

immediately halt a specific product from entering the United States. In the **Federal Register** of November 4, 2010 (75 FR 67981), FDA published

a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| FDA imported products | Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|--|-----------------------|-------------------------------|------------------------|--------------------|-------------|
| Non-Tobacco (approved by OMB 09/01/2009) | 3,406 | 1,089 | 3,709,134 | .14 | 519,279 |
| Tobacco (new estimated burden) | 200 | 68 | 13,600 | .14 | 1,904 |
| Total | | | | | 521,183 |

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

Dated: February 9, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA–2011–N–0076]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to FDA’s electronic records and electronic signatures.

DATES: Submit either electronic or written comments on the collection of information by April 18, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document.

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, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Electronic Records; Electronic Signatures—21 CFR Part 11 (OMB Control Number 0910–0303)—Extension

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the Agency has stated its ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require the following standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The Agency anticipates the use of electronic media will

substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR section | Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|----------------|-----------------------|-------------------------------|------------------------|--------------------|-------------|
| 11.100 | 4,500 | 1 | 4,500 | 1 | 4,500 |
| Total | | | | | 4,500 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

| 21 CFR section | Number of recordkeepers | Annual frequency per recordkeeping | Total annual records | Hours per record | Total hours |
|----------------|-------------------------|------------------------------------|----------------------|------------------|-------------|
| 11.10 | 2,500 | 1 | 2,500 | 20 | 50,000 |
| 11.30 | 2,500 | 1 | 2,500 | 20 | 50,000 |
| 11.50 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| 11.300 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| Total | | | | | 280,000 |

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

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Governmentwide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0075]

Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the good laboratory practice (GLP) for nonclinical laboratory studies regulations.

DATES: Submit either electronic or written comments on the collection of information by April 18, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.