

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

KURT R. KARST

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600

Direct Dial (202) 737-7544
Kkarst@hpm.com

FACSIMILE
(202) 737-9329

www.hpm.com

May 27, 2022

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

Hyman, Phelps & McNamara, P.C. submits this Petition in accordance with 21 C.F.R. §§ 10.25 and 10.30, and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act (“FDC Act”) and 21 C.F.R. §§ 314.122 and 314.161 to request that the Food and Drug Administration (“FDA”) determine whether a listed drug was withdrawn for safety or effectiveness reasons.

A. ACTIONS REQUESTED

Petitioner requests that FDA determine whether Sinemet CR (carbidopa/levodopa) Tablets, 50 mg/200 mg and 25 mg/100 mg, approved under New Drug Application (“NDA”) number 019856, held by Organon, LLC, has been voluntarily withdrawn for reasons of safety or effectiveness.

B. STATEMENT OF GROUNDS

Under the FDC Act, an Abbreviated New Drug Application (“ANDA”) must rely on FDA’s approval findings for a Reference Listed Drug (“RLD”). *See* FDC Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. *See* 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. *See id.* § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

The Orange Book currently identifies Sinemet CR (carbidopa/levodopa) Tablets, 50 mg/200 mg and 25 mg/100 mg, approved on May 30, 1991 (50 mg/200 mg) and December 24, 1992 (25 mg/100 mg) under NDA 019856, in the “Discontinued Drug Product List” section of the Orange Book. FDA appears to have moved NDA 019856, Product 001 (50 mg/200 mg) to the “Discontinued Drug Product List” in the October 2019 Cumulative Supplement to the Orange Book., and Product 002 (25 mg/100 mg) to the “Discontinued Drug Product List” in the January 2020 Cumulative Supplement to the Orange Book

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of Sinemet CR (carbidopa/levodopa) Tablets, 50 mg/200 mg and 25 mg/100 mg, under NDA 019856 was due only to commercial considerations.

Petitioner requests that FDA determine that Sinemet CR (carbidopa/levodopa) Tablets, 50 mg/200 mg and 25 mg/100 mg, approved under NDA 019856, was not withdrawn for reasons of safety or effectiveness.

C. ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

D. ECONOMIC IMPACT STATEMENT

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kurt R. Karst', with a stylized flourish at the end.

Kurt R. Karst