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.