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- Requests for waivers from the electronic submission process as described in the draft guidance.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[1]

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
Total					183,927

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

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
Total					43,295

[1] 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.

[FR Doc. 2011–27389 Filed 10–21–11; 8:45 am]

BILLING CODE 4160–01–P

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]

BILLING CODE 4160–01–P