4164-01-P

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; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice entitled "Center for Drug Evaluation and Research; Use of Innovative Packaging, Storage, and/or Disposal Systems to Address the Misuse and Abuse of Opioid Analgesics," which published in the Federal Register of April 9, 2014. FDA is reopening the comment period to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Colleen Brennan, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Surveillance and Epidemiology, 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

In the Federal Register of April 9, 2014 (79 FR 19619), FDA announced the establishment of a docket to receive suggestions, recommendations, and comments on innovative packaging, storage and disposal systems, technologies or designs that could be used to prevent or deter misuse and abuse of opioid analgesics by patients and others. In the notice, FDA stated that comments about specific system or technology designs should include a description of the following: (1) Design features and functionality; (2) results of any formative or summative human factors assessments conducted; (3) applications to date, including information on the effectiveness and acceptability of those applications (with literature references or other documentation); (4) recommendations for how the system/technology design could be applied or adapted (either alone and/or in combination with other systems/technologies) to help prevent or deter misuse and abuse, and any limitations of that application; (5) specific problems that could be addressed (e.g., serious complications such as addiction or overdose due to improper dosage and/or administration, improper disposal, accidental use by someone for whom the medication was not prescribed); and (6) to the extent possible, considerations for implementation into routine dispensing and clinical use (e.g., how the solution would impact the workflow in a retail pharmacy).

To help FDA prioritize among proposed approaches, the Agency is also interested in receiving feedback about methods that could be used to assess a system or technology's potential abuse-deterrent characteristics and real-world impact (e.g., actual ability to prevent or deter

misuse and abuse, effect on access for appropriate patients, patient confidentiality, burden on the healthcare system, feasibility of implementation, whether the design could create unintended medication errors). Finally, FDA is interested in receiving feedback on methods for encouraging further research and development in this area, and, if promising technologies are identified, incentivizing the pharmaceutical industry (e.g. via patent extensions) to adopt such technologies.

Interested persons were given until June 9, 2014, to submit comments. On our own initiative, the Agency is reopening the comment period until **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** to allow interested persons additional time to submit comments. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

II. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: July 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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