U.S. FOOD & DRUG ADMINISTRATION

LICENSING LETTER

June 27, 2018

Saol Therapeutics Research Limited
Attn: Sharon Hamm, PharmD, R.Ph.
Saol Therapeutics
1000 Holcomb Woods Parkway
Suite 270
Roswell, GA 20076

Digitally signed by Bolea Petru
Date: 2021.02.18 11:35:42 EET
Reason: MoldSign Signature
Location: Moldova

Dear Dr. Hamm:

We have been advised by your letter of November 16, 2017, that Saol Therapeutics Research Limited has acquired the rights to the biological products formerly held by Aptevo BioTherapeutics LLC, U.S. License No. 2054.

It is our understanding that Saol Therapeutics Research Limited will continue to prepare the following products in the same manner as Aptevo BioTherapeutics LLC, using the same equipment, manufacturing procedures and methods, and responsible personnel.

STN	**Name of Biological Product**
BL 103649	Rho(D) Immune Globulin Intravenous (Human)
BL 125035	Hepatitis B Immune Globulin (Human)
BL 125237	Hepatitis B Immune Globulin Intravenous (Human)
BL 125430	Varicella Zoster Immune Globulin (Human)

It is our understanding that you will be the authorized official for Saol Therapeutics Research Limited. The appropriate license applications and other information required for the change in licensure have been reviewed, and found to be in compliance with required standards.

Therefore, in accordance with the provisions of Section 351(a) of the Public Health Service Act, U.S. License No. 2098 is hereby issued to Saol Therapeutics Research Limited, of Dublin, Ireland, effective this date.

Under this license you are authorized to manufacture and introduce or deliver for introduction into interstate commerce the products listed in the table above manufactured at the following contract manufacturing locations: Emergent BioSolutions, Inc., Baltimore, Maryland; National Genetics Institute, 130-2440 South Sepulveda Boulevard and 2311 Pontius Avenue Los Angeles, California locations; and Emergent BioSolutions Canada, Inc., Winnipeg, Manitoba, Canada.

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Please provide your final content of labeling including the carton and container labels in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to all licensed BLAs at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

All pending supplements submitted under U.S. License No. 2054 for the above listed products have been transferred to U.S. License No. 2098. All future correspondence for this submission should be submitted under the originally assigned STN. We recommend that a copy of this letter be available at the time of FDA inspections.

We request that you acknowledge receipt of this letter to the Director, Division of Manufacturing and Product Quality, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., WO71-G112, Silver Spring, MD 20993.

Sincerely yours,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Wilson Bryan, M.D.
Director
Office of Tissues and
Advanced Therapies
Center for Biologics
Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov