TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/Form No.	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
FDA–2656 (Registration of Drug Establishment) 207.21 207.22 207.25 207.26 207.40	18,430	.36	6,700	2.50	16,750
FDA–2656 (Annual Update of Drug Establishment) 207.21 207.22 207.25 207.26 207.40	8,382	.82	6,859	2.50	17,147.50
FDA–2657 (Drug Product Listing) 207.21 207.22 207.25 207.30 207.31 207.40	15,530	3	46,713	2.50	116,782.50
FDA–2658 (Registered Establishments' Report of Private Label Distributors) 207.21 207.22 207.25 207.30 207.31	7,216	2.14	15,415	2.50	38,537.50
Total Reporting Burden					189,217.50

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

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7907 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0463]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Infant Formula Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 13, 2004 (69 FR 1985), 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 0910–0256. The approval expires on March 31, 2007.

A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8024 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0507]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study of Trans Fat Claims on Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Experimental Study of Trans Fat Claims on Food'' has been approved by the Office of Management and Budget

(OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 10, 2003 (68 FR 63799), 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 0910–0533. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8025 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0133]

Electronic Record; Electronic Signatures; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss various topics concerning our regulations on electronic records and electronic signatures in part 11 (21 CFR part 11). FDA has begun to re-examine part 11 as it applies to all FDA-regulated products. We will consider the input from the public meeting and comments on the topics presented in this document as we evaluate potential changes to part 11.

DATES: The public meeting will be held on June 11, 2004, from 8 a.m. to 4:30 p.m. Submit written or electronic requests to speak plus a presentation abstract by May 12, 2004. Although written or electronic comments on the issues presented in this document will be accepted until July 9, 2004, to have your comments considered at the meeting, submit them by May 12, 2004.

ADDRESSES: The public meeting will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594, 202–314–6421. The center may be reached by Metro, using the L'Enfant Plaza Station on the green, yellow, blue, and orange lines; for further information see *http://www.ntsb.gov/events/newlocation.htm*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

You may submit comments, identified by Docket No. 2004N–0133, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0133 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Request for Comments'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane,rm. 1061, Rockville, MD 20852.

Transcripts of the public meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets*.

FOR FURTHER INFORMATION CONTACT:

For General Information: Joseph C. Famulare, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8940, *part11@cder.fda.gov*; or David Doleski, Center for Biologics Evaluation and Research (HFM–676), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3031, *doleski@cber.fda.gov*; or

John Murray, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4659, *jfm@cdrh.fda.gov*; or

Vernon D. Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0312, *vtoelle@cvm.fda.gov*; or

JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3116, *jziyad@cfsan.fda.gov*; or

Scott MacIntire, Office of Regulatory Affairs (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857–1706, 301–827–0386, *smacinti@ora.fda.gov*.

For Registration Information: Anne M. Henig, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5576, *heniga@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Part 11 provides the criteria under which FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records, and handwritten signatures executed on paper (62 FR 13430, March 20, 1997). These regulations, which apply to all FDA program areas, were intended to permit the widest possible use of electronic technology, consistent with FDA's responsibility to protect the public health.

After part 11 became effective in August 1997, significant discussions ensued among industry, contractors, and the agency concerning the scope, interpretation, and implementation of the regulations. Concerns were raised that some interpretations of the part 11 requirements would do the following: (1) Unnecessarily restrict the use of electronic technology in a manner inconsistent with FDA's stated intent in issuing the rule, (2) significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted, and (3) discourage innovation and technological advances without providing a