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.

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 statutes and regulations.

II. Comments

The agency is soliciting public comment, and is recommending the implementation of the guidance by June 1, 2003, because of public health concerns related to the possible risk of transfusion transmitted WNV.

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding this guidance document. Two copies of mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11980 Filed 5–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG 2003–15096]

Collection of Information under Review by Office of Management and Budget (OMB): OMB Control Numbers 1625–0046 and 1625–0071

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of two Information Collection Requests (ICRs). The ICRs comprise (1) Financial Responsibility for Water Pollution (Vessels), and (2) Boat Owner's Report, Possible Safety Defect. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

DATES: Comments must reach the Coast Guard on or before July 14, 2003.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG 2003–15096] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001. Caution: Because of recent delays in the delivery of mail, your comments may reach the Facility more quickly if you choose one of the other means described below.

(2) By delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at *http://dms.dot.gov*.

The Facility maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

Copies of the complete ICRs are available through this docket on the Internet at *http://dms.dot.gov,* and also from Commandant (G–CIM–2), U.S. Coast Guard Headquarters, room 6106 (Attn: Barbara Davis), 2100 Second Street SW., Washington, DC 20593–0001. The telephone number is 202–267–2326.

FOR FURTHER INFORMATION CONTACT: Barbara Davis, Office of Information Management, 202–267–2326, for questions on this document; or Dorothy Beard, Chief, Documentary Services Division, U.S. Department of Transportation, 202–366–5149, for questions on the docket.

Request for Comments

The Coast Guard encourages interested persons to submit comments. Persons submitting comments should include their names and addresses, identify this document [USCG 2003–15096], and give the reasons for the comments. Please submit all comments and attachments in an unbound format no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped self-addressed postcards or envelopes.

Information Collection Requests

1. *Title:* Financial Responsibility for Water Pollution (Vessels).

OMB Control Number: 1625–0046.

Summary: The collection of information requires operators of vessels over 300 gross tons to submit to the U.S. Coast Guard evidence of their financial responsibility to meet the maximum amount of liability in case of a spill of either oil or hazardous substances.

Need: Under 33 U.S.C. 2716 and 42 U.S.C. 9608, the Coast Guard has the authority to ensure that those persons directly subject to these rules are in compliance with the provisions.

Respondents: Operators or owners of vessels over 300 gross tons.

Frequency: On occasion.

Burden: The estimated burden is 2,162 hours a year.

2. *Title:* Boat Owner's Report, Possible Safety Defect.

OMB Control Number: 1625–0071.

Summary: The collection of information provides a form for consumers who believe their recreational boats or designated associated equipment either contains substantial-risk defects or fails to comply with Federal safety standards to report the deficiencies to the Coast Guard for investigation and possible remedy.

Need: 46 U.S.C. 4310 gives the Coast Guard the authority to require manufacturers of recreational boats and certain items of designated associated equipment to notify owners and remedy (1) defects that create a substantial risk of personal injury to the public and (2) failures to comply with applicable Federal safety standards.

Respondents: Owners and users of recreational boats and of items of designated associated equipment.

Frequency: One time.

Burden: The estimated burden is 10 hours a year.

Dated: May 5 2003.

Nathaniel S. Heiner,

Acting Director of Information & Technology.

[FR Doc. 03–11985 Filed 5–13–03; 8:45 am]

BILLING CODE 4910–15–P