project, and their applicability to policy and practice. The provision of a detailed discussion of the objectives and of the extent to which they are realistic, specific, and achievable.

Evaluation Criterion III: Results and Benefits (Maximum: 20 Points)

The extent to which the application identifies the results and benefits to be derived, the extent to which they are consistent with the objectives of the application, the extent to which the application indicates the anticipated contributions to policy, practice, and theory, and the extent to which the proposed project costs are reasonable in view of the expected results. Identify, in specific terms, the results and benefits, for target groups and human service providers, to be derived from implementing the proposed project.

Evaluation Criterion IV: Organizational Profiles (Maximum: 15 Points)

The extent to which the participating organizations and entities have discussed, through letters and other documentation, the proposed collaboration and cooperation. Assess the extent to which the financial and physical resources provided by the participating entities will be adequate and to what extent will the coordinating organizations participate in the day to day operations of the project.

Evaluation Criterion V: Budget (Maximum: 15 Points)

Relate the proposed budget to the level of effort required to obtain the project's objectives and provide a cost/benefit analysis. Demonstrate that the project's costs are reasonable in view of the anticipated results. Applications will be evaluated on the extent to which they include a budget that is concise and provides a detailed justification of the amount of Federal funds that are requested.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds, granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

45 CFR Part 74 or 92.

3. Reporting

Programmatic Reports: Semi-annually and a final report is due 90 days after the end of the grant period.

Financial Reports: Semi-annually and a final report due 90 days after the end of the grant period.

All grantees are required to submit semi-annual program reports and semi-annual financial status reports using the required financial standard form (SF–269).

VII. Agency Contacts

Program Office Contact: William D. Riley, Family Violence Division, 330 C Street, Rm. 2117, Switzer Building, Washington, DC 20447, E-mail: *wriley@acf.hhs.gov*, Telephone: (202) 401–5529.

Grants Management Office Contact: William Wilson, Grants Officer, Administration on Children, Youth and Families, Room 2070 Switzer Building, 330 C Street, SW., Washington, DC 20447, 202–205–8913, E-mail: *wwilson@acf.hhs.gov.*

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web site: *http://www.acf.hhs.gov/programs/fysb.*

Dated: May 25, 2004.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 04–12349 Filed 5–28–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[ACYF/FYSB 2004–0006]

Notice of Correction for the FY04 Street Outreach Program Announcement HHS–2004–ACF–ACYF–YO–0016 CFDA# 93.557

AGENCY: Administration on Children, Youth, and Families, ACF, DHHS.

ACTION: Notice of correction.

SUMMARY: This notice is to inform interested parties of corrections made to the Street Outreach program Announcement published on Tuesday, April 27, 2004. The following corrections should be noted:

Under cost sharing or Matching Required: The paragraph should read as follows: Grantees must provide at least 10% of the Federal project dollars of the project. The non-Federal share may be met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. For example, in order to meet the match requirements, a project requesting $200,000 federal dollars, must provide a match of at least $20,000.

Under Application Review Information, Evaluation: Evaluation paragraph is deleted and new paragraph is inserted for Staff and Position Data and reads as follows:

Staff and Position Data

Provide a biographical sketch for each key person appointed and a job description for each vacant key position. A biographical sketch will also be required for new key staff as appointed.

FOR FURTHER INFORMATION CONTACT: ACYF Operations Center at (866) 796–1591 or *fysb@dixongroup.com.*

Dated: May 21, 2004.

Joan E. Ohl.

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 04–12350 Filed 5–28–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0309]

Guidance for Industry and Food and Drug Administation Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions for Reprocessed Single-Use Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised guidance entitled ''Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices'' (validation data guidance). This guidance document is being revised to include the procedures and timeframes that the agency intends to follow in its review of the validation data required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA),

for certain reprocessed single-use devices (SUDs), to include updated references to relevant **Federal Register** notices, and to include a section addressing the Paperwork Reduction Act of 1995 (the PRA). This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4692.

SUPPLEMENTARY INFORMATION:

I. Background

Section 302(b) of MDUFMA (Public Law 2003D–0309) added new requirements for reprocessed SUDs to section 510(o) of the act (21 U.S.C. 360(o)). One of these provisions required FDA to review the reprocessed SUDs that were exempt from premarket notification requirements and to determine which of these devices require the submission of 510(k)s with validation data to ensure their substantial equivalence to predicate devices. The new law also requires the submission of validation data specified in the statute for certain reprocessed SUDs, identified by FDA, that were already subject to 510(k) submission requirements when MDUFMA was enacted. The types of validation data to be submitted include cleaning, sterilization, and functional performance data.

On July 8, 2003, FDA issued guidance under the same title describing the types of validation data that FDA recommended be submitted to the agency to support a substantial equivalence determination for the reprocessed SUDs for which validation data are required by MDUFMA. FDA is now revising the guidance to include the review procedures and timeframes the agency intends to follow when processing the required validation data. This guidance supersedes the July 8, 2003, document.

FDA is implementing this level 1 guidance upon issuance because it is essential for the agency to provide immediate guidance on the procedures and timeframes that FDA intends to follow in reviewing the validation data required by MDUFMA. The agency has determined that, in light of the need to provide immediate guidance to manufacturers of reprocessed SUDs, a request for comments before issuance of this revised guidance is not feasible. FDA is also considering additional changes to the validation guidance based on comments and questions received since this guidance was initially implemented. These changes would be incorporated into a future revision of the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on validation data regarding the cleaning, sterilization, and functional performance of reprocessed SUDs, as well as the procedures and review times that should be used by FDA in evaluating these validation data. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices'' by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (Office GGP Rep will insert DOC number) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12362 Filed 5–26–04; 3:59 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0042]

Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until August 10, 2004, the comment period for the draft guidances entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,'' ''Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms,'' and ''Consumer-Directed Broadcast Advertising of Restricted Devices.'' FDA published a notice of availability of the draft guidances in the **Federal Register** of February 10, 2004 (69 FR 6308). FDA is taking this action in response to requests for an extension and to allow interested parties additional time to submit comments.

DATES: Submit written or electronic comments on the draft guidances by August 10, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), 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 written comments on the draft guidances to the Division of Dockets Management (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 documents.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Lesley R. Frank, Center for Drug Evaluation and Research (HFD–42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2831.

Regarding prescription human biological products: Glenn N. Byrd, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028.

Regarding medical device products: Deborah Wolf, Center for Devices and Radiological Health (HFZ–300), 2098 Gaither Rd., Rockville, MD 20850, 301–594–4589.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 10, 2004 (69 FR 6308), FDA published a document announcing the availability of three draft guidance documents entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,'' ''Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms,'' and ''Consumer-Directed Broadcast Advertising of Restricted Devices.'' The draft guidances are intended to provide clear advice to medical product firms on how to fulfill the requirements in FDA's rules applicable to certain communications to consumers and health care professionals.

In the February 2004 notice of availability, FDA specifically requested comments on a number of issues addressed in the draft guidances. The agency also requested submission of research and data related to these issues. The initial comment period closed on May 10, 2004. FDA received a request dated April 2, 2004, and numerous requests dated May 8, 2004, that the agency extend the comment period. The requests cite the need for additional time because of the importance of the subject matter to be commented on. The requests also state an extension is needed for consultation with interested parties, to complete research, and to prepare comments. In response to these requests, FDA has decided to reopen the comment period until August 10, 2004.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the draft guidance documents by August 10, 2004. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. Comments should identify clearly which guidance they are commenting on. The draft guidance documents and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the draft guidances are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines*, or *http://ww.fda.gov/ohrms/dockets/default.htm*.

Dated: May 25, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12270 Filed 5–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Proposed Project: 2004–2006 National Survey on Drug Use and Health: Methodological Field Tests—New—The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA), is a survey of the civilian, noninstitutionalized population of the United States 12 years of age and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

This will be a request for generic approval for information collection for NSDUH methodological field tests designed to examine the feasibility,