4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that VIMIZIM (elosulfase alfa), manufactured by BioMarin Pharmaceutical, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Vicki Moyer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6467, Silver Spring, MD 20993-0002, 301-796-2200, FAX: 301-796-9855, vicki.moyer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that VIMIZIM (elosulfase alfa), manufactured by BioMarin Pharmaceutical, Inc., meets the criteria for a

priority review voucher. VIMIZIM (elosulfase alfa) is indicated for the treatment of Mucopolysaccharidosis Type IV A (Morquio A syndrome). Morquio A syndrome is a rare congenital disorder caused by the absence or malfunctioning of an enzyme involved in an important metabolic pathway, leading to problems with bone development, growth, and movement.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.

For further information about VIMIZIM (elosulfase alfa), go to the Drugs@FDA Web site at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-05410 Filed 03/11/2014 at 8:45 am; Publication Date: 03/12/2014]