amedra
pharmaceuticals

2 Walnut Grove Drive, Suite 190
Horsham, PA 19044-7707
(215) 259-3601 Fax: (215) 674-9817
www.amedrapharma.com

July 18, 2013

VIA HAND DELIVERY
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-P-0766
Citizen Petition, Supplement No. 1

Amedra Pharmaceuticals LLC ("Amedra") respectfully submits this supplement to the citizen petition submitted on June 18, 2013 and assigned Docket No. FDA-2013-P-0766.

Pursuant to 21 CFR 20.61(d) and instruction from the Food and Drug Administration's ("FDA's") Division of Dockets Management, Amedra is submitting under cover of this supplement, the enclosed confidential source documents, and is requesting that the documents be treated confidentially and remain exempt from disclosure.

Because these supplemental documents contain trade secrets and confidential commercial information, as defined by 21 CFR 20.61, that are protected from public disclosure under the Freedom of Information Act ("FOIA") and the Trade Secrets Act, Amedra considers them exempt from disclosure in their entirety under exemption 4 of the FOIA.

These source documents are not for public dissemination either by posting on www.regulations.gov or through the Division of Dockets Management. They are enclosed for the agency's internal and confidential use.

Pursuant to 21 CFR 61(e), if FDA receives a request for the enclosed documents and determines that disclosure may be required, Amedra requests to be notified, and be permitted five (5) business days from receipt of such notice, to object to any disclosure.

Respectfully submitted,

Eric Pomerantz
Vice President, Legal Affairs
Amedra Pharmaceuticals LLC

Enclosures

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