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0320 '06 FEB -2 P4 '24

February 2, 2006

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

Re: Docket No. 2004P-0074 - Article in Support of the Citizen Petition filed by Savient Pharmaceuticals, Inc.

Dear Sir or Madam:

The enclosed article is submitted on behalf of Savient Pharmaceuticals, Inc. ("Savient") in support of its February 2004 Citizen Petition. Savient's Citizen Petition requested, in pertinent part, that the Food and Drug Administration ("FDA") establish bioequivalence and clinical testing requirements for generic versions of oxandrolone to safeguard against adverse drug interactions. The enclosed article, written in part by an FDA pharmacologist, provides further evidence of the severe risks of adverse drug interactions with oxandrolone.

Specifically, the article describes the case of a 93-year-old woman on long-term warfarin sodium treatment who received oxandrolone to facilitate weight gain. After two weeks of taking oxandrolone in combination with warfarin, the patient's prothrombin time had increased over 400% – from 15.6 seconds to over 65 seconds. The article also states that a similar drug interaction causing hypocoagulation had occurred in a 69-year-old patient taking warfarin and topical testosterone, which is chemically related to oxandrolone. In this case, a 25% reduction in the warfarin dose was required to maintain therapeutic prothrombin time. The article concluded that increased use of oxandrolone in the geriatric population increased the risk of a "clinically significant drug interaction resulting in bleeding."

The cases cited in the enclosed article confirm the serious risk of excessive bleeding for patients using oxandrolone in combination with warfarin therapy. As previously stated in Savient's Citizen Petition, the failure to maintain appropriate warfarin levels will cause either unnecessary anti-coagulation with the risk of excessive bleeding, as shown in the article, or inadequate anti-coagulation, which makes the warfarin therapy ineffective.¹ The result in either situation can be death or serious injury. The severity and probability of this risk necessitates that

¹ Citizen Petition, Docket No. 2004P-0074, Feb. 16, 2004, at 2.

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FDA establish adequate bioequivalence and clinical testing requirements for generic versions of oxandrolone so that physicians have the information necessary to ensure proper warfarin dosage when beginning oxandrolone treatment.

Respectfully yours,

A handwritten signature in black ink, appearing to read "Edward John Allera". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Edward John Allera
William A. Garvin