Tuesday, March 23, 2021

cGMP Statement – Magnesium Stearate NF/EP/JP (Powder) Kosher Passover HyQual®, Code 2257

To Whom It May Concern:

SpecGx LLC hereby declares that production at our St. Louis facility adheres to cGMP requirements. Our manufacturing address is:

SpecGx LLC
3600 North Second Street
St. Louis, Missouri 63147

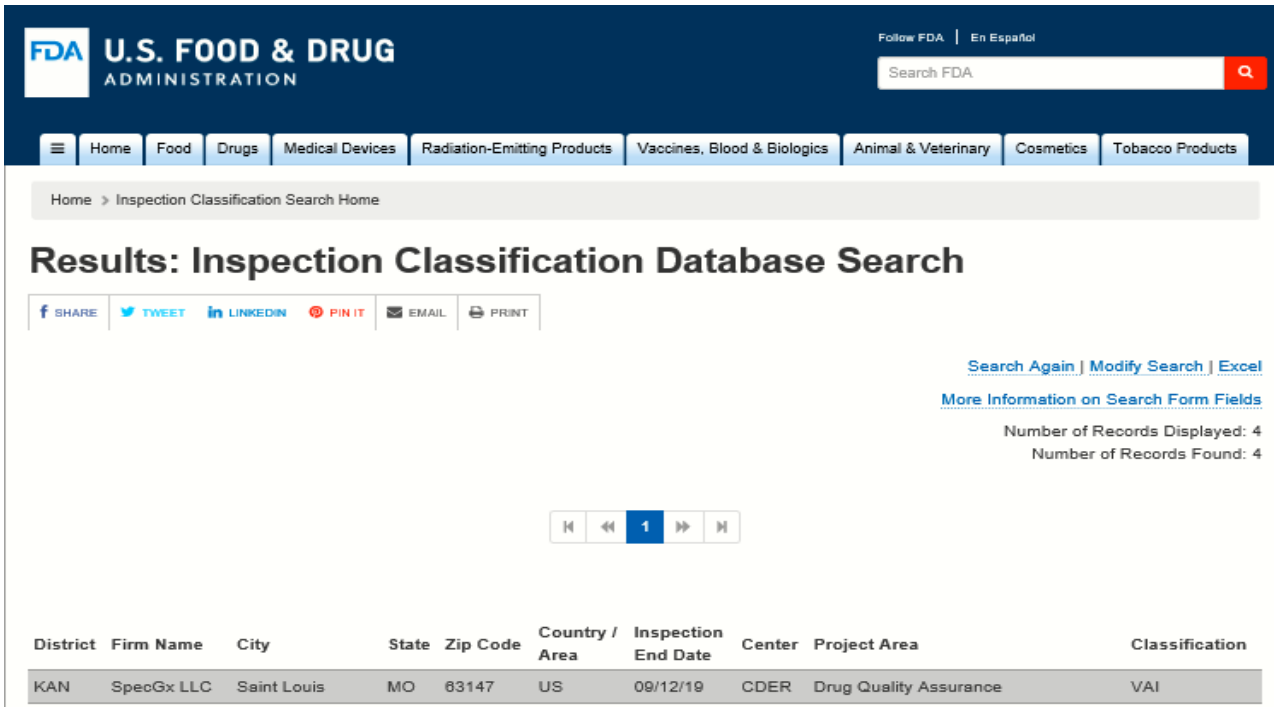
This is to certify that our facilities, processes and controls used for the manufacture, laboratory testing, holding and distribution of materials produced at this plant are in compliance with the Guidance for Industry: Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. In addition, we are compliant with 21 CFR parts 210 and 211.

Furthermore, Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Union, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices, becoming fully effective July 11, 2019, allows equivalency for inspections of manufacturing sites for human medicines in their respective territories. As the US FDA does not issue GMP certificates, following is a summary of the information available as proof of GMP compliance for US manufacturing sites that have been previously inspected by US FDA:

- The 90-day facility classification decisional letter issued by FDA - FDA has determined that the inspection classification of this facility is “voluntary action indicated” (“VAI”) and will not take or recommend regulatory or enforcement actions because the conditions do not meet the threshold for action at this time. A copy of this letter is available upon request.

- A screenshot from the FDA Inspection Classification Database from the link below:

  https://www.accessdata.fda.gov/scripts/inspsearch/results.cfm



- The most recent relevant FDA Establishment Inspection Report (EIR) - The last FDA inspections was in September 2019 with four 483 issued (2 items on documentation deviation and scope, 1 item on data integrity gap and 1 item on our finished dosage product per NDA- FAR requirements/ not applicable on the APIs). A copy of the EIR is available to be sent directly to the health authorities, upon request.

The St. Louis facility's Dun and Bradstreet (DUNS) number is 16-320-5300. SpecGx LLC (FDA Establishment Identifier 1940521) site is currently registered with the FDA. The following is a screenshot from the FDA website, using the following link:

https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
SpecGx LLC	1940521	163205300	ANALYSIS; API MANUFACTURE; MANUFACTURE;	3600 N. 2nd Street, St. Louis, Missouri (MO) 63147, United States (USA)	12/31/2021

We commit to notify our customers, in advance, of any changes in the manufacturing or control of the product that could affect the quality, safety or specification of the product.

SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

Michaela Reid | Quality Analyst II
Mallinckrodt Pharmaceuticals
345 Marshall Ave, Suite 201 l Webster Groves, MO 63119 l USA
CQuality@mnk.com l www.mallinckrodt.com