to the List of Recognized Standards, Recognition List Number: 033**

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for

devices. We will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency’s searchable database, using the term “Recognition List Number: 033” to identify these current modifications.

In table 1 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors

made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard <sup>1</sup>	Change
<b>A. Anesthesia</b>			
1-60 .....	.....	IEC 60601-2-12 (2001-10) Medical electrical equipment—Part 2-12: Particular requirements for the safety of lung ventilators—Critical care ventilators.	Withdrawn. Transition period expired. See 1-88.
1-61 .....	.....	IEC 60601-2-13 (2003-05) Medical electrical equipment—Part 2-13: Particular requirements for the safety and essential performance of anesthetic systems.	Withdrawn. Transition period expired. See 1-82.
1-66 .....	.....	ISO 9919:2005 Medical electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.	Withdrawn. Transition period expired. See 1-85.
<b>B. Cardiovascular</b>			
3-38 .....	.....	IEC 60601-2-34 (2000-10) Medical electrical equipment—Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment.	Withdrawn. Transition period expired. See 3-115.
<b>C. Dental/ENT</b>			
4-122 .....	.....	IEC 60601-2-18:1996 Amendment 1 2000 Medical electrical equipment—Part 2-18: Particular requirements for the safety of endoscopic equipment.	Withdrawn. Transition period expired. See 4-187.
<b>D. General</b>			
5-4 .....	.....	IEC 60601-1 1988; Amendment 1, 1991-11, Amendment 2, 1995 Medical electrical equipment—Part 1: General requirements for safety and essential performance.	Withdrawn. Transition period expired. See 5-77.
5-27 .....	.....	IEC 60601-1-1:2000 Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems.	Withdrawn.
5-34 .....	.....	IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1) (Edition 2:2001 consolidated with Amendment 1:2004).	Withdrawn. Transition period expired. See 5-53.
5-35 .....	.....	ANSI/AAMI/IEC 60601-1-2:2001 Medical electrical equipment—Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests.	Withdrawn. Transition period expired. See 5-54.
5-41 .....	.....	IEC 60601-1-4 Edition 1.1 2000-04 Medical electrical equipment—Part 1-4: General requirements for safety—Collateral standard: Programmable electrical medical systems.	Withdrawn.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard <sup>1</sup>	Change
5-49 .....	.....	IEC 60601-1-8 First edition 2003-08 Medical electrical equipment—Part 1-8: General requirements for safety—Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.	Withdrawn. Transition period expired. See 5-76.
5-60 .....	.....	IEC 60601-1-2 Int. 1 Third edition/I-SH 01:2007 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests, interpretation sheet.	Withdrawn. See 5-53.
5-77 .....	.....	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).	Transition period extended.
<b>E. General Hospital/General Plastic Surgery</b>			
6-9 .....	.....	IEC 60601-2-21 First edition 1994-02 Medical electrical equipment—Part 2: Particular requirements for the safety of infant radiant warmers.	Withdrawn. Transition period expired. See 6-300.
6-29 .....	.....	IEC 60601-2-19 First edition 1990-12 Medical electrical equipment—Part 2: Particular requirements for safety of baby incubators.	Withdrawn. Transition period expired. See 6-298.
6-32 .....	.....	IEC 60601-2-20 First edition 1990-12 Medical electrical equipment—Part 2: Particular requirements for safety of transport incubators.	Withdrawn. Transition period expired. See 6-299.
6-146 .....	.....	ANSI/AAMI/IEC 60601-2-21 First edition 1994-02 and Amendment 1:2000 Medical electrical equipment—Part 2: Particular requirements for safety of infant radiant warmers.	Withdrawn. Transition period expired. See 6-227.
6-182 .....	.....	IEC 60601-2-38 First edition 1996-10 and Amendment 1:1999 Medical electrical equipment—Part 2-38: Particular requirements for the safety of electrically operated hospital beds.	Withdrawn. Transition period expired. See 6-233.
6-197 .....	.....	IEC 60601-2-2 Ed. 1.0 Medical electrical equipment—Part 2-2: Particular requirements for the safety of high-frequency surgical equipment.	Withdrawn. Transition period expired. See 6-228.
<b>F. Neurology</b>			
17-5 .....	.....	IEC 60601-2-10 First edition 1987, Amendment 1 2001-09 Medical electrical equipment—Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.	Withdrawn. Transition period expired. See 17-11.
<b>G. OB-GYN/Gastroenterology</b>			
9-4 .....	.....	IEC 60601-2-16 Second edition 1998-02 Medical electrical equipment—Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration, and haemofiltration equipment.	Withdrawn. Transition period expired. See 9-80.
9-42 .....	.....	IEC 60601-2-18 Second edition 1996-08, Amendment 1 2000-07 Medical electrical equipment—Part 2-18: Particular requirements for the safety of endoscopic equipment.	Withdrawn. Transition period expired. See 9-61.
9-46 .....	.....	IEC 60601-2-2 Fourth edition 2006-07 Medical electrical equipment—Part 2-2: Particular requirements for the safety of high frequency surgical equipment.	Withdrawn. Transition period expired. See 9-62.
<b>H. Radiology</b>			
12-34 .....	.....	IEC 60601-2-7 Second edition 1998-02 Medical electrical equipment—Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic x ray generators.	Withdrawn. Transition period expired. See 12-251.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard <sup>1</sup>	Change
12-54 .....	.....	IEC 60601-2-8 Edition 1.1 1999-04 Medical electrical equipment—Part 2-8: Particular requirements for the safety of therapeutic x ray equipment operating in the range 10 kilovolt (kV) to 1 millivolt (mV).	Withdrawn. Transition period expired. See 12-254.
12-63 .....	.....	IEC 60601-2-43 Edition 1.0 2000-06 Medical electrical equipment—Part 2-43: Particular requirements for the safety of x ray equipment for interventional procedures.	Withdrawn. Transition period expired. See 12-202.
12-120 .....	.....	IEC 60601-2-44 Edition 2.1 2002-11 Medical electrical equipment—Part 2-44: Particular requirements for the safety of x ray equipment for computed tomography.	Withdrawn. Transition period expired. See 12-256.
12-126 .....	.....	IEC 60601-2-28 First Edition 1.0 1993-03 Medical electrical equipment—Part 2-28: Particular requirements for the safety of x ray source assemblies and x ray tube assemblies for medical diagnosis.	Withdrawn. Transition period expired. See 12-204.
12-127 .....	.....	60601-2-32 First edition 1994-03 Medical electrical equipment—Part 2-32: Particular requirements for the safety of associated equipment of x ray equipment.	Withdrawn. Transition period expired. See 12-201.
12-133 .....	.....	IEC 60601-2-11 Second edition 1997-08, Amendment 1, 2004-07 Medical electrical equipment—Part 2-11: Particular requirements for the safety of gamma beam therapy equipment.	Withdrawn. Transition period expired. See 12-255.
12-147 .....	.....	IEC 60601-2-5 Edition 2.0 2000-07 Medical electrical equipment—Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment.	Withdrawn. Transition period expired. See 12-205.
12-152 .....	.....	IEC 60601-2-1 Second edition 1998-06, Amendment 1 2002-05 Medical electrical equipment—Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 megaelectronvolts (MeV) to 50 MeV.	Withdrawn. Transition period expired. See 12-206.
12-178 .....	.....	IEC 60601-2-45 Edition 2.0 2001-05 Medical electrical equipment—Part 2-45: Particular requirements for the safety of mammographic x ray equipment and mammographic stereotactic devices.	Withdrawn. Transition period expired. See 12-236.
12-189 .....	.....	IEC 60601-2-33 Edition 2.2 2008-04 Medical electrical equipment—Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.	Withdrawn. Transition period expired. See 12-207.
12-197 .....	.....	IEC 60601-2-22 Second edition 1995-11 Medical electrical equipment—Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment.	Withdrawn. Transition period expired. See 12-208.
12-198 .....	.....	IEC 60601-2-37 First edition 2007-01, Amendment 1 2004-08, Amendment 2 2005-11 Medical electrical equipment—Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.	Withdrawn. Transition period expired. See 12-209.
12-199 .....	.....	IEC 60601-1-3 First edition 1994-07 Medical electrical equipment—Part 1-3: General requirements for safety—3. Collateral standard: General requirements for radiation protection in diagnostic x ray equipment.	Withdrawn. Transition period expired. See 12-210.
12-200 .....	.....	IEC 60601-2-29 Second edition 1999-01 Medical electrical equipment—Part 2-29: Particular requirements for the safety of radiotherapy simulators.	Withdrawn. Transition period expired. See 12-211.
12-207 .....	.....	IEC 60601-2-33 Edition 3.0 2010-03, Medical electrical equipment—Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic.	Transition period extended.
12-208 .....	.....	IEC 60601-2-22 Third edition 2007-05 Medical electrical equipment—Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment.	Transition period extended.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard <sup>1</sup>	Change
12-210 .....	.....	IEC 60601-1-3 Edition 2.0 2008-01 Medical electrical equipment—Part 1-3: General requirements for basic safety and essential performance—Collateral standard: Radiation protection in diagnostic x ray equipment.	Transition period extended.

<sup>1</sup> All standard titles in this table conform to the style requirements of the respective organizations.

**III. Listing of New Entries**

In table 2 of this document, FDA provides the listing of new entries and

consensus standards added as modifications to the list of recognized

standards under Recognition List Number: 033.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard <sup>1</sup>	Reference No. and date
<b>A. General</b>		
5-78 .....	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).	ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text).
<b>B. Radiology</b>		
12-257 .....	Medical electrical equipment—Part 2-44: Particular requirements for the basic safety and essential performance of x ray equipment for computed tomography.	IEC 60601-2-44 Edition 3.0 2009-02.
12-268 .....	Medical electrical equipment—Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.	IEC 60601-2-22 Edition 3.1 2012-10.
12-269 .....	Medical electrical equipment—Part 1-3: General requirements for basic safety and essential performance—Collateral standard: radiation protection in diagnostic x ray equipment.	IEC 60601-1-3 Edition 2.1 2013-04.
12-271 .....	Medical electrical equipment—Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.	IEC 60601-2-33 Edition 3.1 2013-04.

<sup>1</sup> All standard titles in this table conform to the style requirements of the respective organizations.

**IV. List of Recognized Standards**

FDA maintains the Agency’s current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at our Internet site at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. We will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. We will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List Number: 033, we will no longer be announcing minor revisions to the list of recognized consensus standards such as technical contact person, relevant guidance, processes affected, Code of Federal

Regulations citations, and product codes.

**V. Recommendation of Standards for Recognition by FDA**

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or

performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

**VI. Electronic Access**

You may obtain a copy of “Guidance on the Recognition and Use of Consensus Standards” by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the **Federal Register**, this notice announcing “Modification to the List of Recognized Standards, Recognition List Number: 033” will be available on the CDRH home page. You may access the

CDRH home page at <http://www.fda.gov/MedicalDevices>.

You may access “Guidance on the Recognition and Use of Consensus Standards,” and the searchable database for “FDA Recognized Consensus Standards” at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

This **Federal Register** document on modifications in FDA’s recognition of consensus standards is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.

**VII. Submission of Comments and Effective Date**

Interested persons may submit either electronic comments concerning this document, or recommendations for additional standards for recognition, by email to [standards@cdrh.fda.gov](mailto:standards@cdrh.fda.gov) or written comments to the contact person (see **FOR FURTHER INFORMATION CONTACT**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 033. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: January 8, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–00477 Filed 1–13–14; 8:45 am]

**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request: Community Evaluation of the National Diabetes Education Program’s Diabetes HealthSense Web Site**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 5, 2013, pages 47326 and 47327 and allowed 60-days for public comment. There was one public comment. The comment conveyed broad discontent with the government’s use of money and the department’s involvement in diabetes prevention. An acknowledgement of receipt and a statement of appreciation was sent in response to this comment. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection:* Community Evaluation of the National Diabetes Education Program’s Diabetes HealthSense Web Site. 0925–NEW, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institutes of Health (NIH).

*Need and Use of Information Collection:* This study will be a multi-component 3-year evaluation of Diabetes HealthSense, an online compendium of psychosocial and behavioral resources to support lifestyle changes. The required forms will support the following evaluation tasks: (1) Assessing community educators’ experience and satisfaction with NDEP resources such as the Diabetes HealthSense Web site; (2) Assess the extent to which, through participation in Diabetes HealthSense educational sessions, community educators can increase their knowledge and ability to promote and use NDEP resources; and (3) Assess the extent to which the Web site, with guided exploration, can facilitate changes in lifestyle to help prevent or manage diabetes. The data collected from this evaluation will provide NDEP with information about how community educators use NDEP-created resources in their communities and whether the Diabetes HealthSense resource has its intended effect on participants. Such data will help inform NDEP’s future decisions about the Diabetes HealthSense Web site, including whether to make changes to Diabetes HealthSense, and whether to invest additional resources to support, promote, or expand this resource.

*Frequency of Response:* One time study. *Affected Public:* Adults with diabetes or at risk of diabetes and educators. *Type of Respondents:* Adult intervention participants and community educators. The annual reporting burden is outlined in the table below, and the annualized cost to respondents is estimated at: \$6,597.15. There are no maintenance or capital costs to respondents to report.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 310.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average time per response (in hours)	Estimated total annual burden hours
Participant Pretest .....	Adult intervention participants .....	200	1	20/60	67
Participant Posttest .....	Adult intervention participants .....	150	1	20/60	50
Participant Exit Satisfaction Survey ..	Adult intervention participants .....	200	1	10/60	33
Participant Follow-up Interview .....	Adult intervention participants .....	10	1	1	10
Participant Pretest .....	Adult comparison group participants	250	1	20/60	83
Participant Posttest .....	Adult comparison group participants	150	1	20/60	50
Community Educator Pre Interview ..	Community educators .....	5	1	1	5
Community Educator Post Interview	Community educators .....	5	1	1	5
Intervention Participant Recruitment Guide.	Community educators .....	5	2	15/60	4
Comparison Participant Recruitment Guide.	Community educators .....	10	1	15/60	3