Lachman CONSULTANTS
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October 18, 2019

Division of Dockets Management
Department of Health and Human Services
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852, U.S.A.

CITIZEN PETITION

Dear Sir or Madam:

The undersigned, Lachman Consultant Services, Inc. (Lachman Consultants), submits this petition as per 21 CFR §10.25(a) and §10.30 to request the Commissioner of Food and Drugs to take action with respect to Reference Standard (RS) designation for nitrofurantoin oral suspension 25 mg/5 mL.

The Reference Listed Drug (RLD) and Reference Standard (RS) for nitrofurantoin oral suspension 25 mg/5 mL designated in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) is Furadantin® (nitrofurantoin) Oral Suspension 25 mg/5 mL, approved by the FDA under NDA 009175. Lachman Consultants respectfully requests designation of a new Reference Standard product due to market availability of the RLD/RS Furadantin® (nitrofurantoin) Oral Suspension 25 mg/ 5 mL (NDA 009175), held by Casper Pharma LLC.

A. ACTIONS REQUESTED

Lachman Consultants requests that FDA designate Nitrofurantoin Oral Suspension 25 mg/5 mL marketed by Nostrum Laboratories Inc. under ANDA 201355, a therapeutic equivalent to the RLD Furadantin® (nitrofurantoin) Oral Suspension 25 mg/5 mL (NDA 009175), as the Reference Standard product.

B. STATEMENT OF GROUNDS

The FD&C Act and FDA regulations require that an ANDA applicant refer in its ANDA to the specific listed drug on which the applicant relies in seeking approval of its ANDA. This drug is the Reference Listed Drug (RLD). FDA identifies products designated as RLDs in the Orange Book. FDA also selects a drug product, which should be used for demonstration of *in vivo* bioequivalence by an applicant seeking ANDA approval. These products are identified in the Orange Book as Reference Standards (RS). In the case of nitrofurantoin oral suspension 25 mg/5 mL, Furadantin® (nitrofurantoin) Oral Suspension 25 mg/5 mL, held by Casper Pharma LLC under NDA 009175, is designated as both the RLD and RS (relevant section of the Orange Book is provided as Attachment 1).

Based on information available in the marketplace, it appears that Casper Pharma LLC is not currently distributing its Furadantin® (nitrofurantoin) Oral Suspension 25 mg/5 mL under NDA 009175. As a result, any applicant seeking to submit an ANDA for a generic equivalent that identifies Casper Pharma's drug product as the Reference Standard is precluded from doing so because the Casper Pharma product is not available or is in distribution so limited that a potential applicant is unable to obtain a sufficient quantity for *in vivo* bioequivalence testing. This lack of drug product availability provides a sound basis for designating a therapeutic equivalent to Furadantin® (nitrofurantoin) Oral Suspension 25 mg/5 mL (NDA 009175) as the Reference Standard product.

The lack of available RS product prevents the filing of applications for generic equivalents. For this reason, the Petitioner, Lachman Consultants, respectfully requests FDA to designate Nitrofurantoin Oral Suspension, marketed by Nostrum Laboratories Inc. under ANDA 201355 as the Reference Standard product. It is our understanding that Nitrofurantoin Oral Suspension marketed under ANDA 201355 by Nostrum Laboratories Inc., is the only nitrofurantoin oral suspension currently available in the U.S. market.

C. ENVIRONMENTAL IMPACT

Lachman Consultants claims a categorical exclusion under 21 CFR §25.31(a) from the requirement to submit an environmental assessment.

D. ECONOMIC IMPACT

Lachman Consultants will, upon request by the commissioner, submit economic impact information, in accordance with 21 CFR 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 which are unfavorable to the petition.

If there are any questions concerning this citizen petition, please contact undersigned by telephone at (516) 972-8664 or via email at a.schutte@lachmanconsultants.com.

Sincerely,

Amy Schutte

Digitally signed by Amy Schutte
DN: cn=Amy Schutte, o=Lachman Consultant Services, Inc., ou, email=a.schutte@lachmanconsultants.com, c=US
Date: 2019.10.18 13:29:14 -04'00'

Amy Schutte
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Attachment:

1. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations listing for nitrofurantoin oral suspension, accessed 10/17/2019.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	NITROFURANTOIN	FURADANTIN	N009175	SUSPENSION	ORAL	25MG/5ML	AB	RLD	RS	CASPER PHARMA LLC
RX	NITROFURANTOIN	NITROFURANTOIN	A205180	SUSPENSION	ORAL	25MG/5ML	AB			ACTAVIS MID ATLANTIC LLC
RX	NITROFURANTOIN	NITROFURANTOIN	A201679	SUSPENSION	ORAL	25MG/5ML	AB			AMNEAL PHARMACEUTICALS
RX	NITROFURANTOIN	NITROFURANTOIN	A201355	SUSPENSION	ORAL	25MG/5ML	AB			NOSTRUM LABORATORIES INC
RX	NITROFURANTOIN	NITROFURANTOIN	A201693	SUSPENSION	ORAL	25MG/5ML	AB			NOVEL LABORATORIES INC