

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|------------------------------------|-------------------------------|------------------------|--------------------|-------------|
| 1,800 (content study: screener) | 1 | 1,800 | .017 | 31 |
| 900 (content study: questionnaire) | 1 | 900 | .33 | 297 |
| 600 (format study: screener) | 1 | 600 | .017 | 10 |
| 300 (format study: questionnaire) | 1 | 300 | .33 | 99 |
| Total | | | | 437 |

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

Dated: April 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-6142 Filed 4-24-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0408]

Regulatory Site Visit Training Program; 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 April 11, 2006. The document reannounced the invitation for participation in its Regulatory Site Visit Training Program. The document was published with an incorrect e-mail address. This document corrects that error.

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

SUPPLEMENTARY INFORMATION: In FR Doc. E6-5221, appearing on page 18340 in the **Federal Register** of Tuesday, April 11, 2006, the following correction is made:

1. On page 18340, in the third column, in the last sentence under the “ADDRESSES” caption and under the “FOR FURTHER INFORMATION CONTACT” caption, the e-mail address is corrected to read *matt@cber.fda.gov*.

Dated: April 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-6120 Filed 4-24-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of March 7, 2006. The document announced a workshop on FDA clinical trial statutory and regulatory requirements. The document was published with an incorrect Internet address. This document corrects that error.

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

SUPPLEMENTARY INFORMATION: In FR Doc. E6-3229, appearing on page 11434 in the **Federal Register** of Tuesday, March 7, 2006, the following correction is made:

1. On page 11434, in the second column, under the “Registration” caption, the Internet address is corrected to read *http://www.socra.org/html/FDA_Conference.htm*.

Dated: April 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-6119 Filed 4-24-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0150]

Guidance for Sponsors, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable.” This guidance is intended to inform sponsors, institutional review boards, clinical investigators, and agency staff that under circumstances described in the guidance, that FDA does not intend to object to the use in device investigations, without informed consent, of leftover human specimens that are not individually identifiable. FDA intends to include in this policy leftover specimens that are remnants of specimens collected for routine clinical care or analysis that would otherwise have been discarded, specimens obtained from specimen repositories, and specimens that are leftover from specimens previously collected for other unrelated research. This guidance document will be implemented immediately, 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. General comments on agency guidance documents are welcome at any time.