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November 25, 2013

**BY FEDERAL EXPRESS**

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, Maryland 20852

**Re: Docket No. FDA-2013-P-1287/CP1  
Supplement Containing Confidential Exhibits**

Dear Sir or Madam:

Attached are copies of an attachment that was filed with a Citizen Petition dated October 15, 2013 and assigned Docket No. FDA-2013-P-1287/CP1, filed on October 25, 2013. Aptalis Pharma ("Aptalis") considers the information included in this submission to be confidential and to contain proprietary information that is exempt from disclosure under Exemption 4 of the Freedom of Information Act. Pursuant to 21 C.F.R. § 20.61, Aptalis requests that FDA not make the contents of this submission public, or any future communication with respect to such contents. FDA's Dockets Management Staff has previously advised that confidential attachments should be submitted under separate cover once a docket number has been assigned by FDA.

Please contact me at (450) 467-5138 # 2458 if you have any questions concerning this submission.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Guy Rousseau", is written over a horizontal line.

Guy Rousseau Ph.D.  
Executive Director, Regulatory Affairs  
Aptalis Pharma

Attachment (Confidential)

ORIGIN ID: YSWA (450) 467-5138  
MAUDE HARPIN  
APTALIS PHARMA CANADA INC.  
597 BOUL. LAURIER

MONT ST-HILAIRE, PQ J3H6C4  
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**FDA**

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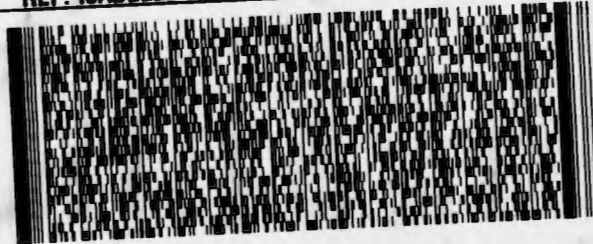
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**REF: ISABELLE LAVIGNE**



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Part # 156148-434 RIT2 08/12 •

