to conduct the safety education program.

Budget and Justification (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with the stated objectives and planned program activities.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original and plus copies of:

1. Semi-annual progress reports;
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' Section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I.

AR–7—Executive Order 12372 Review
AR–8—Public Health System Reporting Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2010
AR–12—Lobbying Restrictions
AR–13—Prohibition on Use of CDC Funds for Certain Gun Control Activities

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a), 317(k)(2), 391, 392, 394, and 394A [42 U.S.C. 241(a), 247b(k)(2), 280b, 280b–1, 280b–2, 280b–3] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page on the Internet: http://www.cdc.gov. If you have questions after reviewing the content of all documents, business management assistance may be obtained from: Sheryl L. Heard, Grants Management Specialist Grants Management Branch, Procurement and Grants Office, Announcement 00084, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341–4146, Telephone (404) 488–2723, Email: slh3@cdc.gov

For program technical assistance, contact: Tim Groza, MPA, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway, N.E., Mailstop K63, Atlanta, GA 30341–3724, Telephone (770) 488–4676, Email: tgroza@cdc.gov.

To order a copy of CDC's Demonstrating Your Program's Worth: A Primer on Evaluation for Programs to Prevent Unintentional Injury go to: www.cdc.gov/ncipc/pub-res/demonstr.htm.

Dated: April 21, 2000.

John L. Williams,

Director, Procurement and Grants Office Centers for Disease Control, and Prevention (CDC).

[FR Doc. 00–10486 Filed 4–26–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00074]

Demonstration Projects for the Early Intervention and Prevention of Sexual Violence and Intimate Partner Violence among Racial and Ethnic Minority Populations; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of FY 2000 funds for a cooperative agreement program to: support the development, implementation and evaluation of culturally competent demonstration projects for the early intervention and prevention of both sexual violence (SV) and intimate partner violence (IPV) among racial and ethnic minority populations. This program addresses ''Healthy People 2010,'' a national activity to reduce morbidity and mortality and improve health. This announcement is related to the focus area of Injury and Violence Prevention. For the conference copy of ''Healthy People 2010'', visit the Internet site: http://www.health.gov/healthypeople.

B. Eligible Applicants

Applications may be submitted by public and private non-profit and for-profit community-based organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations. Organizations serving American Indian or Alaskan Native tribal entities must have resolutions from the tribal councils of the tribes they intend to serve supporting their application for funding under this announcement.

The applicant organization or agency must have at least two years of experience serving the proposed population(s). The applicant may propose services to one or more of the following racial or ethnic minority community, *i.e.,* African American, American Indian or Alaska Native, Hispanic American, Asian American, or Pacific Islander. Communities or groups which cannot be specified under these categories will not be considered.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

C. Availability of Funds

Approximately $1.6 million is available in FY 2000 to fund approximately three to four awards. It is expected that the average award will be $400,00. It is expected that the awards will begin on or about September 1, 2000, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Allowable Uses

Funds can be used to support personnel and to purchase modest amounts of hardware, and software required to implement the project. Applicants may contract with other organizations under these cooperative agreements; however, applicants must perform a substantial portion of the activities (including program management and operations and delivery of prevention and intervention services) for which funds are requested. Applications requesting funds to support only administrative and managerial functions will not be accepted.

Prohibited Uses

Funds for this project cannot be used for construction, renovation, the lease of

passenger vehicles, the development of major software applications, or supplanting current applicant expenditures.

Funding Preferences

In making awards, preference for funding may be given to ensuring a mix of the interventions listed under Section D, ''Programmatic Interests,'' of this announcement as well as a distribution among ethnic populations or geographic areas.

D. Programmatic Interests

Each applicant must conduct (develop, implement, and evaluate) at least one, but on more than two of the following priority prevention or early intervention activities, which addresses both SV and IPV. Because of the resources, special expertise, and organizational capacities needed for success, applicants should carefully consider the feasibility of undertaking more than one of the priority interventions listed in this section of the Program Announcement.

Interventions may be focused either on the individual or the entire family.

The applicant must develop, implement and evaluate:

1. Culturally competent strategies and programs aimed at prevention and early intervention of sexual violence (SV) and intimate partner violence (IPV), such as parenting or child development classes, and support groups for children who have witnessed SV and IPV or experienced child abuse, including child sexual abuse, in conjunction with witnessing SV and IPV,

2. Culturally competent victim support prevention and intervention programs that work through programs designed to address perpetrators of SV and IPV and children who witness SV and IPV or experience child abuse, including child sexual abuse, in conjunction with witnessing SV and IPV.

3. Culturally competent perpetrator re-education programs that work through programs designed to address victims of SV and IPV and children who witness SV and IPV or experience child abuse, including child sexual abuse in conjunction with witnessing SV and IPV.

4. Culturally competent school or community-based early intervention/prevention programs designed to promote healthy relationships and prevent dating violence (SV and IPV) among school-aged youth, whether the youth are in school or not.

5. Culturally competent school or community-based prevention and intervention programs designed to identify and assist pre-school, school-aged children and adolescents who witness SV and IPV or experience child abuse, including child sexual abuse, in conjunction with witnessing SV and IPV.

6. Culturally competent advocacy programs/strategies that link the population community's health care system, criminal justice system, child protection service system, SV and IPV prevention and intervention programs, and other sectors of the community deemed appropriate (*e.g.,* the faith community, traditional healers, business community) such that victims, perpetrators, and children who witness IPV or experience child abuse, including child sexual abuse, in conjunction with witnessing SV and IPV—have access to culturally competent intervention and prevention services.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities:

a. Coordinate and collaborate with other organizations and agencies working with the proposed intervention population(s), especially those involved in SV and IPV prevention and intervention.

b. Develop and implement the proposed activities, in collaboration with these working partners to prevent duplication of efforts.

c. Incorporate cultural competency, linguistic and developmental appropriateness into all program activities and prevention messages.

d. If the applicant is a community-based organization, they must establish and maintain a full working partnership with a university, academic institution of higher education or research institute to develop their research protocol, data collection instruments and conduct an overall evaluation of the proposed intervention and prevention activities. Universities, academic institution of higher education or research institutes applying for funding are required to establish and maintain a full working partnership with a either a community-based organization or health department to carry out the proposed intervention or prevention activities.

e. Develop a research protocol, including all instruments and consent documents, for IRB review by all cooperating institutions participating in the research project. All IRBs must review and approve the protocol initially and on an annual basis until the research is completed.

f. Compile lessons learned from the project and facilitate the dissemination of lessons learned and successful prevention interventions and program models.

2. CDC Activities:

a. Provide up-to-date scientific and programmatic information about SV and IPV prevention.

b. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 50 double-spaced pages, (not including, attachments, and line item budget and justifications), printed on one side, with unreduced 12 point font on 8½″ by 11″ paper, with 1″ margins, headings and footers. Number each page sequentially, including appendices, and provide a complete Table of Contents to the application and its appendices. Each section of the application as defined under format, shown below, must begin on a new page. The original and each copy of the application set must be submitted unstapled and unbound. Materials which should be part of the basic narrative will not be accepted if placed in the appendices. The applicant should provide a detailed description of first year activities and briefly describe future-year objectives and activities.

In developing the application, you must follow the format shown below:

Format

1. Abstract
2. Assessment of Need and Justification of Proposed Activities
3. Organizational History and Capacity
4. Program Design and Plan of Operation
5. Program Evaluation Plan
6. Project Management and Staffing
7. Budget and Staffing Breakdown and Justification
8. Human Subjects
9. Required Attachments

For specific content requirements for each item shown under ''Format '' (above) see details listed in ''Evaluation Criteria'' (Section G).

F. Submission and Deadline

Letter of Intent (LOI)

Although not a prerequisite of the application, a non-binding letter of intent-to-apply is requested from potential applicants. Your letter of intent should identify the announcement number, name the principal investigator, and state which of the priority prevention and intervention activities you intend to conduct if awarded funding. On or before June 1, 2000, submit the letter of intent to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Submit the original and two copies of PHS 5161 (OMB Number 0937–0189). Forms are in the application kit. On or before July 10, 2000, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain in a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each applicant will be evaluated individually against the following criteria by a special emphasis panel (SEP) appointed by CDC.

1. Abstract (Not to Exceed 2 Pages) (Not Scored)

The extent to which the applicant summarizes which categories of the six priority prevention/interventions, (maximum number of two) listed under Section D. ''Programmatic Interests'', they intend to implement and the extent to which the abstract contains the following:

a. Brief summary of the need for the proposed activities;

b. Short-term and long-term goals;

c. Brief summary of proposed plan of operation, including the population(s) to be served, activities to be undertaken and services to be provided, location of the services, and the location of the organization and how it will serve the local community; and

d. A brief summary of plans for evaluating the activities of this project.

2. Assessment of Need and Justification for the Proposed Activities: (15 Points)

The extent to which the applicant:

a. Describes the incidence and prevalence of sexual violence and abuse, intimate partner violence and associated injury and death among the intervention population(s), for each intervention proposed;

b. Describes the intervention population(s), both qualitatively and quantitatively, for each intervention proposed, including demographics by age, sex, socioeconomic status, and geographic location; and

c. describes the availability and accessibility of SV and IPV prevention and intervention programs for the intervention population(s), as well as existing gaps and barriers in program delivery, for each proposed intervention, and how they will be addressed.

3. Organizational History and Capacity: (20 Points)

The extent of the applicant's documented experience, capacity, and ability to address the identified needs and implement the proposed activities, including:

a. A description and documentation of the organization's record of services to the target population. A minimum of two years experience is required;

b. A description of the organizational management, administrative and program components;

c. A description of collaborating organizations or networks;

d. A description of how the organizational structure will support the proposed intervention activities; and how the structure facilitates the capacity to reach targeted populations;

e. A description of how the organizational structure includes, or has the ability to obtain meaningful input and representation from, members of each proposed intervention populations;

f. A description of the applicants experience in developing and implementing effective SV or IPV prevention and/or intervention strategies and activities, and in developing and implementing interventions similar to the one(s) proposed in this application;

g. A description of the mechanisms used by the organization to monitor program implementation and quality assurance;

h. A description of the organizations experience in coordinating and collaborating with other organizations and agencies providing SV and IPV prevention and intervention services to the proposed intervention population(s). Universities, academic institutions of higher education or research institutes applying for funding are required to establish and maintain a full working partnership with a either a community-based organization or health department to carry out the proposed intervention or prevention activities;

i. A description of the organizations capacity to provide the proposed interventions in a manner that is culturally competent, linguistically and developmentally appropriate, and which responds effectively to the gender, environmental, and social characteristics of the intervention population(s); and

j. For any of the above areas in which the organization does not have direct experience or current capacity, describing how they will ensure that the organization will gain capacity (*e.g.,* through staff development, collaboration with other organizations, or a contract).

4. Program Design and Plan of Operation: (25 Points)

The extent to which the applicant:

a. Describes the specific program goals that remain consistent during the five-year project period, as well a short-term (year one) objectives and long-term (years two-five) objectives related to the project and the extent to which the goals are feasible and objectives are clear, time-phased, specific, measurable, and will achieve the desired program results;

b. Describes a theoretical framework outlining the rationale for the development, implementation and evaluation of proposed activities;

c. Describes outcomes, which are theoretically or empirically justified to result from program activities;

d. Describes or provides samples of proposed data collection instruments that are appropriate for collecting information relevant to the project;

e. Program planning time line is realistic and provides sufficient detail about who will do what and when; and

f. Describes how the organization will meet the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. Including:

1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation;

2. The proposed justification when representation is limited or absent;

3. A statement as to whether the design of the project is adequate to measure differences when warranted; and

4. A statement as to whether the plans for recruitment and outreach for participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

5. Program Evaluation Plan: (25 Points)

The extent to which the applicant's evaluation plan:

a. Describes the process to be used in developing and implementing the proposed intervention(s) evaluation;

b. Describes the process to be used in developing and implementing the working partner(s) activities evaluation;

c. Describes the process for identifying existing gaps in programs as well as other needs in the community;

d. Describes the extent to which intended short-term outcomes that may be achieved will be measured;

e. Describes how the change in short-term outcomes resulting from the respective prevention and early intervention activities from baseline to project completion, including, at a minimum, a six-month post-intervention follow-up, will be measured;

f. Describes the evaluation design;

g. Describes the methods for collecting process and outcome data, and for ensuring reliability and validity of all data collected;

h. Describes how data will be maintained (*i.e.,* databases);

i. Describes the applicant's and proposed academic and community working partners' capacity (facilities, computers) for collecting and managing data;

j. Describes the statistical techniques to be used for analyzing the data;

k. Describes how client confidentiality and safety will be addressed and maintained;

l. Describes how staff performance will be assessed to ensure they are providing information and services accurately and effectively.

If the applicant is a community-based organization, the extent to which items (a–l) were developed in full working partnership with a university, academic institution of higher education or research institute.

6. Project Management and Staffing: (15 Points)

The extent to which the applicant has experience in the management and delivery of intimate partner violence primary prevention programs at the community level and:

a. Describes how the proposed project will be managed and staffed, noting existing staff as well as additional staffing needs;

b. Describes the roles and responsibilities, skills and experience of the applicant's program staff and any working partner's staff;

c. Provides an organizational chart of the applicant's and working partner's organizations showing how the proposed project will be integrated into these organizations; and

d. Provides evidence that a full-time Program Manager (one individual, one full-time equivalent) and the equivalent of a full-time Program Evaluator will be available for the entire project.

7. Budget/Staffing Breakdown and Justification: (Not Scored)

The extent to which the budget request is clearly explained, adequately justified, reasonable, sufficient for the proposed project activities, and consistent with the intended use of the cooperative agreement funds.

8. Human Subjects: (Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects.

9. Required Attachments: (Not Scored)

The extent to which the applicant complies with providing the following:

a. Memoranda of understanding or agreement as evidence of established or agreed-upon collaborative relationships. Memoranda of agreement should specifically describe the proposed collaborative activities. Evidence of continuing collaboration must be submitted each year to ensure that the relationships are still in place; and

b. Resolutions from the tribal councils in support of their applications, if the applicant is proposing to serve American Indian/Alaskan Native tribal entities.

H. Other Requirements

Technical Reporting Requirements

1. Provide CDC with the original and two copies of semi-annual progress reports.

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1—Human Subjects Requirements
AR–2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7—Executive Order 12372 Review
AR–8—Public Health System Reporting Requirements
AR–9—Paperwork Reduction Act Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2010
AR–12—Lobbying Restrictions
AR–13—Prohibition on Use of CDC Funds for Certain gun Control Activities
AR–14—Accounting System Requirements

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 393 and 394 of the Public Health Service Act (42 U.S.C. 280b–1a and 280b–2) as amended and section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)). The Catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is http://www.cdc.gov.

To receive additional information and to request an application kit, call 1–888–GRANTS4 (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Carrie Clark, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone number 770 488–2719, E-mail Address zri4@cdc.gov.

For program technical assistance, contact: John Hemphill, Project Officer, National Center for Injury Prevention and Control, National Centers for Disease Control and Prevention, 4770 Buford Highway, N.E.; MS K60, Atlanta, GA.30341, 770 488–1285, E-mail Address jdh2@cdc.gov.

Dated: April 21, 2000.

John L. Williams,

Director, Procurement and Grants Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–10487 Filed 4–26–00; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1256]

Over-the-Counter Drug Products; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing about the agency's approach to regulating over-the-counter (OTC) drug products. The purpose of the hearing is to solicit information from, and the views of, interested persons, including scientists, professional groups, and consumers. FDA intends to elicit comment on general issues regarding the status of OTC drug products, including the criteria the agency should consider in rendering decisions on OTC availability of drugs, the classes of products, if any, that are not currently available OTC that should or should not be available OTC, how FDA can be assured that consumers understand the issues relating to OTC availability of drug products, how rational treatment decisions are affected by coexisting prescription and OTC therapies for a given disease, whether the current structure for marketing OTC products in the United States is adequate, and FDA's role in switching products from prescription to OTC status.

DATES: The public hearing will be held on Wednesday, June 28, and Thursday, June 29, 2000, from 8:30 a.m. to 4:30 p.m. Submit written notices of participation and comments for consideration at the hearing by June 2, 2000. Written comments will be accepted after the hearing until August 25, 2000.

ADDRESSES: The public hearing will be held at the Gaithersburg Holiday Inn, 2 Montgomery Village Ave., Gaithersburg, MD 20879. Submit written notices of participation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; email: FDADockets@oc.fda.gov; or through the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. Submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; email: FDADockets@oc.fda.gov; or through the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above) and on the Internet at http://www.fda.gov/ohrms/dockets.

FOR FURTHER INFORMATION CONTACT: Patricia L. DeSantis, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, e-mail: desantis@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulates all prescription and OTC drug products marketed in the United States. Section 503(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)) describes the criteria for determining whether a drug product is subject to prescription classification. Under section 503(b)(1) of the act, a drug requires a prescription if:

> (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
>
> (B) [it] is limited by an approved application under section 505 [of the act] to use under the professional supervision of a practitioner licensed by law to administer such drug.

All drug products not meeting the above criteria may be sold OTC.

In 1972, FDA initiated rulemaking procedures (the OTC Drug Review) to determine which OTC drugs can be generally recognized among qualified experts as safe and effective and not misbranded under prescribed, recommended, or suggested conditions of use. Through the OTC Drug Review, FDA establishes monographs for classes of OTC drug products (*e.g.,* antacids, skin protectants) that are found to be generally recognized as safe and effective and not misbranded when the products contain the ingredients and are labeled according to the monograph. OTC drug monographs describe the active ingredients, amount of drug, formulation, labeling, and other general requirements for drugs to be lawfully sold OTC.

The regulations for the OTC Drug Review are found in part 330 (21 CFR part 330) and the monographs are in 21 CFR parts 331 through 358. The regulations set forth standards for safety, effectiveness, benefit-to-risk considerations, and labeling of OTC drug products.

The standards for safety, effectiveness, and labeling for OTC products are described in § 330.10(a)(4). Safety for OTC use means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use, as well as low potential for harm which may result from abuse under conditions of widespread availability. Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. The benefit-to-risk ratio of a drug must be considered in determining both safety and effectiveness.

The labeling of OTC drug products must be clear and truthful in all respects and may not be false or misleading in any particular. The labeling must state: (1) The intended uses and results of product use; (2) the adequate directions for proper use; and (3) the warnings against unsafe use, side effects, and adverse reactions in terms that render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use (§ 330.10(a)(4)(v)).

During the course of the OTC Drug Review, advisory review panels of nongovernment experts evaluated the various classes of OTC drug products and recommended that a number of drugs be switched from prescription to OTC status. FDA acted on these recommendations and switched a number of products to OTC status, including antihistamines (*e.g.,* diphenhydramine hydrochloride (HCl), doxylamine succinate), topical nasal decongestants (*e.g.,* oxymetazoline HCl, xylometazoline HCl), topical hydrocortisone, topical antifungals (*e.g.,* haloprogin, miconazole nitrate), an anthelmintic (pyrantel pamoate), an oral anesthetic (dyclonine HCl), and various fluoride dental rinses.

FDA has also approved the switch of a number of drugs from prescription to OTC status under new drug applications. These include an antidiarrheal (loperamide), topical antifungals (*e.g.,* clotrimazole, terbinafine HCl), antihistamines (*e.g.,*