Technology	Off-cycle credit—cars (grams/mile)	Off-cycle credit—trucks (grams/mile)
Active seat ventilation	1.0	1.3
Active aerodynamics	Based on measured reduction in the coefficient of drag	
Active transmission warm-up	1.5	3.2
Active engine warm-up	1.5	3.2
Engine idle start-stop	2.5	4.4

C. General Motors Corporation

Using the alternative methodology approach discussed above, GM is applying for credits for model years 2013 through 2015. These credits are for a component of the air conditioning system that results in air conditioning efficiency credits beyond those provided in the regulations. GM has applied for off-cycle credits for the Denso SAS air conditioner compressor with variable crankcase suction valve technology. GM is requesting an off-cycle GHG credit of 1.1 grams CO_2 per mile for this technology. EPA currently provides Mobile Air Conditioner (MAC) GHG credits for reduced reheat using an externally-controlled variable displacement compressor (EVDC), which provides significant efficiency improvements compared to the baseline fixed displacement compressors that were the norm at the time EPA created the GHG program. Under the 2012–2016 light-duty GHG program, the credit for using an EVDC is 1.7 grams of CO_2 per mile. GM has a new EVDC design from Denso that further improves the efficiency of the MAC compressor through the addition of a variable crankcase suction valve (variable CS valve). The Denso SAS compressor improves the internal valve system within the compressor to reduce the internal refrigerant flow necessary throughout the range of displacements that the compressor may use during its operating cycle. The variable CS valve can provide a larger mass flow under maximum capacity and compressor start-up conditions, when high flow is ideal, then reduce to smaller openings with reduced mass flow in mid or low capacity conditions. The refrigerant exiting the crankcase is optimized across the range of operating conditions, creating benefits for the energy consumption of the MAC system.

The ''5-cycle'' methodology would not adequately measure the real world GHG reduction benefits of either the EVDC or the variable CS valve. Only one of the five tests is conducted with the air conditioner on and that test cycle represents worse case conditions (*e.g.,* high temperature, solar load, and humidity) and would not represent the real world benefits of the technology. Therefore, GM has chosen to determine the appropriate off-cycle credits through use of an alternative methodology.

GM worked with Denso to perform bench testing of EDVC with and without the variable CS valve and quantified the difference. Based on this analysis, GM determined an off-cycle credit of 1.1 grams of CO_2 per mile were appropriate. GM substantiated these results by also performing vehicle tests using the AC17 test procedure.

III. EPA Decision Process

EPA has reviewed the applications for completeness and is now making the applications available for public review and comment as required by the regulations. The off-cycle credit applications submitted by FCA, Ford, and GM (with confidential business information redacted) have been placed in the public docket (see **ADDRESSES** section above) and on EPA's Web site at *http://www.epa.gov/otaq/regs/ld-hwy/greenhouse/ld-ghg.htm.* EPA is providing a 30-day comment period on the applications for off-cycle credits described in this notice, as specified by the regulations. The manufacturers may submit a written rebuttal of comments for EPA's consideration, or may revise an application in response to comments. After reviewing any public comments and any rebuttal of comments submitted by manufacturers, EPA will make a final decision regarding the credit requests. EPA will make its decision available to the public by placing a decision document (or multiple decision documents) in the docket and on EPA's Web site at *http://www.epa.gov/otaq/regs/ld-hwy/greenhouse/ld-ghg.htm.* While the broad methodologies used by these manufacturers could potentially be used for other vehicles and by other manufacturers, the vehicle specific data needed to demonstrate the off-cycle emissions reductions would likely be different. In such cases, a new application would be required, including an opportunity for public comment.

Dated: May 27, 2015.

Byron Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2015–13503 Filed 6–2–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0168]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 15, 2015, the Agency submitted a proposed collection of information entitled, ''Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements'' 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 0910–0785. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13473 Filed 6–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0313]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings With the Office of Orphan Products Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings with the Office of Orphan Products Development'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 4, 2015, the Agency submitted a proposed collection of information entitled, ''Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings with the Office of Orphan Products Development'' 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 0910–0787. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13472 Filed 6–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0882]

Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2012 Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to request that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA). The statutory authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the generic drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate by August 14, 2015.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *GenericDrugPolicy@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1718, Silver Spring, MD 20993–0002, 240–402–7946, *Connie.Wisner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect fees from drug companies that submit marketing applications for certain generic human drug applications, certain drug master files, and certain facilities. GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements. The statutory authority for GDUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human generic drug review process. Section 744C(d) (21 U.S.C. 379j–43(d)) of the FD&C Act requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts. FDA will initiate this process on June 15, 2015, by holding a public meeting at which stakeholders and other members of the public will be given an opportunity to present their views on reauthorization (80 FR 22204). The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, health care professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensuring progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this