Since this collection of information was last approved by OMB on December 2, 2010, its burden has decreased by 407,421 hours, from 408,775 to 1,354 reporting hours. This adjustment is a result of FDA experience over the past 2 years in the regulation of tobacco products and is based on the actual number of establishment registration and product ingredient submissions received during this time period. In 2010, when this collection was first published for public comment in the **Federal Register**, FDA attempted to determine the actual number of tobacco manufacturers by using the Security and Exchange Commission's Standard Industrial Classification (SIC) codes, which are identifying codes that appear in a company's EDGAR filings to show the company's type of business. When preparing the collection of information package for publication in 2010, the tobacco industry codes indicated that over 10,000 tobacco manufacturers existed under the SIC codes for tobacco products and cigarettes. However, upon further examination of these codes, it appears that the number of tobacco manufacturers was greatly inflated, as the SIC codes included tobacco retail in addition to tobacco manufacturers. In addition, no comments were received from the 2010 initial 60-day **Federal Register** notice regarding either the number of respondents or the number of reporting burden hours listed in the notice, so FDA used the collection's SIC-researched manufacturer numbers for this collection of information. Actual FDA registration and product listing report submissions and FDA experience indicate in the past 2 years, the number of tobacco manufacturers required to register and list their products and ingredient listings is approximately 125, a substantial decrease from the number of potential respondents listed in 2010. By applying the revised number of manufacturers to the burden chart, the total burden for registration and listing now is currently estimated to be 1,354 reporting burden hours, much less than the 408,775 OMB-approved reporting burden hours stated in 2010.

Based on the actual number of registration and product ingredient listing reports received by FDA over the past 2 years, the number of expected annual responses is projected to decrease from 100,000 registration responses to 200 annual responses, and from 11,000 annual product ingredient listing responses to 200 annual product ingredient responses. The Agency bases its estimate on the actual number of registration and listing and product ingredient listing reports received, its experience with the submission of registration and listing requirements applicable to other FDA regulated products, and ongoing interactions with industry. FDA estimates that the submission of registration information as required by section 905 of the FD&C Act will remain at 3.75 hours per establishment. Based on the actual number of registration information submitted in the past 2 years and its experience, the Agency estimates that approximately 200 registrations will be submitted from 125 tobacco product establishments annually, for a total 750 hour burden (125 respondents × 1.6 responses per respondent × 3.75 hours per response).

FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will remain at 3.0 hours per tobacco product. Based on the actual number of product ingredient listings submitted over the past 2 years and its experience, the Agency estimates that approximately 200 ingredient listings will be submitted from 125 tobacco establishments, for a total 600 burden hours (125 respondents × 1.6 responses per respondent × 3.0 hours per response).

FDA estimates that obtaining a Dun and Bradstreet (DUNS) number will take 0.5 hours, and that 8 respondents (1 percent (1.25) of establishments required to register under section 905 and 5 percent (6.25) of submitters required to list ingredients under section 904) will not already have a DUNS number. The total burden, therefore, will be 4 hours (8 respondents × 1 response per respondent × 0.5 hours per response).

Total burden hours for this collection, therefore is 1,354 hours (750 + 600 + 4 hours).

Dated: July 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18975 Filed 8–2–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0627]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 27, 2012, the Agency submitted a proposed collection of information entitled '' General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' 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 0910–0183. The approval expires on June 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: July 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18976 Filed 8–2–12; 8:45 am]

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