April 18, 2017

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

CITIZEN PETITION

Subject: Citizen Petition requesting the agency to determine that withdrawal of NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC was not due to safety and efficacy reasons and also requesting the agency to designate it as Reference Listed Drug (RLD) for the purpose of submitting an ANDA

Dear Sir/Madam,

The attached petition submitted on behalf of Aurobindo Pharma Limited requests FDA to:

1. Determine that the formulation of NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC was not discontinued for safety and efficacy reasons and
2. to designate NDA 019038 as an RLD for the purpose of submitting an ANDA.

Please contact the undersigned at AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520, USA, Tel: 609-642-1136, Cell: 267-474-4516, Fax: 732-917-0780, e-mail: vandolina@aurobindousa.com; if you have any questions regarding this submission.

CITIZEN PETITION

The undersigned submits this petition on behalf of Aurobindo Pharma Limited under 21 CFR §§ 10.30, 10.20, 10.25(a), 314.122 and 314.161 to request the Commissioner of Food and Drugs to

1. Determine that the formulation of NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC was not discontinued for safety and efficacy reasons and
2. To designate NDA 019038 as an RLD for the purpose of submitting an ANDA.

A. Action Requested

The petitioner requests the Commissioner of Food and Drugs to determine that the formulation of NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC;

1. Was not discontinued for safety and efficacy reasons and
2. To designate it as RLD for the purpose of submitting an ANDA.

The petitioner requests FDA to determine that Aurobindo's proposed generic product referring to the originally approved formulation, CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL (now discontinued), may be submitted under an ANDA.

B. Statement of Grounds

NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC was approved by the Agency on March 30, 1984. According to both Drugs@FDA and the Orange Book, it has been discontinued.

Aurobindo Pharma Limited intends to develop a formulation of Verapamil Hydrochloride Injection, 2.5 mg/mL (5 mg/2 mL and 10 mg/4 mL) and submit an ANDA citing the discontinued formulation of NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC as RLD for the basis of submission.

Hence, Aurobindo Pharma Limited hereby requests the Commissioner of Food and Drugs to make a determination that the formulation of NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC is not discontinued for safety and efficacy reasons.

Per FD&C Act and FDA's regulations, an ANDA applicant must cite a specific listed drug in its ANDA on which the applicant relies on, for seeking approval of its ANDA. However, per the "Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)", no application is designated as RLD for Verapamil Hydrochloride Injection.

The proposed drug product Verapamil Hydrochloride Injection, 2.5 mg/mL (2 mL and 4 mL fill volumes) contains same active and inactive ingredients in the same concentration, dosage form and indications as CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL. The details are as tabulated below.

Product	**CALAN® (verapamil hydrochloride) Injection (NDA 019038)** (Discontinued)	**Verapamil Hydrochloride Injection, USP** (Proposed Generic Drug Product)
Strength(s)	2.5 mg/mL; 5 mg/2 mL and 10 mg/4 mL	2.5 mg/mL; 5 mg/2 mL and 10 mg/4 mL
Active	Verapamil HCl	Verapamil HCl
Inactive(s)	Sodium Chloride (Tonicity Agent)	Sodium Chloride (Tonicity Agent)
	Hydrochloric Acid (pH adjusting agent)	Hydrochloric Acid (pH adjusting agent)
	Sodium Hydroxide (pH adjusting agent)	Sodium Hydroxide (pH adjusting agent)
Dosage Form	Injection	Injection
Indications	It is indicated for the treatment of supra-ventricular tachyarrhythmias, including: • Rapid conversion to sinus rhythm of paroxysmal supraventricular tachycardias, including those associated with accessory bypass tracts (Wolff-Parkinson-White [WPW] and Lown-Ganong-Levine [LGL] syndromes). When clinically advisable, appropriate vagal maneuvers (e.g., Valsalva maneuver) should be attempted prior to CALAN administration. • Temporary control of rapid ventricular rate in atrial flutter or atrial fibrillation, except when the atrial flutter and/or atrial fibrillation are associated with accessory bypass tracts (Wolff-Parkinson-White [WPW] and Lown-Ganong-Levine [LGL] syndromes).	It is indicated for the treatment of supra-ventricular tachyarrhythmias, including: • Rapid conversion to sinus rhythm of paroxysmal supraventricular tachycardias, including those associated with accessory bypass tracts (Wolff-Parkinson-White [WPW] and Lown-Ganong-Levine [LGL] syndromes). When clinically advisable, appropriate vagal maneuvers (e.g., Valsalva maneuver) should be attempted prior to verapamil administration. • Temporary control of rapid ventricular rate in atrial flutter or atrial fibrillation, except when the atrial flutter and/or atrial fibrillation are associated with accessory bypass tracts (Wolff-Parkinson-White [WPW] and Lown-Ganong-Levine [LGL] syndromes).

Aurobindo Pharma Ltd. hereby requests the Commissioner of Food and Drugs to designate NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC as RLD upon determination that the formulation of NDA 019038 for CALAN® (verapamil hydrochloride) Injection, 2.5 mg/mL of GD Searle LLC was not discontinued for safety and efficacy reasons.

C. Environmental Impact

Action on an ANDA is categorically excluded from the requirements of an environmental assessment or impact statement under 21 CFR § 25.31(a).

D. Economic Impact

Information regarding economic impact will be made upon request by the commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all the 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.

Sincerely yours,

AuroMedics Pharma LLC
(U.S. Agent for Aurobindo Pharma Limited)

Vincent P. Andolina

Digitally signed by Vincent P. Andolina
DN: c=US, st=NJ, l=Dayton, o=AuroMedics Pharma LLC, cn=Vincent P. Andolina, email=vandolina@aurobindousa.com
Date: 2017.04.18 15:45:58 -04'00'

Vincent P. Andolina
Vice President, Regulatory Affairs