FOR FURTHER INFORMATION CONTACT: Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 75, Rm. 6686, Silver Spring, MD 20993–0002, 301–796–3191; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Jonathan Bray, Center for Veterinary Medicine (HFV–232), Food and Drug Administration, 7519 Standish Pl., Rm. 130, Rockville, MD 20855, 240–402–5623.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Data Integrity and Compliance With Drug CGMP: Questions and Answers.'' In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections. This is troubling because ensuring data integrity is an important component of industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health. These data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. The underlying premise in 21 CFR 210.1 and 212.2 is that CGMP sets forth minimum requirements to assure that drugs meet the standards of the Federal Food, Drug, and Cosmetic Act regarding safety, identity, strength, quality, and purity.

The guidance addresses specific questions about how data integrity relates to compliance with CGMP for drugs, as well as more general data integrity concepts, in question and answer format. This guidance was published as a draft guidance in April 2016—''Data Integrity and Compliance With CGMP''—and has been revised in response to comments from the docket for clarity. Other comments to the docket requested additional details on FDA's thinking on current best practices and additional examples. The Agency has used clarifying language and additional examples that also address best practices for ensuring data integrity. A paragraph regarding independent security role assignments for small operations or facilities was removed because the guidance for industry ''PET Drugs—Current Good Manufacturing Practice (CGMP)'' covering this topic is sufficiently clear.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). 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

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *https://www.regulations.gov.*

Dated: December 7, 2018.

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. The Federal Food, Drug, and Cosmetic Act (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 approved rare pediatric disease product applications 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: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: *althea.cuff@fda.hhs.gov.*

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/DevelopingProductsforRareDiseasesConditions/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/.*

Dated: December 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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