V. Presenter and Presentation Criteria

The additional criteria below must be supplied to the DFO by the August 18 deadline (along with hardcopies of presentations).

- Required personal information regarding presenter(s):
- Name of presenter(s),
- Title(s),
- Organizational affiliation,
- Address,
- E-mail address, and
- Telephone number(s).

All presentations must contain, at a minimum, the following supporting information and data:

- Financial relationship(s) of presenter(s), if any, with any company whose products, services, or procedures that are under consideration;
- Physicians' Current Procedural Terminology (CPT) codes involved;
- APC(s) affected;
- Description of the issue(s);
- Clinical description of the service under discussion (with comparison to other services within the APC);
- Recommendations and rationale for change;
- Expected outcome of change; and
- Potential consequences of not making the change(s).

Form CMS–20017, Presenter/Presentation Information Checklist.

To assist presenters in meeting the above criteria, Form CMS–20017, which identifies the specific standard for Panel presentations, can be found on our Internet Web site at: *http://www.cms.hhs.gov/forms/cms20017.pdf.*

VI. Oral Comments

In addition to formal oral presentations, there will be opportunity during the meeting for public oral comments that will be limited to 1 minute for each individual and a total of 5 minutes per organization.

VII. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Attendance will be determined on a first-come, first-served basis.

Persons wishing to attend this meeting, which is located on Federal property, must call or e-mail the Panel DFO to register in advance no later than 5 p.m. (e.d.t.), Monday, August 23, 2004.

The following information must be e-mailed or telephoned to the DFO by the date and time above:

- Name(s) of attendee(s),
- Title(s),
- Organization,
- E-mail address(es), and
- Telephone number(s).

VIII. Security, Building, and Parking Guidelines

Persons attending the meeting must present photographic identification to the Federal Protective Service or Guard Service personnel before they will be allowed to enter the building.

Individuals who are not registered in advance will not be permitted to enter the building, and will be unable to attend the meeting. The public may not enter the Central Office (CO) complex earlier than 30 to 45 minutes prior to when the meeting convenes each day. For example, entrance into CO on Day 1 (Wednesday, September 1) would not be until 12:15 p.m., at the earliest, for the 1 p.m. meeting. Likewise, entrance into CO on Days 2 and 3 would not be until 7:15 a.m., at the earliest, for the 8 a.m. meetings.

All visitors must be escorted in areas other than the lower-lobby and first floor levels in CO building.

Parking permits and instructions are issued upon arrival by the guards at the main entrance on Security Boulevard.

IX. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must send a request for these services to the DFO by 5 p.m. (e.d.t.), Monday, August 23, 2004.

Authority: Section 1833(t) of the Act (42 U.S.C. 1395l(t), as amended by section 201(h) of the BBRA of 1999 (Pub. L. 106–113). The Panel is governed by the provisions of Pub. L. 92–463, as amended (5 U.S.C. Appendix 2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: July 8, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–17992 Filed 8–4–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Grant to Center for Economic Progress of Chicago, IL; Office of Family Assistance

AGENCY: Office of Family Assistance, ACF, DHHS.

ACTION: Grant award announcement.

SUMMARY: Notice is hereby given that an award is being made to the Center for Economic Progress of Chicago, IL in the amount of $50,000 to provide outreach on the Earned Income Tax Credit to TANF recipients and other low income individuals. After the appropriate reviews, it has been determined that this unsolicited proposal qualifies for funding.

The goal of the Center for Economic Progress is to increase access to tax credits and asset building opportunities for low and moderate income individuals, families and communities. The Center serves hundreds of thousands of low income taxpayers each tax filing season, and has developed critical knowledge and understanding of the experiences of the taxpayers and the barriers they face accessing the EITC and other low income tax credits.

The Center for Economic Progress is the only organization in the country that has a statewide contract with a State TANF Agency to provide EITC outreach to TANF recipients. They have distinguished itself as a Chicago, statewide and national leader through its innovative programs, partnerships with community organizations, corporate allies, and government agencies. The Center for Economic Progress is uniquely qualified to conduct this project because of its many successes in EITC outreach.

The period of this funding will extend through September 30, 2004.

FOR FURTHER INFORMATION CONTACT: Paul Maiers, Office of Family Assistance, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone: 202–401–5438.

Dated: July 27, 2004.

Andrew S. Bush,

Director, Office of Family Assistance.

[FR Doc. 04–17889 Filed 8–4–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0383]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

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 (the PRA).

DATES: Fax written comments on the collection of information by September 7, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

This document provides guidance on the voluntary use of selected symbols in place of text to convey some of the information required for in vitro diagnostic devices (IVDs) intended for professional use under § 809.10 (21 CFR 809.10) (FDA's labeling requirements for IVDs) and parts 610 and 660 (21 CFR parts 610 and 660) (FDA's labeling requirements for biologics (including IVDs)) that are licensed under the Public Health Service Act. Use of these symbols will not result in a new collection of information but is a means of fulfilling underlying labeling requirements that are subject to OMB clearance. Under section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), a drug or device is misbranded

> If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

This guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. Furthermore, this guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and the educational outreach help to ensure that IVD users will have enough general familiarity with the symbols, as well as quick reference materials available, to be likely to understand the symbols used in IVD labeling, further ensuring that such labeling satisfies the requirements of section 502(c) of the act.

Respondents: The likely respondents are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

In the **Federal Register** of October 28, 2003 (68 FR 61449), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment regarding information collection from a manufacturer. This comment stated ''We believe no additional educational outreach is needed for the symbols contained within the draft guidance document. A user comprehension study was conducted showing acceptance of these symbols and an explanation is provided in the glossary.'' FDA disagrees with this comment. The educational outreach will enhance the understanding of the newly introduced symbols among the intended audience.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
Glossary	1,742	1	1,742	4	6,9681
Educational outreach	1,742	1	1,742	16	27,872
Total					34,840

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

The glossary and educational outreach activities would be carried out by domestic and foreign IVD manufacturers. The Center for Devices and Radiological Health Information Retrieval System's Registration and Listing Information database provided the number of IVD manufacturers as 1,742; 1,206 are domestic IVD manufacturers and 536 are foreign manufacturers. Consequently, FDA has based its burden estimate on the maximum possible number of manufacturers choosing to implement the use of symbols in labeling. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary, as shown in the draft guidance, for the specific symbols used in labels or labeling for the IVDs they manufacture. The 16-hour estimate for educational outreach includes activities manufacturers will use to educate the various professional users of IVDs about the meaning of the IVD symbols. This estimate is based on FDA 's expectation that IVD manufacturers will jointly sponsor many educational outreach activities.

The draft guidance document also refers to labeling requirements, annual reporting requirements, and other information collections established under existing regulations. The collections of information described in section III of the guidance that result from § 809.10 were approved under OMB control number 0910–0485. The collections of information described in

section III of the guidance that result from §§ 610.60, 610.61, and 610.62 were approved under OMB control number 0910–0338. In accordance with section 3506(c)(2)(A) of the PRA, a 60-day notice soliciting public comment on the collections of information described in section III of the guidance that result from part 660 (§§ 660.2, 660.28, 660.35, 660.45, and 660.55) published in the **Federal Register** of July 22, 2003 (68 FR 43359). The collections of information described in section X of the guidance, regarding annual reports, were approved under OMB control numbers 0910–0231 and 0910–0315. The collections of information described in section X of the guidance, regarding adverse event reporting, were approved under OMB control numbers 0910–0437 and 0910–0291.

Dated: July 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17879 Filed 8–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0246]

Agency Emergency Processing Under Office of Management and Budget Review; Experimental Study of Petitioned Health Claims on Glucosamine and Chondroitin Sulfate; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a notice that published in the **Federal Register** of June 3, 2004 (69 FR 31395).

DATES: This notice is withdrawn on August 5, 2004.

FOR FURTHER INFORMATION CONTACT: May D. Nelson, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1722.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 3, 2004, FDA published a notice informing interested parties that the proposed collection of information entitled ''Experimental Study of Petitioned Health Claims on Glucosamine and Chondroitin Sulfate'' had been submitted to the Office of Management and Budget (OMB) for emergency processing under section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j) and 5 CFR 1320.13). The notice contains a number of errors. In addition, we are reevaluating the design and objective of the study. Therefore, we are withdrawing both the notice itself and the request for OMB approval of the proposed collection of information.

Dated: July 29, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–17877 Filed 8–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; California Health Interview Survey 2005

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institute of Health (NIH), National Cancer Institute (NCI) will public periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: California Health Interview Survey (CHIS) 2005 Cancer Control Module (CCM). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The NCI has sponsored two Cancer Control Modules to the California Health Interview Survey (CHIS), and will be sponsoring a third to be administered in 2005.

The CHIS is a telephone survey designed to provide population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the state. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy Research, the California Department of Health Services, and the California Public Health Institutes, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults. These adults are a representative sample of California's non-institutional population living in households.

CHIS 2005, the third bi-annual survey, is planned for administration to 55,000 adult Californians. The cancer control module, which is similar to that administered in CHIS 2001 and CHIS 2003, will allow NCI to examine trends in breast cancer screening and diagnosis, as well as to study other cancer-related topics, such as, diet, physical activity and obesity.

Because California is the most populous and the most racially and ethnically diverse state in the nation, the CHIS 2005 sample will yield adequate numbers of respondents in key ethnic and racial groups, including African Americans, Latinos, Asians, and American Indian/Alaska Natives. The Latino group will include large numbers of Mexican-origin, Central Americans, South Americans, and other Latino subgroups; the Asian group will include large numbers of respondents in the Chinese, Filipino, Japanese, Vietnamese, and Korean subgroups. NCI will compare the CHIS and National Health Interview Survey (NHIS) data in order to conduct comparative analyses and better estimate cancer risk factors and screening among racial/ethnic minority populations. The CHIS sample size also permits NCI to create estimates for ethnic subdomains of the population, for which NHIS has insufficient numbers for analysis.

Frequency of Response: One-time. *Affected public:* Individuals or households. *Types of Respondents:* U.S. adults (persons 18 years of age and older). The annual reporting burden is as follows.

TABLE A.—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2005 DATA COLLECTION

Data collection	Estimated number of respondents	Frequency of response	Average time per response	Annual hour burden
Adult Core	55,000	1	.42	23,100
CCTM	55,000	1	.08	4,400