DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1064]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Application for Participation in the Medical Device Fellowship Program; Form FDA 3608'' 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On January 24, 2014, the Agency submitted a proposed collection of information entitled ''Application for Participation in the Medical Device Fellowship Program; Form FDA 3608'' 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 0910–0551. The approval expires on March 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0233]

Center for Drug Evaluation and Research; Use of Innovative Packaging, Storage, and/or Disposal Systems To Address the Misuse and Abuse of Opioid Analgesics; Request for Comments; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments on innovative packaging, storage, and disposal systems, technologies or designs (''designs'') that could be used to prevent or deter misuse and abuse of opioid analgesics by patients and others. FDA is interested in receiving comments on new designs as well as enhancements to existing designs, and is particularly interested in comments from academic institutions, regulated industry, technology companies (e.g., those producing technologies for medication adherence, disposal, or tracking), healthcare professionals, patient representatives, clinical trial service providers, and other interested organizations. Comments submitted in response to this notice will help the Agency determine whether innovative designs for opioid analgesic packaging, storage, and/or disposal systems could help prevent or deter misuse and abuse without diminishing access for patients with legitimate prescriptions.

DATES: Submit either electronic or written comments by June 9, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–301), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Colleen Brennan, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4410, Silver Spring, MD 20993–0002, 301–796–2316, email: *Colleen.Brennan@fda.hhs.gov,* with the subject line identified as ''Packaging Abuse Deterrence Strategies.''

SUPPLEMENTARY INFORMATION:

I. Background

Prescription opioid analgesics are important medications that are widely prescribed for the treatment of both non-cancer and cancer-related pain. When used properly for their approved indications, opioid drugs provide significant benefits for patients. However, they also carry a risk of misuse, abuse, addiction, overdose, and death. According to an analysis from the Centers for Disease Control and Prevention, in 2010, prescription opioid drugs were involved in 16,651 overdose deaths, which represented a 313 percent increase over the past decade (Ref. 1). The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that for each overdose death, there were an additional 11 treatment admissions (Ref. 2), 33 emergency department visits (Ref. 3), and 880 non-medical users of these drugs (Ref. 4).

Although inappropriate or illicit use, such as sharing the drug with family and friends or using drugs stolen from home medicine cabinets account for some of the problems with prescription opioids, legitimate use of opioids for pain may also lead to adverse events, addiction, and death. FDA plays a central role in the development, review, and approval of opioid drug products and must strike a balance between their benefit in the legitimate treatment of patients with pain and the risks to those patients and others associated with misuse, abuse, and addiction.

Combating opioid misuse, abuse, and addiction has long been both a public health priority and a priority for the Agency. FDA has taken many steps to address these problems; however, we recognize that more can be done and have established a task force that has embarked on a multi-pronged approach, building upon existing initiatives and developing new initiatives (*http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337852.htm*). Exploring innovative designs for drug packaging, storage, and/or disposal is one of the many initiatives targeted by the task force.

Designs for drug packaging, storage, and disposal have evolved considerably in the past decade to include many technology-based features such as electronic systems for monitoring, assessing, and improving adherence to medication regimens. For example, these systems may include functionality to remind patients to take a dose, track