Dated: July 1, 2003.

Edward Schultz,

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

[FR Doc. 03–17173 Filed 7–7–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03112]

Enhancement of Antenatal Care Services and Blood Safety for Preventing Transmission of HIV, Syphilis, and Malaria in the Republic of Tanzania; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2003 funds for a cooperative agreement program in the Republic of Tanzania for (1) the enhancement of antenatal care (ANC) services with emphasis on prevention of mother to child transmission (PMTCT) of HIV; and (2) the enhancement of blood safety with emphasis on preventing transmission of HIV, syphilis, and malaria. The Catalog of Federal Domestic Assistance number for this program is 93.941.

B. Eligible Applicants

Assistance will be provided only to the Department of Diagnostic Services (DDS) of the Ministry of Health (MOH) in Tanzania. No other applications are solicited.

The DDS is currently the only appropriate and qualified organization to conduct a specific set of activities supportive of the CDC Global AIDS Program's (GAP) goals for enhancing ANC services and blood safety in Tanzania for the following reasons:

1. The DDS is uniquely positioned, in terms of legal authority, ability, and credibility among Tanzanian citizens, to coordinate the implementation of national initiatives for PMTCT and blood safety.

2. The DDS has developed national PMTCT and blood safety guidelines, and strategic plans for enhancing PMTCT services and blood safety in Tanzania, which allows the DDS to immediately become engaged in the activities listed in this announcement.

3. The purpose of the announcement is to build upon the existing framework of health policy and programming that the MOH itself has initiated.

4. The MOH in Tanzania has been mandated by the Tanzanian constitution to coordinate and implement activities necessary for the control of epidemics, including HIV/AIDS and STDs.

C. Funding

Approximately $1,000,000 is available in FY 2003 to fund this award; $500,000 for enhancing ANC services, and $500,000 for blood safety. It is expected that the award will begin on or about September 1, 2003, and will be made for a 12-month budget period within a project period of up to five years. Approximately $1,000,000 will be available for years two through five of the project. Funding estimates may change.

D. Where To Obtain Additional Information

For general questions or comments about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For program technical assistance, contact: Eddas M. Bennett, Deputy Director, CDC Tanzania AIDS Program, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 686 Old Bagamoyo Road, Dar es Salaam, Tanzania, Telephone: 255 222 667 8001 x4819, e-mail: *ebennett@tancdc.co.tz*.

Dated: June 1, 2003.

Sandra Manning,

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

[FR Doc. 03–17174 Filed 7–7–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Collection of Specimen Panels for Validation for Incidence Assays, Contract Solicitation Number 2003–N–00872

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Collection of Specimen Panels for Validation for Incidence Assays, Contract Solicitation Number 2003-N–00872.

Times and Dates: 7 p.m.–8 p.m., July 24, 2003 (Open); 8 a.m.–8:30 a.m., July 25, 2003 (Open); 8:30 a.m.–5 p.m., July 25, 2003 (Closed).

Place: The Westin Atlanta North at Perimeter Center, 7 Concourse Parkway, Atlanta, GA 30328, Telephone 770.395.3900.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Contract Solicitation Number 2003–N–00872.

For Further Information Contact: Esther Sumartojo, Ph.D., Deputy Associate Director for Science, National Center for HIV, STD, and TB Prevention, CDC, 1600 Clifton Road, NE., MS–E07, Atlanta, GA 30333, Telephone 404.639.8006.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 27, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–17172 Filed 7–7–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0191]

Agency Emergency Processing Under OMB Review; Submission of Validation Data for Reprocessed Single-Use Devices

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information will be used by FDA to determine whether reprocessed single-use devices (SUDs) are substantially equivalent to legally marketed predicate devices. FDA is requesting this emergency processing under the PRA to implement the statutory provision under section 302 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: Submit comments on the collection of information by August 7,

2003. FDA is requesting approval of this emergency processing by August 22, 2003.

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 electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). This information is needed immediately so that the agency can provide guidance to implement the statutory provision under section 302 of MDUFMA requiring manufacturers to submit validation data for certain reprocessed SUDs. Under section 302 of MDUFMA, FDA was required to publish a list of reprocessed SUDs currently subject to premarket notification requirements for which validation data are necessary, as well as a list of reprocessed SUDs for which an existing exemption from premarket notification requirements will no longer apply. Manufacturers of reprocessed SUDs included in these lists are required by MDUFMA to submit validation data (through the appropriate mechanism) within timeframes specified in the statute.

MDUFMA was signed into law on October 26, 2002. The use of normal clearance procedures would likely result in the prevention or disruption of this collection of information. Therefore, FDA has requested approval of this emergency processing of this proposed collection of information by (see **DATES**).

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Submission of Validation Data for Reprocessed Single Use Devices

Section 302(b) of MDUFMA adds new requirements for reprocessed SUDs to section 510 of the Food Drug and Cosmetic Act (the act) (21 U.S.C. 360)). One of MDUFMA's provisions requires the submission of validation data specified in the statute for certain reprocessed SUDs (as identified by FDA). The types of validation data include cleaning and sterilization data and functional performance data.

MDUFMA requires that FDA review the types of reprocessed SUDs now subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. MDUFMA also requires that FDA review critical and semi-critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require the submission of 510(k)s to ensure their substantial equivalence to predicate devices. Under MDUFMA, the validation data submitted for a reprocessed SUD must demonstrate that the device will remain substantially equivalent to its predicate after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

On April 30, 2003 (68 FR 23139), as required by MDUFMA, FDA published two lists in the **Federal Register**: (1) A list of critical reprocessed SUDs whose exemption from 510(k) requirements will be terminated; and (2) a list of reprocessed SUDs that are currently subject to 510(k) requirements for which validation data must be submitted. FDA will update these lists as necessary.

The validation data required by MDUFMA must be submitted according to the following timetable:

- After publication of the lists manufacturers submitting new 510(k)s for listed devices must include validation data.
- Within 9 months after publication of the list (by January 30, 2004), manufacturers of listed devices with 510(k)s pending for these devices at the time the lists were published should either supplement these 510(k)s with validation data or resubmit them with validation data after clearance.
- Manufacturers of listed devices with 510(k)s for these devices cleared by FDA before publication of the lists must submit validation data for these devices within 9 months after publication of the lists (by January 30, 2004).
- Manufacturers of listed devices that were previously exempt from 510(k) submission requirements must submit validation data for these devices in 510(k) submissions within 15 months after publication of the lists (July 30, 2004).
- By April 26, 2004, FDA must publish a list of semi-critical reprocessed SUDs that will require the submission of validation data in 510(k) submissions. The publication of this list will trigger submission timeframes the same as those in the previous paragraphs.

Respondents to the proposed collection of information will likely be businesses or other for-profit organizations.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Item	No. of respondents	Annual rrequency per response	Total annual responses	Hours per response	Total hours
Submission of validation data (2003)	20	5	100	40	4,000
Submission of validation data (2004)	20	20	400	40	16,000
Submission of validation data (2005)	20	10	200	40	8,000

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Item	No. of respondents	Annual rrequency per response	Total annual responses	Hours per response	Total hours
Total Hours					28,000

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

Based on submissions received to date and registration and listing records for the affected devices, FDA estimates that there are 20 reprocessors of SUDs that will need to submit validation data. In calendar year 2003, FDA estimates that there will be 5 new 510(k)s for reprocessed SUDs. Based on its experience with reviewing 510(k)s and discussions with reprocessors, FDA estimates that it will take 40 hours per 510(k) to develop and submit the validation data. This results in a total burden of 4,000 for 2003. (In this estimate, FDA is only taking into account the burden related to validation data. The other collections of information related to the submission of information in a 510(k) 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).

In 2004, reprocessors with previously exempt and cleared devices will need to submit their validation data by January 30, 2004, and July 30, 2004. For 2004, FDA estimates that the 20 manufacturers will submit an average of 20 510(k)s each for a total burden of 16,000 hours.

In 2005, FDA estimates that the 20 manufacturers will submit 10 new 510(k)s each. This will result in a total burden of 8,000.

Dated: July 1, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17136 Filed 7–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0285]

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of the medical and clinical pharmacology reviews of pediatric studies submitted in supplements for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). The summaries are being made available consistent with the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: The summaries are available for public examination between 9 a.m. and 4 p.m., Monday through Friday, in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD–950), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, CrescenziT@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of the medical and clinical pharmacology reviews of pediatric studies conducted for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet (*http://www.fda.gov/cder/pediatric/index.htm*) summaries of the medical and clinical pharmacology reviews of the pediatric studies submitted in supplements for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). Copies are also available for public examination in the Division of Dockets Management or may be requested by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cder/pediatric/index.htm.*

Dated: June 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17134 Filed 7–7–03; 8:45 am]

BILLING CODE 4160–01–S