the number of respondents for listing of ingredients under section 904 of the act from 100,000 to 11,000 in response to comments that this estimate was too high. FDA also added the activity of applying for a Dun and Bradstreet D-U-N-S number to the burden of this information collection for those who chose to use eSubmitter.

In the **Federal Register** of February 18, 2010 (75 FR 7269), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was outside the scope of the PRA requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

| Activity | Number of Respondents | Annual Frequency per Response | Total Annual Respondents | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Registration and Product Listing for Owners and Operators of Domestic Establishments | 100,000 | 1 | 100,000 | 3.75 | 375,000 |
| Listing of Ingredients | 11,000 | 1 | 11,000 | 3.0 | 33,000 |
| Obtaining a Dun and Bradstreet D-U-N-S Number | 1,550 | 1 | 1,550 | 0.5 | 775 |
| Total | 112,550 | | 112,550 | | 408,775 |

Dated: May 4, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–10781 Filed 5–6–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0487]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, email: *Daniel.Gittleson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 19, 2010 (75 FR 2868), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0582. The approval expires on February 28, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: May 4, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; REDS–II—Does Pre-Donation Behavioral Deferral Increase the Safety of the Blood Supply?

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung and Blood Institute (NHLBI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 24, 2010 in Volume 75, No. 36, pages 8367–8368 and allowed 60-days for public comment. (No public comments were received.) The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection: Title:* REDS–II Does Pre-Donation Behavioral Deferral Increase the Safety of the Blood Supply?

*Type of Information Collection Request:* New. *Need and Use of Information Collection:* While it is well-accepted that deferrals, as part of the "layers of safety" concept, increase the safety of the blood supply, studies with sufficiently large sample size to quantify HIV infection and other infectious marker rates in deferred donors are lacking. Evidence in support of increased safety is frequently inferred from studies conducted in other health care settings. For example, a small hospital-based case control study conducted in Brazil examined the association between infectious markers and body tattoos. Even though tattoos are not used as a criteria to determine blood donor eligibility in Brazil, having a tattoo was associated with HCV and also with having at least one positive infectious marker.(1) Significant associations were not independently observed for HIV, HBV, syphilis or Chagas. The authors reported an overall sensitivity of 11% and specificity of