

[www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm));

- Obtaining the digital certificate used with FDA’s electronic submission gateway and uploading the SPL file for submission (accessible at <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>); and

- Requests for waivers from the electronic submission process as described in the draft guidance.

When FDA published the 2009 guidance on submitting establishment

registration and drug listing information in electronic format, the Agency also amended its burden estimates for OMB control number 0910–0045 to include the additional burden for collection of information that had not been submitted using the FDA Forms, and to create and upload the SPL file. The amended burden estimates included the one-time preparation of an SOP for creating and uploading the SPL file. Although most firms will already have prepared an SOP for the electronic submission of drug establishment registration and drug listing information, each year additional firms will need to create an SOP. As

provided in table 2 of this document, FDA estimates that approximately 1,000 firms will have to expend a one-time burden to prepare, review, and approve an SOP, and the Agency estimates that it will take 40 hours per recordkeeper to create 1,000 new SOPs for a total of 40,000 hours.

The information collection requirements of the drug listing and establishment registration regulations have been grouped according to the information collection areas of the regulations.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| Activity  | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours    |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|----------------|
| New registrations, including new labeler codes requests ... | 39                    | 14.72                              | 574                    | 4.5                         | 2,583          |
| Annual updates of registration information .....            | 3,256                 | 2.99                               | 9,735                  | 4.5                         | 43,808         |
| New drug listings .....                                     | 1,567                 | 6.57                               | 10,295                 | 4.5                         | 46,328         |
| New listings for private label distributor .....            | 146                   | 10.06                              | 1,469                  | 4.5                         | 6,611          |
| June and December updates of all drug listing information   | 1,677                 | 11.21                              | 18,799                 | 4.5                         | 84,596         |
| Waiver requests .....                                       | 1                     | 1                                  | 1                      | 1                           | 1              |
| <b>Total .....</b>  |                       |                                    |                        |                             | <b>183,927</b> |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| Activity resulting from section 510(p) of the FD&C act as amended by FDAAA | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours   |
|--|-------------------------|------------------------------------|----------------------|----------------------------------|---------------|
| One-time preparation of SOP .....  | 1,000                   | 1                                  | 1,000                | 40                               | 40,000        |
| SOP maintenance .....  | 3,295                   | 1                                  | 3,295                | 1                                | 3,295         |
| <b>Total .....</b>   |                         |                                    |                      |                                  | <b>43,295</b> |

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

Dated: October 18, 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–0001]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Health and Diet Survey**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing

that a collection of information entitled “Health and Diet Survey” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

**SUPPLEMENTARY INFORMATION:** On May 27, 2011, the Agency submitted a proposed collection of information entitled “Health and Diet Survey” 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 0910–0545. The approval expires on September 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 18, 2011.  
**David Dorsey,**  
*Acting Associate Commissioner for Policy and Planning.*  
 [FR Doc. 2011–27397 Filed 10–21–11; 8:45 am]  
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