Arnall Golden Gregory LLP

Direct phone: 404.873.8690
Direct fax: 404.873.8691
E-mail: Alan.Minsk@agg.com
www.agg.com

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May 23, 2013

Via Certified Mail

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

CITIZEN PETITION

The undersigned (the "Petitioner") submits this petition, in quadruplicate, under section 505 of the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), 21 U.S.C. § 355, and 21 C.F.R. §§ 10.20, 10.25, 10.30, and 314.161, to request the Commissioner of Food and Drugs to determine that the drug, Intal® (cromolyn sodium) Inhalation Capsule, 20mg (New Drug Application (NDA) # 016990) was voluntarily withdrawn from the market for reasons other than safety or effectiveness.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs (hereinafter referred to as "FDA") make a determination that then-Sanofi Aventis' Intal® (cromolyn sodium) Inhalation Capsule, 20 mg (NDA # 016990) was withdrawn from the market for reasons other than safety or effectiveness and, therefore, an abbreviated NDA may be submitted and approved under section 505(j) of the FDC Act, using Intal® as a Reference Listed Drug (RLD).

B. Statement of Grounds

The Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as "the Orange Book", contains all FDA–approved drug products. Although FDA approved Intal® (cromolyn sodium) Inhalation Capsule, 20 mg (NDA # 016990), the Orange Book currently lists the drug in the Discontinued Drug Product List section. Attachment A.

Before FDA can approve an application that references a discontinued drug, FDA must determine whether a discontinued drug was withdrawn for reasons of safety or effectiveness. See 21 C.F.R. § 314.161. If FDA determines that the drug was not withdrawn for safety or effectiveness reasons, FDA must publish a notice in the Federal Register about its conclusion. See 21 C.F.R. § 314.161(e).

FDA-2013-P-0665

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2013-4230

The Petitioner has no information to suggest the market withdrawal of Sanofi's Intal® was for safety or effectiveness reasons. Therefore, the Petitioner requests that FDA determine the withdrawal was made for reasons other than safety or effectiveness and, therefore, an abbreviated NDA may be submitted and approved, using Intal® as an RLD.

C. Environmental Impact

As provided in 21 C.F.R. § 25.31, neither an environmental assessment nor an environmental impact statement is required.

D. Economic Impact

As provided in 21 C.F.R. § 10.30(b), economic impact information will be provided if requested by FDA.

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 which are unfavorable to the Petition.

Respectfully submitted,

Alan G. Minsk
Kelley C. Nduom
Arnall Golden Gregory LLP
171 17th Street, N.W.
Suite 2100
Atlanta, Georgia 30363
404-873-8500

AGM/cdbi
Attachment

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Rockville, MD 20852

171 17th Street, NW | Suite 2100 | Atlanta, GA 30363-1031
404.873.8500 | Fax: 404.873.8501