Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 23, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on July 23, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 14, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–13293 Filed 6–20–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2018–0009; OMB No. 1660–NEW]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Transcript Request Form

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (i.e., the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before July 23, 2018.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to dhsdeskofficer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address FEMA-Information-Management@fema.dhs.gov or Clarence (Smiley) White, Chief, Operations and Support Branch, United States Fire Administration, 301–447–1055 or by email at Smiley.White@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the Federal Register on February 22, 2018 at 83 FR 7752 with a 60 day public comment period. FEMA received two anonymous comments that were not relevant to the information collection. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Transcript Request Form. Type of Information Collection: New information collection.

OMB Number: 1660–NEW.

Form Titles and Numbers: FEMA Form 064–0–0–12, Transcript Request Form.

Abstract: FEMA provides training to advance the professional development of personnel engaged in fire prevention and control and emergency management activities through its Center for Domestic Preparedness (CDP), Emergency Management Institute (EMI), National Fire Academy (NFA), National Training and Education Division, National Domestic Preparedness Consortium, and Rural Domestic Preparedness Consortium. FEMA collects information from students who have completed courses at the National Fire Academy (NFA) and the Emergency Management Institute (EMI) for the purpose of fulfilling the student’s request to provide a copy of his or her transcript for their personal records and/or for transmittal to an institution of higher education that delivers training and education also in support of the FEMA mission.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Estimated Number of Respondents: 4,500.

Estimated Number of Responses: 4,500.

Estimated Total Annual Burden Hours: 225 hours.

Estimated Total Annual Respondent Cost: $7,978.50.

Estimated Respondents’ Operation and Maintenance Costs: $0.

Estimated Respondents’ Capital and Start-Up Costs: $0.


Comments

Comments may be submitted as indicated in the ADDRESSES caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Rachel Frier,

[FR Doc. 2018–13291 Filed 6–20–18; 8:45 am]
BILLING CODE 9111–45–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2018–0024; OMB No. 1660–0140]

Agency Information Collection Activities: Proposed Collection; Comment Request; Integrated Public Alert and Warning Systems (IPAWS) Memorandum of Agreement Applications

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved...

DATES: Comments must be submitted on or before August 20, 2018.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:


(2) Mail. Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at http://www.regulations.gov, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:
Wade Witmer, Deputy for the Integrated Public Alert and Warning System (IPAWS) Program, FEMA, Continuity Communications Division, (202) 646–2523, wade.witmer@fema.dhs.gov. You may contact the Information Management Division for copies of the proposed collection of information at email address: FEMA-Information-Collections-Management@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: Public Law 114–143. The IPAWS Modernization Act of 2015, and Presidential Executive Order 13407 establishes the policy for an effective, reliable, integrated, flexible, and comprehensive system to alert and warn the American people in situations of war, terrorist attack, natural disaster, or other hazards to public safety and wellbeing. The Integrated Public Alert and Warning System (IPAWS) is the Department of Homeland Security’s (DHS) response to the Executive Order. The Stafford Act (U.S.C., Title 42, Chapter 68, Subchapter II) requires that FEMA make IPAWS available to Federal, State, and local agencies for the purpose of providing warning to governmental authorities and the civilian population in areas endangered by disasters. The information collected is used by FEMA to create a Memorandum of Agreement (MOA) that regulates the management, operations, and security of the information technology system connection between a Federal, State, territorial, tribal or local alerting authority and IPAWS–OPEN (Open Platform for Emergency Notifications).

Collection of Information

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0140.

FEMA Forms: FEMA Form 007–0–25, IPAWS Memorandum of Agreement (MOA) Application; FEMA Form 007–0–26, Memorandum of Agreement Application for Tribal Governments.

Abstract: A Federal, State, territorial, tribal, or local alerting authority that applies for authorization to use IPAWS is designated as a Collaborative Operating Group or “COG” by the IPAWS Program Management Office (PMO). Access to IPAWS is free; however, to send a message using IPAWS, an organization must procure its own IPAWS compatible software. To become a COG, a Memorandum of Agreement (MOA) governing system security must be executed between the sponsoring organization and FEMA.

Affected Public: State, Local or Tribal Government.

Estimated Number of Respondents: 160.

Estimated Number of Responses: 160.

Estimated Total Annual Burden Hours: 160 hours.

Estimated Total Annual Respondent Cost: $8,150.4.

Estimated Respondents’ Operation and Maintenance Costs: $0.

Estimated Respondents’ Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $115,890.42.

Comments
Comments may be submitted as indicated in the ADDRESSES caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Rachel Frier,

[PR Doc. 2018–13290 Filed 6–20–18; 8:45 am]

BILLING CODE 9111–AB–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service


Updated Collision Risk Model Priors for Estimating Eagle Fatalities at Wind Energy Facilities

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and request for comments.

SUMMARY: The U.S. Fish and Wildlife Service (Service) uses a collision risk model (CRM) to predict the number of golden and bald eagles that may be killed at new wind facilities. The model incorporates existing information on eagle exposure and collision probability in the form of prior distributions (priors). The Service has undertaken an analysis to update the priors using all available data that meet specific criteria for both species of eagle. This notice announces the availability of a summary report of that analysis, which generates new exposure and collision priors for both species of eagle. We are soliciting public comments on the summary report, which will be considered by the Service before using the new priors in the CRM.

DATES: To ensure consideration of written comments, they must be submitted on or before August 20, 2018.

ADDRESSES: You may submit written comments by one of the following methods: