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8433 00 MAR 23 02:38  
March 16, 2000

Dockets Management Branch (HFA-305)  
Center for Drug and Evaluation Research  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857

Re: Docket No. 99 D-4809

Dear Sir or Madam:

On behalf of a client, we respectfully submit this comment to the Food and Drug Administration (FDA) seeking clarification of a specific provision in the October 4, 1999 Draft Guidance Document entitled "Applications Covered By Section 505(B)(2)" (draft guidance document). We believe our comment merely alerts the Agency to the omission of information that the Agency likely intended to include in this draft guidance document. We appreciate the Agency's willingness to review this comment despite the completion of the comment period (as per Khyati Robert's February 24, 2000 telephone message) and we expect that the Agency will find this comment helpful as it finalizes this draft guidance document. Moreover, we also anticipate that FDA will immediately recognize that orphan drug exclusivity is an additional consideration in its review of a 505(b)(2) NDA and thus, will not wait until the final guidance is issued to remedy this omission in the draft guidance.

We refer you to Part VI, Section B of the draft guidance document that attempts to describe how patent or exclusivity rights can delay the approval or filing of a 505(b)(2) application. In so doing, FDA identifies only the so-called Waxman-Hatch patent and exclusivity rights that were created in 1984. However, we believe that the Agency omitted from this section recognition of the orphan drug exclusivity that was created in 1983. FDA states in 21 C.F.R. § 316.31(a), "[a]fter approval of a sponsor's marketing application for a designated orphan-drug product for treatment of [a] rare disease . . . , FDA will not approve

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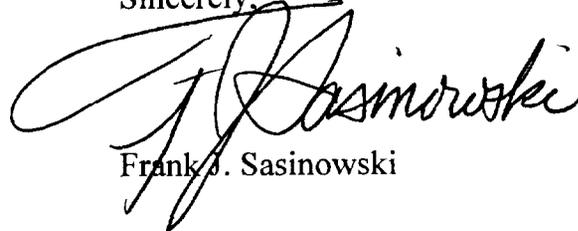
Dockets Management Branch (HFA-305)  
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Page 2

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another sponsor's marketing application for the same drug before the expiration of 7 years from the date of such approval . . . ." Clearly, FDA should include orphan drug exclusivity in the draft guidance document identification of the patent and exclusivity rights that may delay the approval of a 505(b)(2) application.

Because we think this is purely an oversight by the Agency, there is no need for a lengthy dissertation on the legal and policy reasons for this necessary revision. If you have any questions on this comment, please do not hesitate to contact me at (202) 737-4287. Thank you for your consideration of this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "F. Sasinowski". The signature is fluid and cursive, with a large initial "F" and "S".

Frank J. Sasinowski

FJS/LEK/tee  
7906.001

cc: Dr. Marlene Haffner  
Director, Office of Orphan Products Development

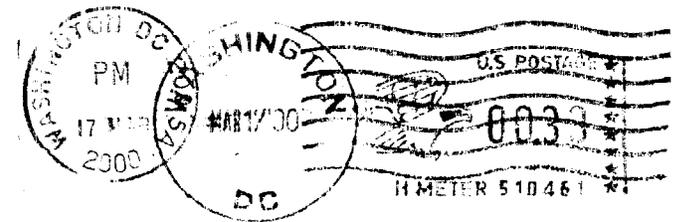
Dr. Janet Woodcock  
Director, Office of the Center for Drug Evaluation and Research

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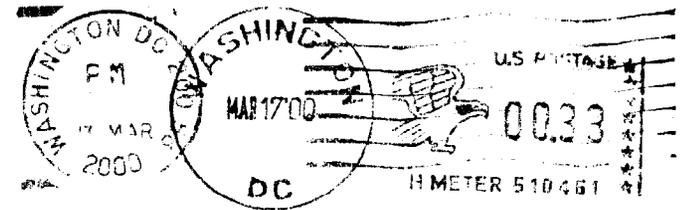
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Products Development  
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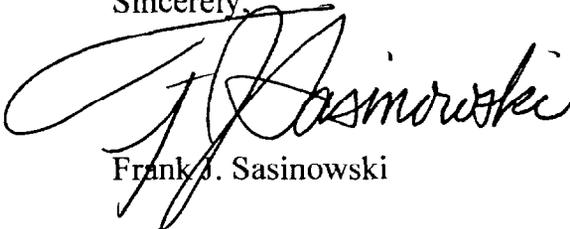
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