The guidance represents the current thinking of FDA on data integrity and compliance with drug CGMP. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 210 and 211 (CGMPs), 212 (positron emission tomography CGMPs), and 11 (electronic records and signatures) have been approved under OMB control numbers 0910–0139, 0910–0667, and 0910–0303, respectively.

III. Electronic Access


Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2018–N–4609]

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 that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that GAMIFANT (emapalumab-lzsg) Injection, manufactured by Novimmune S.A., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that GAMIFANT (emapalumab-lzsg) Injection, manufactured by Novimmune S.A., meets the criteria for a priority review voucher. GAMIFANT (emapalumab-lzsg) Injection is indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

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 https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm. For further information about GAMIFANT (emapalumab-lzsg) Injection, go to the “Drugs@FDA” website at https://www.accessdata.fda.gov/scripts/cder/daf/.


Leslie Kux,
Associate Commissioner for Policy.

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