Include an organizational chart that shows placement of the program within the agency's organizational system.

The extent to which the applicant provides detailed descriptions of the intervention design, implementation plans, and all methods that will be used in each phase of the intervention(s) in the communities served.

The extent to which the applicant clearly describes the methodology for establishing the magnitude of the problem in the target population and methods to be used in collecting baseline and post-intervention measures.

The extent to which the applicant has the knowledge and documented skills needed to carry out data collection, entry, and management; analyze data and report findings; perform surveillance activities and conduct program evaluation.

3. Evaluation (25 percent)

The extent to which the applicant provides detailed descriptions for evaluation of each program component and for the program overall, including process, impact, and outcome evaluations.

Descriptions should include what data will be used, how it will be evaluated, how it will be collected, who will perform the evaluation including epidemiological analysis, and the time-frame for the evaluation. This should include progress in meeting the objectives and conducting activities during the project period.

The extent to which the applicant provides sample data collection and evaluation instruments.

The extent to which the applicant demonstrates that there will be available staff with the expertise and capacity to perform the proposed evaluation.

4. Collaboration (15 percent)

The extent to which the applicant describes any proposed collaboration with other entities, such as, municipal departments, injury control research centers, professional organizations, local businesses, school systems, parent/teacher organizations, health care providers, fire departments, police, civic organizations, local public officials, and the media.

The extent to which the applicant provides the documented evidence of partnerships and access to local injury data.

The extent to which the applicant provides letters of commitment from each outside entity documenting their willingness, skills, and capacities to fulfil their specific roles and responsibilities.

The extent to which the applicant provides a clear description of the working relationships between the program and its partners.

5. Facilities, Staff, and Resources (15 percent)

The extent to which the applicant demonstrates prior experience in the intervention area and has demonstrated the capacity for conducting and evaluating the proposed injury prevention program.

The extent to which the applicant describes the facilities and resources that are available for this program.

The extent to which the applicant describes proposed staffing, and includes job descriptions and curriculum vitae indicating the applicant's ability to carry out the objectives of the program. Descriptions should include the position titles, education and experience, capabilities, and the percentage of time each person will devote to the program.

Where applicable, identify a state and/or community program level coordinator(s) who has/have the authority, responsibility, and expertise to conduct and manage the program.

6. 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 plus two copies of

1. semiannual progress reports;

2. financial status report, 90 days after the end of the budget period; and

3. final financial status 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–7 Executive Order 12372 Review
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

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. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

This announcement and forms may be downloaded from the CDC Web Site. If you cannot download the needed information you may receive additional written information and an application kit, by calling 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.

Please refer to Program Announcement 01076 when making your request. If you have questions after reviewing the content of all documents, business management and assistance may be obtained from: Angela Webb, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01076, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341–4146, Telephone (770) 488–2784, Email address awebb@cdc.gov.

For program technical assistance, contact: Mark Jackson, R.S., National Center for Injury Prevention and Control, Centers for Disease Control and Prevention 4770 Buford Highway, NE, Mailstop K63, Atlanta, GA 30341–3724, Telephone (770) 488–4754, E-mail address: mcj4@cdc.gov.

Dated: April 17, 2001.

John L. Williams,

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

[FR Doc. 01–9929 Filed 4–20–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Studies of Adverse Effects of Marketed Drugs; Availability of Grants (Cooperative Agreements); Request for Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 4, 2001 (66 FR 17907). The document announced the anticipated availability of funds for cooperative agreements to study adverse affects of drugs marketed in the United States and its territories. The document was published with some inadvertent errors. This document corrects those errors.

DATES: Submit applications by June 4, 2001.

ADDRESSES: Application kits are available from, and completed applications should be submitted to Rosemary T. Springer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182.

Note: Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852. Please DO NOT send applications to the Center for Scientific Review (CSR), National Institutes of Health. Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. Application forms can also be found at http://www.nih.gov/grants/phs398/forms-toc.html.

FOR FURTHER INFORMATION CONTACT: Rosemary T. Springer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182.

SUPPLEMENTARY INFORMATION: In FR Doc. 01–8246, appearing on page 17907 in the **Federal Register** of Wednesday, April 4, 2001, the following corrections are made:

1. On page 17910, in the first column, section VI.B.1.*b* is corrected to read as follows:

b. Size (70 points). Applicants should list number of patients enrolled in their database as of December 31, 2000.

- >3 million covered lives (70 points)
- >2.5 to 3 million covered lives (40 points)
- >2 to 2.5 million covered lives (30 points)
- >1.5 to 2 million covered lives (10 points)

2. On page 17910, in the first column, section VI.B.1.*c* is corrected to read as follows:

c. Duration (55 points). The calender time-period for which detailed patient longitudinal data are available and linked for routine, day-to-day analysis from at least 80 percent of the multiple State sites.

- <5 years of data online (0 points)
- 5 years of data online (25 points)
- 6 points for each additional year beyond 5 years of online data to a possible total of 55 points

3. On page 17910, in the third column, section VI.B.2. is corrected to read as follows:

2. New Molecular Entity (NME) Identification (200 points)

In table 1 of this document, 40 recently approved NMEs are listed. Applicants should respond with the number of unique patients in their system with at least 1 outpatient prescription for each of the 40 drug products listed in table 1. For each drug, points will be awarded by the review panel according to the following schedule:

- >25,000 exposed patients (5 points)
- 20,001 to 25,000 exposed patients (4 points)
- 15,001 to 20,000 exposed patients (3 points)
- 10,001 to 15,000 exposed patients (2 points)
- 5,001 to 10,000 exposed patients (1 point)
- 5,000 or fewer exposed patients (0 points).

Dated: April 17, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–9949 Filed 4–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0162]

Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements.'' This draft guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements directed toward consumers (DTC) in print media contain adequate risk disclosure. FDA does not intend to object to the use of certain FDA-approved patient labeling, reprinted exactly as approved, to fulfill the requirement that DTC print advertisements contain a brief summary of the product's risks.

DATES: Submit written comments on the draft guidance by July 23, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD–42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828.

Regarding prescription human biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements.'' The draft guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements DTC in print media contain adequate risk disclosure.

The requirement that all prescription drug and biological product advertisements disclose product risks comes from section 502(n) of the Federal Food, Drug, and Cosmetic Act