AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–19 Third Party Agreements—ATSDR
AR–22 Research Integrity

Executive Order 12372 does not apply to this program.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC web site, Internet address: *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

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

For business management and budget assistance, contact: Edna Green, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2743, E-mail address: *EGreen@cdc.gov*.

For business management and budget assistance in the territories, contact: Julie Grace, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2782, E-mail: *amn3@cdc.gov*.

For program technical assistance, contact: Morris L. Maslia, P.E., Project Officer, Agency for Toxic Substances and Disease Registry, 1825 Century Boulevard, Room 3094, Mail Stop E–32, Atlanta, Georgia 30345, Telephone number: (404) 498–0415, E-mail address: *mmaslia@cdc.gov*.

Dated: May 8, 2003.

Sandra R. Manning,

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

[FR Doc. 03–11975 Filed 5–13–03; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Advisory Committee on Children and Terrorism: Conference Call Meeting and Advisory Meeting

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 Federal advisory committee conference call meeting.

Name: National Advisory Committee on Children and Terrorism (NACCT).

Time and Date: 10:30 a.m.–12 p.m., May 16, 2003.

Place: The conference call will originate at the Office of Terrorism Preparedness and Emergency Response (OTPER), in Atlanta, Georgia. Please *see* **SUPPLEMENTARY INFORMATION** for details on accessing the conference call.

Status: Open to the public, limited only by the availability of telephone ports.

Purpose: The committee is charged with advising the Secretary, Health and Human Services, on (a) the preparedness of the health care system to respond to bioterrorism as it relates to children; (b) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of children; and (c) changes, if necessary, to the National Strategic Stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to meet the emergency health security of children.

Matters to be Discussed: The National Advisory Committee on Children and Terrorism will convene by conference call to discuss the draft report to the Secretary.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the meeting.

SUPPLEMENTARY INFORMATION: This conference call is scheduled to begin at 10:30 a.m., Eastern Standard Time. To participate in the conference call, please dial (404) 639–3277 or (800) 311–3437 and enter conference code 864530. You will then be automatically connected to the call.

Contact Person for More Information: Victor Balaban, Office of Terrorism Preparedness and Emergency Response, CDC, 1600 Clifton Road, NE., (D–44), Atlanta, Georgia 30333, telephone (404) 639–7428, fax (404) 639–7977.

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 Advisory Committee meeting.

Name: National Advisory Committee on Children and Terrorism, HHS, CDC.

Time and Date: 8 a.m.–5 p.m., May 21, 2003.

Place: Doubletree Hotel National Airport, 300 Army Navy Drive, Arlington, Virginia 22202 telephone: 1–800–222–TREE.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The committee will make recommendations to the Secretary of HHS on matters related to bioterrorism and its impact on children.

Matters to be Discussed: Agenda items will include from the chairperson of the committee an introduction of committee members and discussion of the Secretary priorities with discussions of recommendations regarding, (a) the preparedness of the health care system to respond to bioterrorism as it relates to children; (b) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of children; and (c) changes, if necessary to the National Strategic Stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to meet the emergency health security of children.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Victor Balaban, Office of Terrorism Preparedness and Emergency Response, CDC, 1600 Clifton Road, NE., (D–44), Atlanta, Georgia 30333, telephone (404) 639–7428, fax (404) 639–7977.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 6, 2003.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–11872 Filed 5–13–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0486]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the information collection provisions by June 13, 2003.

ADDRESSES: The Office of Management and Budget (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.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements—21 CFR Part 3 (OMB Control Number 0910–0435)—Extension

The Food and Drug Administration (FDA) is requesting OMB approval under the Paperwork Reduction Act (44 U.S.C. 3507) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Public Law 100–293). PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk of counterfeit, adulterated, misbranded, subpotent, or expired drugs being sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against U.S. manufacturers and had provided the cover for the importation of foreign counterfeit drugs.

Congress also determined that the system of providing drug samples to physicians through manufacturers' representatives had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

The bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail also helped to fuel the diversion market and was an unfair form of competition to wholesalers and retailers who had to pay otherwise prevailing market prices.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements:

TABLE 1.—REPORTING REQUIREMENTS

21 CFR Section	Reporting and Recordkeeping Requirements
203.11	Applications for re-importation to provide emergency medical care.
203.30(a)(1) and (b)	Drug sample requests for drug samples distributed by mail or common carrier.
203.30(a)(3), (a)(4), and (c)	Drug sample receipts for drug samples distributed by mail or common carrier.
203.31(a)(1) and (b)	Drug sample requests for drug samples distributed by means other than the mail or a common carrier.
203.31(a)(3), (a)(4), and (c)	Drug sample receipts for drug samples distributed by means other than the mail or a common carrier.
203.37(a)	Investigation of falsification of drug sample records.
203.37(b)	Investigation of a significant loss or known theft of drug samples.
203.37(c)	Notification that a representative has been convicted of certain offenses involving drug samples.
203.37(d)	Notification of the individual responsible for responding to a request for information about drug samples.
203.38(a)	Printing lot or control numbers on the drug sample unit label.
203.39(g)	Preparation by a charitable institution of a reconciliation report for donated drug samples.
203.50(a)	Drug origin statement.
203.23(a) and (b)	Credit memorandom for returned drugs.
203.23(c)	Documentation of proper storage, handling, and shipping conditions of returned drugs.
203.30(a)(2) and 203.31(a)(2)	Verification that a practitioner requesting a drug sample is licensed or authorized to prescribe the product.
203.31(d)(4)	Investigation of apparent discrepancies and significant losses revealed through the reconciliation report.
203.31(e)	Lists of manufacturers' and distributors' representatives.
203.34	Written policies and procedures describing administrative systems.
203.37(a)	Report of investigation of falsification of drug sample records.
203.37(b)	Report of investigation of significant loss or known theft of drug samples.
203.38(b)	Records of drug sample distribution identifying lot or control numbers of samples distributed.
203.39(d)	Records of drug samples destroyed or returned by a charitable institution.

TABLE 1.—REPORTING REQUIREMENTS—Continued

21 CFR Section	Reporting and Recordkeeping Requirements
203.39(e)	Record of drug samples donated to a charitable institution.
203.39(f)	Records of donation and distribution or other disposition of donated drug samples.
203.39(g)	Inventory and reconciliation of drug samples donated to charitable institutions.
203.50(a)	Drug origin statement.
203.50(b)	Retention of drug origin statement for 3 years.
203.50(d)	List of authorized distributors of record.

The reporting and recordkeeping requirements are intended to help achieve the following goals:

1. To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care;

2. To ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any drug sample;

3. To limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other health care entities at the request of a licensed or authorized practitioner;

4. To require licensed or authorized practitioners to request samples in writing;

5. To mandate storage, handling, and recordkeeping requirements for drug samples;

6. To prohibit, with certain exceptions, the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or other health care entities, or which were donated or supplied at a reduced price to a charitable organization;

7. To require unauthorized wholesale distributors to provide, prior to the wholesale distribution of a prescription drug to another wholesale distributor or retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

In the **Federal Register** of December 2, 2002 (67 FR 71572), FDA requested comments on the proposed collection of information. FDA received one comment requesting that it be deemed an ''other health care entity'' and be permitted to receive and dispense samples to its patients. This comment does not pertain to the information collection estimates in the December 2, 2002, notice, and has been forwarded to the appropriate office in FDA that reviews these types of requests.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.11	12	1	12	.5	6
203.30(a)(1) and (b)	61,961	12	743,532	.06	44,612
203.30(a)(3), (a)(4), and (c)	61,961	12	743,532	.06	44,612
203.31(a)(1) and (b)	232,355	135	31,367,925	.04	1,254,717
203.31(a)(3), (a)(4) and (c)	232,355	135	31,367,925	.03	941,038
203.37(a)	25	1	25	6.00	150
203.37(b)	200	1	200	6.00	1,200
203.37(c)	50	1	50	1.00	50
203.37(d)	2,208	1	2,208	.08	177
203.38(a)	2,208	1	2,208	3.00	6,624
203.39(g)	3,221	1	3,221	2.00	6,442
203.50(a)	125	100	12,500	.08	1,000
Total Reporting Burden Hours					2,300,628

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40.00	88,320
203.31(d)(4)	442	1	442	24.00	10,608
203.31(e)	2,208	1	2,208	1.00	2,208
203.34	2,208	1	2,208	40.00	88,320
203.37(a)	25	1	25	18.00	450
203.37(b)	200	1	200	18.00	3,600
203.38(b)	2,208	14,543	32,111,457	.02	642,229
203.39(d)	65	1	65	1.00	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8.00	25,768

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
203.39(g)	3,221	1	3,221	8.00	25,768
203.50(a)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2.00	1,382
Total Recordkeeping Burden Hours					1,061,368

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

Dated: May 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11925 Filed 5–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5435]

Guidance for Industry on Photosafety Testing; 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 May 7, 2003 (68 FR 24487). The document announced the availability of a guidance for industry entitled ''Photosafety Testing.'' The document was published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–11216, appearing on page 24487 in the **Federal Register** of Wednesday, May 7, 2003, the following correction is made:

1. On page 24487, in the first column, in the heading of the document, ''[Docket No. 99D–5453]'' is corrected to read ''[Docket No. 99D–5435]''.

Dated: May 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11924 Filed 5–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0467]

''Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection'' dated May 2003. The guidance provides our revisions to the guidance of the same title dated October 2002 in which FDA provided its recommendations for assessing donor suitability and product safety for donors with proven recent West Nile Virus (WNV) infections or with illness potentially due to WNV. The guidance is intended to recommend deferral of donors infected or potentially infected with WNV, and to recommend quarantine of blood and blood products previously collected from such donors. These measures are intended to reduce the possibility of WNV transmission by blood and blood products and are for immediate implementation. This guidance supersedes the guidance of the same title dated October 2002.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written or electronic requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800 or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection'' dated May 2003. The guidance document provides information related to the possible risk of WNV transmission by blood or blood products. The presence of WNV in blood components and transfusion transmission from blood components has been documented. FDA developed this guidance in consultation with other Public Health Service agencies of the Department of Health and Human Services. The guidance supersedes the guidance of the same title dated October 2002.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic.