4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1038]

Over-the-Counter Ophthalmic Drug Products--Emergency Use Eyewash Products; Rescheduling of Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public hearing.

SUMMARY: The Food and Drug Administration (FDA) is rescheduling a December 4, 2013, public hearing to obtain information on the formulation, manufacturing, and labeling of currently marketed over-the-counter (OTC) emergency use eyewash products, announced in the Federal Register of Wednesday, September 18, 2013. Based on a request received by the Agency, we are rescheduling the public hearing to March 7, 2014, and updating the related procedural dates that appeared in the September 18, 2013, notice.

DATES: The public hearing will be held on March 7, 2014, from 9 a.m. to 5 p.m. Submit electronic or written requests to make oral presentations and comments by February 14, 2014. If you wish to attend the hearing or make an oral presentation during the hearing, you must register by submitting an electronic request to CDEREYEWASHMEETING@fda.hhs.gov by close of business on February 14, 2014. For those unable to attend in person, FDA will provide a Webcast to the meeting; additional information about the Webcast location will be posted on the Web page at http://www.fda.gov/Drugs/NewsEvents/ucm356526.htm prior to March 7, 2014. Electronic or written comments will be accepted after the hearing until June 6, 2014.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-3519, FAX: 301-847-8753, mary.gross@fda.hhs.gov; or Elaine Abraham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-0843, FAX: 301-796-9899, elaine.abraham@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 18, 2013 (78 FR 57397), FDA announced that it would hold a public hearing on December 4, 2013, to obtain information on the formulation, manufacturing, and labeling of currently marketed OTC emergency use eyewash products. Based on a request received by the Agency, we are rescheduling the public hearing to March 7, 2014. Because we are rescheduling the hearing, we are also rescheduling the procedural dates (see DATES) that appeared in the September 18, 2013, notice. For additional information about the purpose and scope of the hearing, see the September 18, 2013, notice available on FDA's Web site at http://www.fda.gov/Drugs/NewsEvents/ucm356526.htm.

Dated: November 8, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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