MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the PMD, then the DME MAC sends an affirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary. When the claim is submitted to the DME MAC by the supplier, it is linked to the Prior Authorization via the claims processing system and so long as all applicable requirements in the applicable NCD/LCD are met, the claim is paid.

• Scenario 2: When a submitter sends a prior authorization request but all relevant Medicare coverage requirements are not met for the PMD, then the DME MAC sends a nonaffirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary advising them that Medicare will not pay for the item. A supplier can deliver the PMD, and submit a claim with a non-affirmative prior authorization decision, at which point the DME MAC would deny the claim. The supplier and/or the beneficiary would then have the Medicare denial for secondary insurance purposes and would have full appeal rights.

If an applicable PMD claim is submitted without a prior authorization decision it will be stopped and documentation will be requested to conduct medical review. After the first 3 months of the demonstration, we will assess a payment reduction for claims that, after review, are deemed payable, but did not first receive a prior authorization decision. As evidence of compliance, the supplier must submit the prior authorization number on the claim in order to avoid a 25 percent payment reduction. The 25 percent payment reduction is non-transferrable to the beneficiary and not subject to appeal. In the case of capped rental items, the payment reduction will be applied to all claims in the series.

The 25-percent reduction in the Medicare payment is for each payable base claim not preceded by a prior authorization request except in competitive bidding areas. If a competitive bid contract supplier submits a payable claim for a beneficiary with a permanent residence in a competitive bidding area, that is included in the supplier's contract, without first receiving a prior authorization decision, that competitive bid supplier would receive the applicable single payment amount under the competitive bid program, and would not be subject to the 25-percent reduction. These suppliers must still adhere to all other requirements of the demonstration.

• Scenario 3: When a submitter sends a prior authorization request where documentation is incomplete, the prior authorization request is sent back to the submitter with an explanation about what information is missing. The submitter can rectify the situation and resubmit the prior authorization request. The physician or treating practitioner, supplier, and Medicare beneficiary are also notified.

• Scenario 4: When the DME supplier fails to receive a prior authorization decision, but nonetheless delivers the item to the beneficiary and submits the claim to the DME MAC for payment, the PMD claim will be reviewed under normal medical review processing timeframes.

++ If the claim is determined to be not medically necessary or insufficiently documented, the claim will be denied. The supplier and/or beneficiary can appeal the claim denial. If the claim, after review, is deemed not payable then all current beneficiary/supplier liability policies and procedures as well as appeal rights remain in effect.

++ If the claim is determined to be payable, it will be paid. However, 3 months after the start of the demonstration, a 25-percent reduction in the Medicare Payment will be applied for failure to receive a prior authorization decision before the submission of a claim. This payment reduction will not be applied for competitive bidding program contract suppliers submitting claims for beneficiaries who maintain a permanent residence in a Competitive Bidding Area in their contracts according to the Common Working File (CWF)); these contract suppliers will continue to receive the applicable single payment amount under their contracts. The 25-percent payment reduction is non-transferrable to the beneficiary for the claims that are deemed payable. This payment reduction will begin 3 months after the start of the demonstration and is not subject to appeal. In the case of capped rental items the payment reduction will be applied to all claims in the series. After a claim is submitted and processed, appeal rights are available as they normally are.

Under the demonstration, we will work to limit the impact on beneficiaries. We will educate beneficiaries as part of this protection. If the prior authorization request is not affirmed, and the claim is still submitted by the supplier, the claim will be denied in full, but beneficiaries will continue to have all normal appeal rights as well as the option of signing an Advance Beneficiary Notice in order to receive and be liable for payment for a denied PMD.

Additional information is available on the CMS Web site at go.cms.gov/PAdemo.

IV. Collection of Information Requirements

We announced and solicited comments for the information collection requirements associated with the Medicare Prior Authorization for Power Mobility Device (PMD) Demonstration for certain PMD codes in 60-day and 30-day **Federal Register** notices that published on February 7, 2012 (77 FR 6124) and May 29, 2012 (77 FR 31616), respectively. The information collection requirements are approved under OMB control number 0938–1169.

Authority: Section 402(a)(1)(J) of the Social Security Amendments of 1967.

Dated: July 30, 2012

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–19014 Filed 8–1–12; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 4, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All

comments should be identified with the OMB control number 0910–0650. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products (OMB Control Number 0910–0650)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(b) of the FD&C Act (21 U.S.C. 387e(b)), as amended by the Tobacco Control Act, requires that ''every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products * * *'' register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(c) of the FD&C Act requires that first-time persons ''engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.'' Section 905(d) states that persons required to register under sections 905(b) or 905(c) shall register any additional establishment that they own or operate in any state which begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Section 905(h) addresses foreign establishment registration requirements, which will go into effect when regulations are promulgated by the Secretary. Section 905(i)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires that all registrants ''shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,'' along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the FD&C Act (21 U.S.C. 387d(a)(1)), as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand or by quantity in each brand and subbrand.'' Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both: (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009; 74 FR 58298) and (2) Listing of Ingredients in Tobacco Products (December 1, 2009; 74 FR 62795) to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing and for ingredient listing. This tool allows for importation of large quantities of structured data, attachment of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (Form FDA 3742—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the eSubmitter application and the paper forms can be accessed at *http://www.fda.gov/tobacco.*

In the **Federal Register** of May 3, 2012 (77 FR 26281), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment beyond the scope of this collection was received that discussed the importance of extending this collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form/activity/tobacco control act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form FDA 3742/Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submission)/Sections 905(b), 905(c), 905(d) 905(h), or 905(i).	125	1.6	200	3.75	750
Form FDA 3743/Listing of Ingredients (Electronic and Paper Submissions)/Sections 904(a)(1) or 904(c).	125	1.6	200	3	600
Obtaining a DUNS Number (10% of total respondents)	8	1	8	0.50 (30 minutes)	4
Total	.....	.....	.....	.....	1,354

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

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]

BILLING CODE 4160–01–P

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]

BILLING CODE 4160–01–P