

new information to Chile. Finally, the revised guidance notes that FDA considers the information on this list, which is provided voluntarily with the understanding that it will be posted on FDA's Internet site and communicated to, and possibly further disseminated by, Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). Under this guidance,

FDA recommends that U.S. firms that want to be placed on the list send the following information to FDA: Name and address of the firm and the manufacturing plant; name, telephone number, and e-mail address (if available) of the contact person; a list of products presently shipped and expected to be shipped in the next 3 years; identities of agencies that inspect

the plant and the date of last inspection; plant number and copy of last inspection notice; and, if other than an FDA inspection, copy of last inspection report. FDA requests that this information be updated every 2 years.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
New written requests to be placed on the list	15	1	15	1.5	22.5
Biannual update	55	1	55	1.0	55.0
Occasional updates	25	1	25	0.5	12.5
Total					90

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the number of firms that will submit new written requests to be placed on the list, biannual updates and occasional updates is based on the FDA's experience maintaining the list over the past 3 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms.

To date, over 110 producers have sought to be included on the list. FDA estimates that, each year, approximately 15 new firms will apply to be added to the list. We estimate that a firm will require 1.5 hours to read the guidance, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list. Under the revised guidance, every 2 years each producer on the list must provide updated information in order to remain on the list. FDA estimates that each year approximately half of the firms on the list, 55 firms, will resubmit the information to remain on the list. We estimate that a firm already on the list will require 1.0 hours to biannually update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA. In addition, FDA expects that, each year, approximately 25 firms will need to submit an occasional update and each firm will require 0.5 hours to prepare a communication to FDA reporting the change.

Dated: July 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-12160 Filed 7-28-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0246]

Draft Manufactured Food Regulatory Program Standards; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of July 20, 2006. The document announced the availability of a draft document entitled "Manufactured Food Regulatory Program Standards." The document was published with an incorrect Internet address. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Beverly Kent, Division of Federal-State Relations, Food and Drug Administration, 300 Pearl St., suite 100, Buffalo, NY 14202, 716-541-0331.

SUPPLEMENTARY INFORMATION: In FR Doc. E6-11539, appearing on page 41221 in the **Federal Register** of Thursday, July 20, 2006, the following correction is made:

1. On page 41222, in the first column, under the "Electronic Access" caption,

the Internet address

"<http://www.fda.gov/ohrms/dockets/default.htm>" is corrected to read "<http://www.fda.gov/ohrms/dockets/98fr/06d-0246-gdl0001.pdf>".

Dated: July 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-12179 Filed 7-28-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Cooperative Agreement for Poison Prevention Education

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Single Source Award.

SUMMARY: HRSA will be forming a partnership with the Home Safety Council (HSC) to collaborate on reaching America's low literacy population. Through this project, easy to read and comprehend poison prevention material will be developed and distributed to the public, poison centers, safety and injury prevention professionals, health educators, and first responders.

FOR FURTHER INFORMATION CONTACT: Shkeda Johnson, Senior Public Health Analyst, Healthcare Systems Bureau, Division of Healthcare Preparedness, Room 13-103, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-1210 Email: sjohnson@hrsa.gov.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award:
Home Safety Council.

Amount of the Award: \$100,000.

Authority: Section 1271 et seq. of the Public Health Service Act, 42 U.S.C. Section 300d-71 et seq. as amended by the Poison Center Stabilization and Enhancement Grant Program.

Project Period: The period of the award will begin on September 1, 2006, through August 31, 2007.

Justification for the Exception to Competition

This project will be implemented through a single source cooperative agreement because the HSC is uniquely positioned to immediately undertake and complete the activities within one year. The HSC has existing organizational knowledge and experience in developing materials for the low literacy population through its Home Safety Literacy Project, which this project will be a component; the HSC has an existing relationship with key stakeholders in place for reaching this vulnerable population; and the HSC project director has extensive expertise in poison prevention education.

Dated: July 3, 2006.

Elizabeth M. Duke,
Administrator.

[FR Doc. E6-12178 Filed 7-28-06; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Request for Information (RFI): Change in Grant Appendix Materials**

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) are evaluating guidelines for grant application appendixes in an effort to streamline the application and review processes. This RFI requests input from interested applicants, reviewers and other members of the research community regarding the way appendix materials should be used in the grant submission, review and management process. Comments will be considered in the development of new policies on appendix materials for various grant programs.

DATES: Responses must be received by September 14, 2006 in order to ensure that NIH and AHRQ will be able to consider the comments in developing

new policies on appendix materials for various grant programs.

FOR FURTHER INFORMATION CONTACT: E-mail inquiries will be accepted at appendix_comments@od.nih.gov.

SUPPLEMENTARY INFORMATION:**Background**

The goal of changing the guidelines for grant application appendix materials is to encourage applications to be as concise as possible while containing the information needed for expert scientific review. These changes should make application preparation and handling easier for both applicants and reviewers.

Current NIH and AHRQ policy indicates that the Appendix may not be used to circumvent the page limitations of the Research Plan. Appended publications may not be used to provide further details of methodologies or preliminary data described in the Research Plan. All applications and proposals for NIH and AHRQ funding must be self-contained. NIH application guide instructions note that the Appendix is sent only to those members of the Scientific Review Group (SRG) assigned as primary reviewers of the application. Currently, unless otherwise stated in the solicitation, the following materials may be included in a grant application Appendix:

- Up to 10 publications or manuscripts accepted for publication, using URL links to publicly accessible journal articles.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Photographs or color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 25-page limit of Items a-d of the research plan. No photographs or color images may be included in the Appendix that are not also represented within the Research Plan.

Investigators spend much time and energy developing applications to Federal Agencies. It is unclear whether appendix material which may or may not be read by members of the SRG improves current applications. Submission of unnecessary materials with grant applications wastes the time, energy and resources of investigators, applicant institutions, reviewers, and the NIH and AHRQ.

Proposed Changes

The following changes are being considered for implementation concurrent with NIH/AHRQ's transition to the electronic grant application process and the SF-424 (R&R):

- Submission of photographs or color images of gels, micrographs, etc., will not be allowed in the Appendix. Use of the SF-424 (R&R) electronic grant application will permit insertion into the body of the Research Plan high resolution images of the same quality found in scientific publications.

- Materials currently submitted in the Appendix which are essential to the review of the application will be submitted as part of the grant application itself. For example, documents such as clinical protocols, informed consent forms, key questionnaires, surveys, and similar items which are needed by the SRG to adequately assess human subjects issues will be submitted as part of the 'Protection of Human Subjects' section of the grant application.

- Reprints or preprints of publications or their PDFs will no longer be allowed as part of the Appendix. Links (URLs) to PubMed Central or publicly available on-line journals will be permitted in the Biographical Sketches, Bibliography & References Cited, and the Research Plan sections of the grant application. Critical information and detail should be included within the Research Plan and cited in the Bibliography & References Cited section and/or figure or table legend(s) to indicate publication status.

- Materials specifically designated in the Funding Opportunity Announcement may be included in the Appendix, within identified page limits. It is anticipated that most FOAs will not permit materials to be included in the Appendix.

- All members of the SRG will receive copies of the full application including any permitted Appendix materials thereby increasing the equity of the review.

Information Requested

Information in the following areas will assist the NIH and AHRQ in developing new policies regarding submission of appendix materials. Respondents will be asked to indicate what perspective(s) they represent, i.e. reviewer and/or applicant, institutional official, etc.

1. Is there a need to reduce the material submitted in the Appendix? If yes, please provide specific types of material that could be eliminated.

2. Is there information essential to the application's review that cannot be included in the body of a grant application as proposed? If yes, please describe the material and identify applicable grant program(s).